Abilene Christian University
Office of Research and Sponsored Programs
Handbook of Policies and Procedures

Version 6/2021

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MISSION OF THE OFFICE OF RESEARCH AND SPONSORED PROGRAMS

The mission of the Office of Research and Sponsored Programs is to promote scholarly activity among the faculty and students of Abilene Christian University, particularly inquiry informed by a Christian perspective.

The Office of Research and Sponsored Programs (ORSP) exists to support a culture of intellectual curiosity and scholarly activity on the ACU campus. The ORSP encourages and supports scholarship by providing **internal** research funding through competitive Math/Science grants and similar Cullen grants designed to help faculty members launch research projects. Moreover, the ORSP aids both faculty and staff in applying for **external** funding by providing technical help with grant applications.

The ORSP serves as the clearinghouse for **all** academic and student services externally funded projects (grants, contracts, or cooperative agreements), **whether or not they relate to research**. The office also monitors areas of regulatory compliance including but not limited to cost principles, ethical review boards for human subjects and animal research, and providing a process for reporting research misconduct.

INTERNAL GRANTS: PROGRAMS AND POLICIES

POLICY STATEMENT & PURPOSE

Abilene Christian University's Internal Grants Programs include the Math-Science, Cullen, Undergraduate Research, and SEED Awards. These awards were established to provide a source of internal research support for any qualified faculty member at ACU and, when appropriate, undergraduate students involved in supported research.

Cullen and Math-Science Awards: The intent of the program is to provide time for faculty scholarship during a summer term in lieu of teaching. In some instances, the grants may be used to buy a course-load reduction in a long semester. Grant funds may also support other necessary costs of scholarship, including materials and supplies.

SEED Award: This is a highly competitive grant designed to fund an investigator over 2 years, for a total of $20,000 ($10,000 each fiscal year), in the conduct of studies aimed at providing preliminary data for an external funding application.

This policy outlines who can apply, allowable expenses, and other expectations for each program. While the Undergraduate Research awards use the same internal grants application process, these awards are managed through the Undergraduate Research Office and, therefore, not outlined in this policy.

APPLICABILITY OF THE POLICY

This policy applies to all faculty who are eligible to apply for the awards outlined herein.

PROCEDURAL GUIDELINES

Math-Science and Cullen Awards

Who Can Apply

Full-time faculty members at the rank of instructor or above are eligible to apply. Applications may be for quantitative research studies, qualitative research studies, technological innovations, and developmental and innovative research activity related to musical compositions or artistic production (Cullen).

Cullen funds are generated by an endowment from the Cullen Foundation and support research projects in all academic areas, with the exception of Mathematics and the Physical Sciences. *(Excluded from eligibility are Agriculture and Environmental Sciences, Biology, Chemistry, Computer Science, Engineering and Physics, and Mathematics.)*

Math-Science funds support research projects in the following academic areas: Agriculture and Environmental Sciences, Biology, Chemistry, Computer Science, Engineering and Physics, Mathematics

All applicants must be in good standing with the Internal Grants programs, having met all obligations with previous awards.

Application Procedures

Proposals are due by 5pm on the last Monday in January and are funded in the next fiscal year (after June 1). Applicants should submit the Common Internal Grants Application Form and the Internal Grants Budget Form (available on the ORSP website) by the deadline. Evidence of completion of Responsible Conduct of Research (RCR) training must also be submitted by the time of the review meeting to be considered for funding. RCR training must be completed once every 4 years. Once applications are received, the Excutive Director of Research will submit a request for approval and commitment to the applicant's department Chair and Dean.

All applicants must be willing to affirm the following assurances in order to successfully apply:

(1) I have completed or will complete Responsible Conduct of Research training. Training for faculty applicants must be completed by the time of the review meeting in order for applicant to be considered.
(2) When applicable, I will ensure that all students who participate in my research will complete Responsible Conduct of Research training prior to participating or receiving any funding support.
(3) I agree to abide by the terms of ACU internal grants program and ACU guidelines (http://www.acu.edu/academics/orsp/grants/index.html). I will complete all assessment tools, including the final report and budget reports.
(4) I have read and agree to the terms in the University's Intellectual Property Agreement and Policy on Research Misconduct (outlined herein).
(5) I understand that the ORSP Office will ask my Department Chair/Program Director and Dean to confirm their support of this application.

Funding Decisions

Decisions for the Math-Science and Cullen Awards are made by the Research Council. Funds are awarded to proposals that demonstrate potential for serious research and creative activity. The Research Council especially encourages those faculty members who are interested in doing research for the first time to apply. The Research Council considers the proposals submitted by the faculty and approves those judged best according to the following criteria: Worth and value to the discipline, researcher, or the university; Clear goals, objectives, and outcomes; Use of sound, clearly explained methodology and procedures; Clear writing that is precise, detailed, and understandable to a lay audience; Expected outcome of project (e.g., a book, article, paper, presentation, video); Likelihood of successful completion in a reasonable time.

Outcomes and Requirements

Projects should be completed during a single fiscal year and must produce a tangible, scholarly product. Examples of acceptable outcomes include completion of a book, an article submitted for publication in a peer reviewed journal, presentation at a professional conference, etc.

A final report further detailing the progress made and the scholarly product completed is due by April 1st of the awarded fiscal year. Reports must be submitted in order to remain in good standing.

Faculty who have received a Cullen award 3 times for the same project/program must submit an application for extramural funding. Faculty who have received a Math/Science award 3 times (total) must submit an application for extramural funding. Faculty will be ineligible for further funding until this outcome has been met.

SEED Award

Who Can Apply

Full-time tenure-track faculty members at the rank of assistant or above are eligible to apply. All applicants must be in good standing with the Internal Grants programs, having met all obligations with previous awards.

Application Procedures

Applications for this internal grant will be due the first Monday of October, allowing faculty to use potential Cullen or Math/Science-supported work toward their application. Awards will be announced in November, with sufficient time for those not receiving an award to prepare an application for other internal grant mechanisms in January. The awarded project period will then begin the following fiscal year, June 1. Applicants should submit the SEED Application Form and the SEED Budget Form (available on the ORSP website) by the deadline. Evidence of completion of Responsible Conduct of Research training must also be submitted by the time of the review meeting to be considered for funding. RCR training must be completed once every 4 years. Once applications are received, the Executive Director of Research will submit a request for approval and commitment to the applicant's department Chair and Dean.

All applicants must be willing to affirm the following assurances in order to successfully apply:

(1) I have completed or will complete Responsible Conduct of Research training. Training for faculty applicants must be completed by the time of the review meeting in order for applicant to be considered.
(2) When applicable, I will ensure that all students who participate in my research will complete Responsible Conduct of Research training prior to participating or receiving any funding support.
(3) I agree to abide by the terms of ACU internal grants program and ACU guidelines. I will complete all assessment tools, including the interim report, the final report, and budget reports.
(4) I have read and agree to the terms in the University's Intellectual Property Agreement and Policy on Research Misconduct.
(5) I understand that the ORSP Office will ask my Department Chair/Program Director and Dean to confirm their support of this application.

Funding Decisions

Decisions for the SEED Awards are made by the Research Council. Funds are awarded to the one proposal each year that demonstrates the greatest potential for success at applying for and obtaining external funding. The Research Council considers the proposals submitted by the faculty and approves the one judged best according to the following criteria: Worth and value to the discipline, researcher, or the

university; Clear goals, objectives, and outcomes; Use of sound, clearly explained methodology and procedures; Clear writing that is precise, detailed, and understandable to a lay audience; Likelihood of successful completion during the 2 year project period; Identification of potential external funding sources with a clear plan for how to prepare a submission; Competitiveness for external award. External funding applications must be submitted within 9 months following the end of the internal project period, and must be for amounts larger than $20,000 and allow for indirect cost collection.

Outcomes and Requirements

Projects should be completed during the 2 year project period and must produce an external funding application submission within 9 months following the end of the project period. Failure to submit the application will result in ineligibility for ACU internal grants for 3 years.

An interim report detailing the progress made toward goals is due by the end of the first year, and a final report further detailing the progress made and the application submitted/planned for submission is due at the end of the second year. If the application has not yet been submitted at the time of the final report, a memo should be provided at the time of its submission documenting completion of the grant requirements. The PI is not required to receive the external award, as this is largely out of our control and external funding is highly competitive.

Budgets & Allowable Costs

Every grantee is assigned a budget for expenses if any are awarded. Salaries are paid through the Office of Research and Sponsored Programs. All budgets must be cleared and accounted for by the April 1 after the summer for which the grant was awarded. Grantees without proper accounting forms are liable for the expenses incurred.

(1) Summer Stipend Request. This amount can be paid in lieu of teaching summer courses and thus is commensurate with university summer pay schedules as the equivalent of two summer classes for Cullen & Math-Science or one summer class for SEED, based upon faculty rank. In some cases, the amount of funding may be reduced due to limited funds or because a project may be judged as less ambitious than others receiving funding.

(2) Long semester adjunct costs: This amount may be paid to the department to cover the costs of an adjunct needed for course release. Any changes to the faculty member's workload is an agreement between the faculty person and the department chair. Once the chair and dean have signed off on a budget for release time, this needs to be met or the faculty person/department will not receive the funds budgeted for time/salary.

(3) Expenses related to the research. This amount is limited to essential and necessary materials or support directly connected with the research project. Ineligible expenses include clerical work, office supplies, telephone, computer equipment, and travel that is not essential to the conduct of the research, as these support services usually can be obtained from Departmental or College resources.

(4) Requests for travel that is necessary to the conduct of the research (e.g., travel to a data collection site) should be justified in the budget narrative.

(5) Partnership with externally funded research support. In certain cases, applications can be made to provide matching funds for an externally funded project. The amount of funding is limited to the equivalent of teaching two summer terms. Also, no salary/stipend funds can be used from the internal

grants while a faculty member is also being paid from an outside agency, thus preventing a "double-dip" situation.

(6) Payments given to consultants or participants must follow the Finance Office policies on such payments, including filing a W-9 with Accounts Payable. A contract should be on file for all consultants prior to providing services and issuing payment.

(7) Gift cards or cash given as payment or incentive to participants is not allowable except under very limited circumstances. Please see "Gift Cards" in the IRB section for further information.

(8) The SEED grant requires the use of a Proposal Developer (though the extent of the services may vary depending on the investigator's needs). Investigators should work with the Developer to set up a timeline that allows the successful submission of an external application. Funds for the Developer are $1500/yr for a total of $3000 over the course of the grant. This works out to approximately 40 total hours of work at $75/hr. ACU will contract with a Proposal Developer for the job, unless the PI requests that we contract with a specific individual identified by the PI. The PI will need to justify the alternate developer.

Teaching Loads

The intent of the Cullen/Math-Science program is to provide time for faculty scholarship during a summer term in lieu of teaching. It is strongly advised that recipients do not teach during the summer if you receive a summer stipend. However, you may not teach more than one course during this time. SEED recipients should communicate with their department to determine the appropriate time needed to complete the award requirements.

Holding Multiple Grants

Applicants may co-apply for a 20/20 award, though it is not advisable to hold both. Recipients cannot hold a Cullen/Math-Science award and a Curriculum Development Stipend concurrently, nor can SEED recipients hold both.

EXTERNAL AWARDS: ROLES & RESPONSIBILITIES

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) encourages faculty to engage in scholarly activity that is funded by external sources. ACU provides support for obtaining such funding, as well as managing the requirements of external funders through the Office of Research and Sponsored Programs (ORSP).

ORSP provides support in finding and applying for external sources of funding. In addition, ORSP monitors expenses on all scholarly activities funded by external sources, in compliance with federal requirements. However, investigators have certain roles and responsibilities in executing an externally funded project. The procedures herein outline the roles & responsibilities for the investigator, ORSP, and other ACU offices in the management of such projects.

APPLICABILITY OF THE POLICY

This policy applies to all faculty who are listed as principal investigator/project directors on externally funded projects. In addition, this policy outlines the roles & responsibilities for the ORSP office, as well as other ACU offices in the management of external awards.

PROCEDURAL GUIDELINES

The tables below outline the roles and responsibilities for the PI, PI's department and college, the Office of Research and Sponsored Programs, and other offices that may be involved in research and grants management, including but not limited to Finance, General Counsel, Provost Office, Risk Management, and Advancement.

Pre-Award

Roles and Responsibilities	**PI**	**Department**	**College**	**ORSP**	**Other (Finance, GC, Provost)**
Generates Idea	X				
Search for Funding Opportunities	X			X	
Provide Guidance on Opportunities		X	X	X	
The PI is primarily responsible for searching for funding opportunities that best match the project idea. However, ORSP may provide substantial assistance in finding potential matches when requested. ORSP will also share funding opportunities that match known interests when appropriate.					

Roles and Responsibilities	PI	Department	College	ORSP	Other (Finance, GC, Provost)
Writes technical narrative for the proposal	X				
Develops budget and writes budget narrative	X	X			
Provides budget guidance and reviews budget for cost allowability, F&A, fringe, etc.				X	
The PI is primarily responsible for developing the budget in line with project needs and in collaboration with departmental administration to ensure resources and time needs are available. The PI is also primarily responsible for ensuring costs are allowable according to the sponsoring agency and ACU policies. ORSP will review the budget items for allowability and ensure that the correct fringe and F&A rates are listed.					
Completes External Approval Form and route for signatures	X			X	
Reviews External Approval Form and signs		X	X	X	X
The PI is primarily responsible for completing the approval form and forwarding to ORSP. ORSP will review the form and requested documentation and route for signatures from Finance, General Counsel, Provost Office, and Advancement (when appropriate).					
Identify subcontractors, when appropriate, and request budget and scope of work	X	X		X	
When cost share is required, identify source, obtain support and approval	X	X	X	X	X
Cost share should only be committed when required and only to the extent required. Cost share sources must be identified and approved by the Provost Office. Please discuss any cost share requirements with ORSP before proceeding with the application process.					
Submits proposal	X			X	
Signs assurances, certifications, contracts				X	X
The PI should submit proposal materials to ORSP no later than noon on the day the submission is due. The PI should coordinate with ORSP to ensure timely submission. ORSP will review the final documents and submit. The sooner the documents are submitted, the more thorough review ORSP can provide. Proposals that require signatures must be signed by either ORSP or the Provost Office, depending on the nature of the agreement. Contractual obligations are typically signed by the Provost Office, and so should be submitted to ORSP well in advance of the due date to ensure timely					

completion. If the sponsor requires the PI to submit, the PI should still seek final approval from ORSP prior to submission

Roles and Responsibilities	PI	Department	College	ORSP	Other (Finance, GC, Provost)
Completes compliance training and forms: e.g., Responsible Conduct of Research, Research Conflict of Interest Disclosure, Biohazard training, IRB/IACUC training and applications	X				
Reviews and endorses compliance forms, as necessary		X	X	X	X
Institutional oversight of compliance issues				X	X

The PI is responsible for ensuring that all compliance issues are met. ORSP will communicate compliance requirements, revise requirements as necessary to ensure continued compliance, and monitor completion of requirements. ORSP will partner with other offices, such as Finance and Risk Management, to ensure that compliance is being met.

RECEIVING & ACCEPTING AWARD

Roles and Responsibilities	PI	Department	College	ORSP	Other
Accept sponsor notification of grant or contract award				X	X
Review and negotiate terms and conditions for Grants, Contracts, Cooperative Agreements, incoming MTA's, Equipment Loan Agreements, and other agreements associated with award				X	X
Provide feedback on non-standard terms and conditions when applicable	X	X	X	X	X
Execute award on behalf of ACU				X	X

ORSP is primarily responsible for receiving and negotiating award offers. PIs must not accept an award or sign any award documents on behalf of ACU. When appropriate, ORSP will partner with other institutional offices to review and negotiate terms. In addition, when an award involves non-standard contractual obligations, the Provost Office will sign on behalf of ACU according to the signature authority policy in this handbook.

Roles and Responsibilities	PI	Department	College	ORSP	Other
Award Set-up: review all compliance requirements, review budget, set up accounts				X	X
ORSP will review compliance requirements at time of award receipt and request any necessary documents from the PI. ORSP will set up a folder in the Google Drive for storage of all award documents and expense documentation, compliance forms, etc. Finance will review budget and set up accounts.					

Post-Award

Roles and Responsibilities	PI	Department	College	ORSP	Other
Prepare financial transactions	X				
Review and approve financial transactions		X		X	X
Initiate re-budgeting or no-cost extensions as needed	X				
Review and submit re-budgeting or no-cost extension requests				X	
Ensure that cost sharing is documented	X				X
Ensure that participant support costs are documented and not re-budgeted without agency approval	X				X
Use financial reports to monitor and oversee expenditures	X				X
Audit expenditures				X	X
The PI is primarily responsible for expenses on their award. The PI should initiate purchases and payments on the award, track expenses against the budget, document expenses properly and in a manner that could stand alone in an audit situation, and monitor and document cost sharing and participant support expenses. PIs are responsible for being knowledgeable on the regulatory/policy requirements of the sponsoring agency and ensuring spending is in line with these rules. The PI is responsible for ensuring that Finance reviews and approves of all financial reports that are submitted to the sponsor. ORSP and Finance are responsible for monitoring and approving transactions. Finance should ensure that cost sharing and participant support costs are documented appropriately, review financial reports, and conduct internal audits as appropriate. Finance is responsible for invoicing or drawing down funds from the sponsor.					

Roles and Responsibilities	PI	Department	College	ORSP	Other
Initiate requests for prior approvals from agency and submit requests to agency	X			X	
PIs should communicate with ORSP to discuss needed approvals. Typically, ORSP will submit the requests to the agency. All requests for approvals should be documented in writing from the agency and stored in the award folder.					
Monitor subrecipient activities, when appropriate	X				X
Review and approve subrecipient invoices	X				X
Monitor subrecipient for regulatory compliance	X			X	X
The PI is primarily responsible for ensuring that any subrecipients under a subaward complete the terms of the award and comply with any regulatory requirements of the contract and the funding agency. ORSP and Finance will also assist in monitoring and communicating with the subrecipient administrative offices, as necessary. Finance will review subrecipient invoices and ensure payment within the terms of the contract.					
Complete all technical and financial reports	X				
Review and approve financial reports					X
Submit reports	X			X (when required)	
The PI is responsible for completing all reports required by the funding agency. Financial reports must be reviewed and approved by Finance prior to submission. The PI is responsible for submitting all reports, unless the funding agency requires otherwise. A copy of all reports should be placed in the Grant Repository folder or sent to ORSP for filing.					
Ensures that continuing requirements for compliance are met, including Conflict of Interest Disclosures, Time & Effort Reports, IRB/IACUC continuing reviews, etc.	X			X	
Ensures that Time & Effort documentation is accurate and, when necessary, adjust salary payments to reflect actual effort	X	X		X	X

The PI is primarily responsible for ensuring that compliance is met by all research team members. The PI should ensure that effort is appropriate to the award commitment and pay received. ORSP and Finance will review these compliance issues and make adjustments when required.
Close-Out Roles & Responsibilities are defined in the applicable section in this Handbook.

EXTERNAL AWARDS: PRE-APPROVAL, SUBMISSION, AND AWARD ACCEPTANCE

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) encourages faculty to engage in scholarly activity that is funded by external sources. ACU provides support for obtaining such funding, as well as managing the requirements of external funders through the Office of Research and Sponsored Programs (ORSP).

The procedures herein ensure that the various offices on campus work together to support external funding submissions, ensure that award obligations can be met, and ensure that project plans and budget expenditures meet regulatory and ACU requirements.

Failure to obtain institutional approvals and properly submit a proposal could result in a delay in accepting an award or inability to accept the award.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are listed as Principle Investigators or Program Directors on an external award and are responsible for the preparation and submission of proposals. This policy also applies to all offices who handle pre-approvals and submissions, including but not limited to ORSP, Finance Office, General Counsel, and Provost Office.

PROCEDURAL GUIDELINES

Proposal Pre-Approval

Prior to submitting a grant proposal to or entering into a contract or cooperative agreement with any external agency, the proposed funding request must be approved by the University.

What is Reviewed

(1) ORSP reviews the Request For Proposals, compliance issues, training requirements, and budget items. ORSP ensures that the package meets regulatory and ACU policies. ORSP also assists in ensuring the package is complete for review by other offices.
(2) General Counsel reviews all relevant Certifications and Assurances or other contractual obligations. GC ensures that any such obligations are able to be met by ACU.
(3) The Finance Office also reviews the budget to ensure that proposed costs are within ACU and regulatory policies.
(4) The Provost Office reviews any institutional commitments that may be required if the award were accepted, including but not limited to space and resource requirements, time and effort commitments, cost share obligations, and other contractual obligations.
(5) When the funding agency is a private agency, the Advancement Office reviews the request to ensure that it does not conflict with any other Development plans.

External Review Process

(1) As soon as a definite decision is made to apply for external funding, contact ORSP.
(2) Complete an External Funding Approval Form (Appendix A)**.** Complete all of the fields and email the unsigned form and all required supporting documents to orsp@acu.edu. The ORSP office will review the materials and budget for completeness and allowability, then route for signatures.
(3) The form should be completed and submitted unsigned via email at least 2 weeks prior to the deadline for grant submission and prior to signing any contracts or agreements. However, the legal review of certifications and assurances can be conducted well in advance of submission. This will ensure that there is enough time to conduct an adequate legal review.
(4) If you are applying for or receiving a grant/gift from a private foundation, you will still complete the External Funding Approval Form, and it will be routed to the Advancement Office for approval. Please note that if you are asking a private foundation for $100,000 or more, then you must receive approval from the Senior Leadership Team before applying. You must submit this approval with your External Approval Form upon submission.
(5) Once all required parties have reviewed the package and signed, you will receive a notification email from ORSP with the executed package attached and detailed instructions for next steps.

Letters of Intent

If a funding agency requires the submission of a Letter of Intent (LOI) as a first step, you do not have to complete the full External Approval Form unless you are invited to submit a full proposal. However, the ORSP and, in some cases, the Advancement Office need to be aware of, approve, and track all LOIs, as many funding agencies limit the number and frequency of LOI submissions from a single institution. Please complete the LOI Approval Form (Appendix B) and submit, unsigned, to orsp@acu.edu at least 2 weeks prior to your submission date. The ORSP Office will review the request and route for appropriate signatures.

Submission Responsibilities

The ORSP office should submit all applications, unless otherwise required by the agency. Please be sure to communicate with ORSP in advance of your submission date to ensure availability.

Complete applications with the Request for Proposal and submission instructions should be delivered to ORSP no later than noon on the day of submission. It is advised to submit your final application to ORSP prior to submission day for complementary pre-review, to ensure agency requirements are met.

All applications that require a signature from an Authorized Official, Institutional Representative, or other such title should be signed by either the Vice President of Research, Director of ORSP or the Provost (or designee). PIs must not sign any documents that obligate ACU to any terms, conditions, assurances, or certifications (see below). Any applications that commit ACU to provide resources must be pre-reviewed by the Provost Office. Please include these commitments in your pre-review packet, otherwise submit the final application to ORSP at least one week before submission to allow review by the Provost Office.

Failure to comply with the above submission requirements could result in delays or even ACU being unable to accept the award if granted.

Signature Authority for Submissions & Award Acceptance

The Office of General Counsel has established a Contract Signature Policy that applies to all contractual obligations made on ACU's behalf. However, it is recognized that grants, contracts, and cooperative agreements for research and other scholarly activities often carry certain additional obligations that are monitored by the Office of Research and Sponsored Programs. For that purpose, the general contract policy states, "Documents regarding grants awarded by government agencies and private organizations are generally not within the scope of this Policy but are subject to the review process managed by the Office of Research and Sponsored Programs." The process for determining signature authority is outlined below.

(1) All proposals for external funding shall be submitted, negotiated, and accepted through the Office of Research and Sponsored Programs.
(2) ORSP shall review the signature requirements for the award and determine who is able and appropriate to sign on behalf of the institution
(3) Any application or award letter that contains any assurances, certifications, or contractual obligations by ACU shall be signed by an authorized representative of the institution. Such representatives include the Vice President of Research, Director of ORSP, the Provost or authorized designee (e.g., Vice Provost), or the President according to the below criteria:

The Director of ORSP is authorized to sign the following documents:

1. Standard Federal submissions, certifications, and assurances.
2. Documents in which the ORSP Director is enrolled as the Authorized Organizational Representative (and other similar titles).
3. Award/acceptance letters with no legal obligations.
4. Federal award letters with standard federal obligations and assurances.
5. Other reports and documents typically prepared by ORSP.

The Vice President of Research is authorized to sign all of the above documents as well as contracts & Agreements with legal institutional obligations that do not otherwise meet the criteria above.

The Provost or authorized designee shall review any grants/contracts with Cost Share obligations or other required institutional commitments involving academic resources.

General Counsel shall review any Contracts & Agreements with legal institutional obligations that fall outside of the scope of standard Federal award requirements.

The Finance Office shall reviewed and sign all official financial reports to the sponsor.

It is at the discretion of the ORSP office to send a document for review and/or signature to one or more of the above offices, as appropriate.

Once an award is accepted by the institution, ORSP will initiate a fund request for the award. Any checks that are received by a funding agency should be delivered to ORSP to initiate the fund and deposit. No spending should occur on a sponsored project until the PI receives confirmation from ORSP that the account is established and ready for spending (see Pre-award/Advance spending policy in the "Costs" section for exceptions).

EXTERNAL AWARDS: CONFLICT OF INTEREST (COI) DISCLOSURE

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) monitors and documents significant financial interests that may conflict or be perceived to conflict with research funded by external sources, in compliance with federal requirements. All investigators are required to report to the Office of Research and Sponsored Programs (ORSP) any significant financial interests that may pose such a conflict. All COI reporting shall be completed at the time of proposal submission and once per year for the life of the award.

The purpose of this Policy is to promote objectivity in the conduct of sponsored projects by ensuring the disclosure of significant financial interests and the appropriate management of COIs on externally sponsored projects in accordance with federal, state, and institutional regulations and policies. The Uniform Guidance (2 CFR 200) states in section 112 that "The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy." The policy herein is established to satisfy the requirements for reporting and managing COIs related to federally-funded activities as well as any COI requirements for projects funded by other non-federal sources.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees (including faculty, staff, and student workers), trainees, interns, subgrantees, contractors, consortium participants, collaborators, and consultants who have a significant role in the design, conduct, or reporting of research and educational programs funded by external sponsors. Subgrantees, contractors, consortium participants, collaborators, and/or consultants may follow their home institution's policy and procedure in lieu of this policy provided that their home institution has a written and enforced policy that meets the federal and state requirements for disclosure of significant financial interests.

PROCEDURAL GUIDELINES

Definitions

Investigator includes the principal investigator (PI), project director (PD), co-principal investigators (co-PIs), and any other person who has a significant role in the design, conduct, or reporting of research or educational activities funded or proposed for funding by an external agency. For the purposes of the requirements of this policy relating to financial interests, "Investigator" also includes the investigator's spouse and dependent relatives or household members, when applicable.

Manage means to take action to address a financial conflict of interest. This can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research or educational activities will be free from bias.

Significant financial interest means anything of monetary value including, but not limited to,

- Salary or other payments for services (e.g., consulting fees or honoraria)
- Equity interests (e.g., stocks, stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

The term does not include:

- Salary, royalties, or other remuneration from Abilene Christian University
- Royalties and honoraria for published scholarly or creative works
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or nonprofit entities
- An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members , meets BOTH of the following tests: (1) Does not exceed $10,000 in value, as determined through reference to public prices or other reasonable measures of fair market value; and (2) Does not represent more than a 5 percent ownership interest in any single entity
- Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members, are not expected to exceed $10,000 from any single entity during the next 12-month period.

Unit head means the dean of a college, or in the case of departments that do not report to a dean, a vice president.

Designated official means the Chief Business Officer or his/her designee.

Procedure

Annual Disclosure

All employees planning to act as investigators shall, prior to the submission of each sponsored project application and annually thereafter if the project is funded, disclose to the Unit Head, Designated Official, and Director of ORSP the following significant financial interests, including interests of their spouse and dependent relatives or household members:

(1) Any significant financial interest that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
(2) Any significant financial interest in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Employees planning to act as investigators who have no significant financial interests as described above shall submit a certification to that effect.

The Significant Financial Interest Disclosure Statement (for non-PHS Funds only) (Appendix C, Attachment A) will be used for either certification of no significant financial interests or disclosure of significant financial interests. Employees with no significant financial interests should complete and sign only Attachment A. Employees with significant financial interests or financial interests that may appear to be significant should complete and sign Attachment A and the Supplemental Disclosure Form (Appendix C, Attachment B) for each entity in which they have a significant financial interest.

The forms should be forwarded first to the unit head, then from the unit head to ORSP, and finally from ORSP to the designated official when conflicts have been reported. ORSP is responsible for retaining the significant financial interest disclosure forms in accordance with funding agency requirements.

If there is a change in the reported information during the year, the employee will submit an updated form within thirty (30) days of discovering or acquiring a new financial interest.

Regardless of the above minimum requirements, an employee may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Such reporting shall not predate any required submissions to the Securities and Exchange Commission, nor shall such reports contain information that would be restricted under insider information regulations of the SEC.

Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to any external agency, each investigator shall certify that he/she has disclosed any significant financial interests, including those of a spouse and dependent relatives or household members, that would reasonably appear to be affected by the project for which funding is sought. The unit head shall certify that, based on the investigator's disclosure, either: (1) no conflicts of interest exist, or (2) existing conflicts will be managed prior to the expenditure of funds under the award. These certifications shall be made by signing the Office of Research and Sponsored Projects' Grant Pre-Approval Form and submitting the appropriate forms as an attachment.

Review of Disclosures

The unit head shall initially determine whether (1) no conflicts of interest exist or (2) conflicts of interest exist or may exist. In making this determination, the unit head shall act in accordance with the guidelines provided in this policy. The unit head shall submit this determination along with the employee's disclosure form to the ORSP. When conflicts exist or may exist, ORSP will forward the report to the designated official.

The designated official shall review the disclosure and the determination of the unit head. If the designated official determines that no conflict of interest exists, the designated official shall make the appropriate notation on the form. If the designated official determines that a conflict of interest does exist, the designated official shall take actions necessary to ensure that such conflicting interests will be managed. In making this determination, the designated official may choose to seek the advice of a committee appointed by the designated official, of the Office of the General Counsel, or of other university administrators. The designated official, in concert with the investigator and his/her dean, will prepare a resolution plan for managing the conflict. This document will be signed by the investigator, the designated official, and the VP of Research.

If, 30 days following determination as to whether a conflict exists, the designated official and the investigator have not agreed upon a resolution plan, the investigator or designated official may seek the intervention of the VP of Research or designee.

The designated official shall forward all records to ORSP, which shall maintain records of all financial disclosures and all actions taken with respect to each conflicting interest for three years after the

termination or completion of the award to which they relate or the resolution of any government action involving those records, whichever is longer.

The unit head, designated official, Director of ORSP, and any other individuals involved in determining and/or managing COI shall maintain, insofar as possible, the confidentiality of disclosures and resolution plans.

Disclosures may be submitted securely and marked "confidential" to the ORSP Office and/or orsp@acu.edu or uploaded to the study-specific grant repository folder in Google Drive. Please contact the ORSP Office if you have any questions about submission options.

External Reporting

The Director of ORSP shall be responsible for all reporting requirements to external agencies. These include the following:

(1) Signing or obtaining signatures for institutional certifications required in proposals.
(2) Ensuring that reports of the existence of a conflict and its management plan are forwarded to the VP of Research.
(3) Notifying the sponsoring agency in the event an employee has failed to comply with university policy.
(4) Notifying the sponsoring agency in the event that ACU is unable to manage a conflict of interest satisfactorily.
(5) In the event that a conflict of interest is identified after the expenditure of funds under an award, the Director of ORSP will, within 60 days of identifying the conflict (less time if required by the sponsoring agency), notify the agency when required of the existence of the conflict and ensure that the conflict has been managed.
(6) Upon request from any sponsoring agency or other authorized government entity, the Director of ORSP will provide information regarding all conflicting interests identified by ACU and describe how those interests have been managed.
(7) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of an externally funded project, the Director of ORSP will notify the agency of corrective action taken by the VP of Research.

Additional Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

Significant financial interests in companies submitting proposals to Small Business Innovation Research Programs and Small Business Technology Transfer Programs are specifically excluded from the federal definition of conflict of interest.

(1) Examples of manageable conflicts of interest include, but are not limited to, the following:
    (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;

(b) Situations that might allow a university employee to influence the university's dealings with an outside organization such that personal gain for the employee or improper advantage for anyone is the result; and
(c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member.

(2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
(a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
(b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors or that inhibit the publication of research results obtained within the university; and
(c) Circumstances in which a substantial body of research that could and ordinarily would be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests.

(3) Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
(a) Public disclosure of significant financial interests;
(b) Review of research protocol by independent reviewers;
(c) Monitoring of research by independent reviewers;
(d) Modification of the research plan;
(e) Disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interests;
(f) Divestiture of significant financial interests; or
(g) Severance of relationships that create conflicts.

In some cases, the reviewer(s) may determine that imposing conditions or restrictions would be either ineffective or inequitable and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare. In such cases, the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions. These cases should be reported to the funding agency.

Compliance

No proposals will be submitted without the required certifications. If a conflict is identified, the proposal may be submitted before the resolution plan is implemented if the designated official determines that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, actions will be taken. Breaches include, but are not limited to: failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as required by the unit head or designated official; or violation of terms outlined in the resolution plan.

If actions are necessary, they will be imposed in accordance with the university's operating policies and procedures (e.g., Performance Improvement, Misconduct in Research, Faculty Handbook Termination Proceedings). The potential actions may include, but are not limited to, the following: Letter of warning; Ineligibility of the employee for grant applications or supervision of graduate students; Suspension; Non-renewal of appointment; and/or Dismissal. Impending actions may be appealed by the employee to the university in accordance with procedures outlined in Policy No. 530 Complaint Procedures.

EXTERNAL AWARDS: COSTS

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) receives funds to complete projects and research from external sources, including the federal government. The U.S. government has developed grant accounting policies (2 CFR 200, "The Uniform Guidance") that outline the costs that are allowable or not allowable, defines direct and indirect costs, and establishes requirements for procurement and procurement monitoring. ACU is committed to following these regulations for all Federal awards. In addition, non-federal funders may have different or additional requirements. ACU is committed to ensuring financial compliance with all funders.

The procedural guidelines herein address cost allowability, expense approval, indirect cost requirements, procurement, and salary and fringe allowability. These procedures are designed to satisfy the Uniform Guidance requirements for federal awards. Non-federal awards may have different requirements which must be addressed. However, in many instances the Uniform Guidance sets limits based on institutional policy that is applied uniformly to federal and non-federal funds, alike. Therefore, the procedures herein may be applied uniformly to all external funds. Exceptions will be handled on a case-by-case basis based upon ACU policy and interpretations of Uniform Guidance applicability.

Failure to comply with this policy could result in unallowable expenses requiring repayment, impairment in ACU's reputation as a grant recipient, and inability to receive such funds in the future.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are listed as Principle Investigators or Program Directors on an external award and are responsible for budgeting and cost allocation. This policy also applies to all offices who handle grant accounting, including ORSP and Finance Office. The salary policy applies to any ACU faculty, staff, and students that receive pay from an externally funded project, whether federal or non-federal in source.

PROCEDURAL GUIDELINES

Allowability and Expense Approval

The PI on the grant is responsible for ensuring allowability of costs. Federal awards generally follow the Uniform Guidance (2 CFR 200) cost principles, though some agencies/awards may have additional restrictions or special allowances. Non-federal entities may still follow Uniform Guidance, or they may have their own guidelines. Please consult with the Director of ORSP, the Senior Accountant, and/or the grants Program Director if questions arise.

ORSP is responsible for monitoring cost allowance and has the final approval on costs charged to external awards. Approval is dependent upon meeting federal and agency requirements, as well as ACU policy.

Costs that violate ACU policy cannot be approved without written permission from the department responsible for the policy and approval from ORSP. Costs that violate federal or agency requirements cannot be approved without written permission from the agency.

The Uniform Guidance establishes several conditions to determine allowability of costs on federal awards:

(1) The cost must be necessary and reasonable for the performance of the project, adhere to the Uniform Guidance and any other agency requirements, and be applied **consistently** by ACU regardless of funding source.
(2) The cost must be **reasonable**. Reasonable is defined as a cost that "in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost."
(3) The cost must be **allocable** to the award. Allocable is defined as "if the goods or services involved are chargeable or assignable to that Federal award or cost objective in accordance with relative benefits received."
(4) In some cases, the Uniform Guidance explicitly requires prior written approval for a cost, or the allowability of a cost as defined above is unclear and so prior written approval may be sought. In such cases, ORSP will typically contact the Program Director for the award to obtain procedures for approval.
(5) Costs that are determined to be unallowable must be returned to the agency and interest may be required.

The Uniform Guidance Subpart E outlines classes of costs, their allowability and limitations. Some costs are generally not allowable, some are generally allowable, and some are only sometimes allowable in certain circumstances (Appendix D). The PI of a federal award should become familiar with this Subpart and the cost categories outlined therein. ORSP may provide tools and guidance to assist PIs in determining allowability. The PI should also become familiar with the requirements of the specific award program, as there may be allowances or restrictions not generally included in the Uniform Guidance.

Charges should be distributed according to appropriate allocation. If a cost is incurred solely for the purpose of the sponsored award, it may be fully allocated to the award. However, if the product or service also benefits other activities (sponsored or ACU), then the cost should be distributed in a manner proportionate to the allocation.

All charges on a grant must be clearly documented to the extent that:

(1) The purpose of the charge can be determined
(2) The allowability of the charge can be assessed including how the charge benefits the program and whether it is allocable to the program and to what degree (i.e., does it benefit only the program or does it benefit other activities and therefore the charge should be distributed).

Documentation should include at minimum an itemized receipt or invoice and a description of the service/product. Additional documentation that helps support a cost may include:

(1) An explanation for how the cost serves/benefits the sponsored project

(2) An explanation of/justication for the allocation method
(3) Written documentation of sponsor approval
(4) Any explanation/justification for unusual costs

Documentation should stand alone. In the case of an audit situation, documentation stored in the grant Google Drive folder should be sufficient to meet audit standards in the absence of the PI. ORSP has documentation tools that the PI can use to ensure this standard is met (Appendix E).

PIs should be aware that expenses incurred at the end of an award may receive additional scrutiny. Capitalized equipment should not be purchased in the final 90 days of an award. Large supply purchases should not be made in the final 30 days of an award unless justification can be provided showing that the supplies will be used for the specified project within the award period.

Funds that are used for unallowable costs (determined at the time the charge is incurred or at a later date, such as during the audit) must be re-allocated or repaid to the funding agency. If the unallowable charges are determined to be due to violations of known procedures by the PI or other project personnel, then it is the responsibility of the grantee to repay the funds using those available at the Program/Departmental level. Indirect costs or other funds from the University, ORSP, or College level will not be used in such instances. If the unallowable charge occurred due to other circumstances, then discussion between the PI, Department, College, ORSP, and other relevant administrators will occur to determine the most appropriate mechanism of returning funds.

Institutional and Agency Approvals

Certain costs or budget changes must be approved by the institution and/or the agency. Those conditions are outlined below. In all instances, the PI should make the request through ORSP first before moving forward.

(1) Pre-award spending (see section below)
(2) Budget costs in which the allowability is unclear, the agency or regulations require sponsor approval, or costs that are typically unallowable but fall into a special category must receive prior approval before moving forward. PIs should contact ORSP for guidance. In some cases, ORSP may approve the cost with proper documentation. In other cases, ORSP will contact the Program Manager to determine steps for agency approval.
(3) Rebudgeting. Not all rebudgeting requires approval; however, certain conditions do require ORSP and/or agency approval: (a) Any cost that the agency or regulations state requires agency pre-approval must receive such approval prior to rebudgeting; (b) Equipment valued at $5,000 or more; (c) Moving participant expenses out of the participant category; (d) Adding trainees to the participant category
(4) Budget increases
(5) Carry forward of unobligated balances at the end of a budget period
(6) No-cost extension at the end of the award
(7) Other changes that require agency approval or notification include: change in key personnel, a reduction in key personnel effort of 25% or an extended absence, and major changes in the scope of the project

Pre-award/Advance Spending

In general, spending on a sponsored project is not permissible until the award notice has been received and funds delivered/released. However, the institution recognizes that there may be times when pre-award/advance spending is necessary. Pre-award/Advance spending **MAY** be approved when:

(1) It is permitted by the funding agency

(2) ORSP has received confirmation from the sponsor that the award is forthcoming
(3) The spending is necessary to the conduct of the project
(4) An alternative funding account is provided as a guarantee should any expenses be determined to be unallowable or should the award be denied

All Pre-award/Advance spending involves some level of financial risk to the institution. It is the responsibility of the PI and the PI's department to incur this risk. As such, the Department Chair (or appropriate Director) must confirm support of the spending and provide a source of funds as a guarantee. These funds will be encumbered by the finance office in the case that charges cannot be made to the sponsored award for any reason (deemed unallowable, funds are not awarded, budget is reduced, etc.).

It is the responsibility of the PI to request approval for pre-award/advance spending (Appendix F). The PI should justify the need and outline the expected costs for the advance period. In general, these costs should not exceed 25% of the first year costs for 90 days. Costs above this threshold may be approved at greater risk for the department and with approval from the Provost Office.

If a single fund is not available as a guarantee, the department may provide multiple fund numbers. All requested funds will be encumbered as a guarantee.

If approved, the PI is responsible for monitoring the spending to ensure it remains within the limits. Once the limit is reached, the PI is responsible for halting any additional spending or requesting further advance spending by submitting a subsequent request.

ORSP will be responsible for reviewing the request including:

(1) Confirming the allowability of pre-award/advance spending (if not otherwise stated in agency policy) and the allowable period of spending
(2) Confirming that the award is forthcoming
(3) Determining the expected start date and arrival of funds
(4) Reviewing the allowability of the costs, any compliance terms, and any other award requirements, terms, and conditions
(5) Communicating any concerns that may exist regarding potential negotiation of terms and how that may affect acceptance of the award
(6) Approving the allowability of the request given the above information
(7) Submitting the fund request once all approvals are obtained

The Finance Office will be responsible for setting up the advance fund and encumbering the guarantee fund/s. The Finance Office will monitor the spending account to ensure it remains within the approved limits and notify the PI when spending approaches those limits.

The Provost Office will review and approve/deny requests in which: the request is for costs above 25% of the first year, over 90 days, a follow-up request for additional advance spending, or for projects in which confirmation that award is forthcoming is not received (in which case, the risk should be assessed, including the impact of the use of the guarantee funds to cover expenses).

Upon receipt of the award, ORSP will notify the Finance Office to release the guarantee funds.

In the case that expenses cannot be charged to the award or the award is not received, the expenses will be charged to the guarantee fund/s. This may occur in the following instances:

(1) Certain costs are determined to be unallowable.
(2) The start date is delayed beyond the period allowed by the sponsor for pre-award/advance spending (usually 90 days), thus costs incurred prior to the 90 day period cannot be charged.
(3) The award amount is significantly reduced.
(4) The award is not received or cannot be accepted by the institution due to contractual disagreements.

It is at the discretion of the Department Chair, ORSP, Finance Office, and/or Provost Office to deny requests for pre-award/advance spending based on the assessment of risk, availability of guarantee funds, and allowability by the sponsoring agency. Requests will generally be denied in the following cases:

(1) Projects sponsored by for-profit companies as the risk is much greater than that of other funders.
(2) Projects with agencies with a known history of denying pre-award expenditures (some or all)
(3) Projects in which the application has not been reviewed, is pending review, or has not otherwise received a recommendation for funding.

Indirect/F&A Costs

The federal government and many non-federal agencies recognize that institutions incur certain costs in support of sponsored projects. These costs are termed Facilities and Administration (F&A) costs or "indirect" costs. These are the costs that ACU incurs which may not be easily identified and allocated to specific awards, including but not limited to buildings, general equipment, operations and maintenance, general administration and supplies, and library services. F&A charges are considered reimbursements to the institution for such expenses.

Costs that are included in F&A calculations should not be charged as direct costs on sponsored awards.

ACU requires that PIs include Indirect/F&A costs in their budgets to the maximum extent allowable by the agency. ACU has a negotiated rate with federal agencies. This rate should always be used for federal awards, unless the agency explicitly requires a different rate.

When applying to non-federal agencies, PIs should use the rate allowable by the institution. When no rate is published:

(1) PIs or ORSP should contact the agency to determine if F&A is an allowable cost and what rate they allow

(2) If the agency does not set limits on the F&A rate, PIs should include either our federal rate or 28% of modified total direct costs, if the proposal does not include salaries & wages. PIs should consult with ORSP to determine the appropriate rate for their proposal.
(3) Modified total direct costs include salaries and wages, fringe, materials and supplies, services, and travel. It excludes equipment, capital, rental, tuition remission, scholarships, fellowships, and participant support.

At ACU, F&A is divided between the university (30%), the Office of Research and Sponsored Programs (40%), the college or area of the principal investigator (10%), and the department of the principal investigator (20%). The university's portion supports facilities, utilities, and financial management services personnel costs. F&A amounts for the Office of Research and Sponsored Programs are used to support ORSP personnel costs and to support research in general across the campus. The colleges and individual departments are free to determine how to allocate their portions. If a sponsored project involves faculty from more than one department or college, the respective F&A portions may be divided among the involved departments or colleges. These allocations should be negotiated between the relevant Chairs and/or Deans and must be reported to ORSP prior to award set-up in Banner. Once the award is set up and expenses have incurred, the F&A allocations cannot be changed.

Procurement of Property and Services

The following federal definitions apply to this section:

(1) *Property* means real property or personal property. *Real property* means land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment. *Personal property* means property other than real property. It may be tangible, having physical existence, or intangible.
(2) *Supplies* means all tangible personal property other than those described in §200.33 Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or $5,000, regardless of the length of its useful life.
(3) *Computing devices* means machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or "peripherals") for printing, transmitting and receiving, or storing electronic information.
(4) *Contract* means a legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in this part does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward
(5) *Equipment* means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000.

All purchases of property or establishment of service contracts should follow the procurement/purchasing policies outlined in ACU's Procurement Handbook and Employee Policies in Section 900. In addition, Federal procurement standards outlined in the Uniform Guidance (2 CFR 200 Subpart D) must be followed for Federal awards. Those requirements are highlighted below. When purchasing any product or service over the micro-purchase threshold, please contact ORSP for guidance on federal requirements.

Federal Thresholds

Small Purchase Procedures—small purchase procedures are those designed to simplify the purchasing process. Small purchase procedures do not require a competition of sealed bids or competitive proposals.

Micro-purchase threshold: purchases at or below the micro-purchase threshold ($10,000) do not require quotes or documentation of vendor selection. The PI should document the allowability and allocability of the purchase (the expense documentation template, Appendix E, may be used). The PI should conduct some measure of cost/price analysis. The PI should select a vendor that offers the best mix of price, quality, and service for the need.

Simplified Acquisition: For purchases of $10,001 to $250,000, a minimum of 2 rates or quotes are required. A Vendor Selection Form (Appendix G) and all documentation must be submitted to ORSP and Finance before ordering.

For purchases greater than $250,000, a minimum of 3 formal quotes (confirmed in writing, fax, or email enclosure) are required. Quotes/bids may be collected by sealed bid or competitive proposals as outlined in 200.320. The Vendor Selection Form and all documentation must be submitted to ORSP and Finance before ordering.

Sole Source Allowance: to make a purchase of $10,001 or more from a specific vendor without soliciting quotes, a Sole Source allowance should be documented on the Vendor Selection Form. Such allowances may be made in conditions including, but not limited to: specialized services or products that can only be purchased by a single vendor, situations that represent a public health emergency in which there isn't sufficient time to solicit quotes/bids, the federal agency has approved in writing the selection of a sole source, and/or competitive bidding was determined to be inadequate.

The Vendor Selection Form serves to satisfy the requirement that the institution maintains records sufficient to detail the history of procurement, which includes the rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the contract price. When quotes are required, these must be submitted with the Vendor Selection Form as auditable documentation.

General Considerations and Requirements for procurement on federal awards (200.318-323)

(1) In reviewing requests for payment, the PI and institution should ensure that the purchase doesn't unnecessarily duplicate resources.
(2) For purchases above the micro-purchase threshold, the PI should consider if leased options are available and evaluate the alternatives to determine the most economical approach.
(3) Contracts (Appendix H) must be established between ACU and any outside professional service that will be charged to a federal award. Contracts must include the provisions of Appendix II of 2 CFR 200, as required in 200.326
(4) When selecting a contractor/vendor, PIs should consider such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources. Selection should be without imposed state, local, or tribal geographical preferences, except in those cases where applicable Federal statutes expressly mandate or encourage geographic preference
(5) All procurement transactions must be conducted in a manner providing full and open competition consistent with the standards of 200.319

(6) Solicitations should: (1) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description must not, in competitive procurements, contain features which unduly restrict competition. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equivalent" description may be used as a means to define the performance or other salient requirements of procurement. The specific features of the named brand which must be met by offers must be clearly stated; and (2) Identify all requirements which the offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(7) If prequalified lists of persons, firms, or products are used, the PI should ensure that such lists are current and include enough qualified sources to ensure maximum open and free competition.

(8) The PI should consider all necessary affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible according to 220.321

(9) The PI must perform a cost or price analysis in connection with every procurement action in excess of the Simplified Acquisition Threshold ($250,000) including contract modifications. The PI/institution must make independent estimates before receiving bids or proposals.

(10) The institution must negotiate profit as a separate element of the price for each contract in which there is no price competition and in all cases where cost analysis is performed. To establish a fair and reasonable profit, consideration must be given to the complexity of the work to be performed, the risk borne by the contractor, the contractor's investment, the amount of subcontracting, the quality of its record of past performance, and industry profit rates in the surrounding geographical area for similar work. The cost plus a percentage of cost and percentage of construction cost methods of contracting must not be used.

Conflict of Interest in Procurement

An ACU employee may not participate in the selection, award, or administration of a contract supported by a federal award if he/she has a real or apparent conflict of interest. Employees also may not accept gratuities, favors, or anything of monetary values from contractors.

If there is a potential (real or perceived) conflict of interest with the payee, regardless of dollar amount, the PI must submit the COI in Procurement Form (Appendix I), documenting how the conflict will be managed, and obtain approval by ORSP.

ACU's general COI threshold is $10,000. When a potential COI in procurement involves values in excess of this, COIs must also be reported to the institution using the COI form (Appendix C) and managed according to the COI policy.

Non-compliance will be managed according to the general COI policy.

Equipment and Capital Assets Management

Capital expenditures for special purpose equipment with a unit cost of $5,000 or more must have the prior written approval of the Federal awarding agency or pass-through entity and follow the requirements outlined in this section.

Equipment purchased with federal funds must be used for the purposes of the project, during the project period, or until it is no longer needed for the project. The asset must be used and disposed of according to 200.313. These requirements are detailed below:

Use. (1) Equipment must be used in the program or project for which it was acquired as long as needed, whether or not the project or program continues to be supported by the Federal award, and the non-Federal entity must not encumber the property without prior approval of the Federal awarding agency. When no longer needed for the original program or project, the equipment may be used in other activities supported by the Federal awarding agency, in the following order of priority: (i) Activities under a Federal award from the Federal awarding agency which funded the original program or project, then (ii) Activities under Federal awards from other Federal awarding agencies.

Management requirements. Procedures for managing equipment (including replacement equipment), whether acquired in whole or in part under a Federal award, until disposition takes place will, as a minimum, meet the following requirements:

> Property records must be maintained that include a description of the property, a serial number or other identification number, the source of funding for the property (including the federal award identification number), who holds title, the acquisition date, and cost of the property, percentage of Federal participation in the project costs for the Federal award under which the property was acquired, the location, use and condition of the property, and any ultimate disposition data including the date of disposal and sale price of the property. Upon purchase of capital equipment, the PI must submit a Capital Asset Memo (Appendix J) and submit a copy to ACU's Controller in the Finance Office and to ORSP to satisfy this record requirement.
>
> A physical inventory of the property must be taken and the results reconciled with the property records at least once every two years. ORSP and Finance should ensure that these inventories are recorded biennially.
>
> The PI should ensure that the equipment is appropriately secured to prevent loss, damage, or theft of the property. Any loss, damage, or theft must be investigated.
>
> The PI should ensure that adequate maintenance are in place to keep the property in good condition.
>
> If the property is sold, ACU and the PI should use sales procedures that ensure the highest possible return, following procedures outlined in the Finance Operations: Property and Equipment Memo.

Fabricated Equipment. When a PI plans to fabricate equipment using sponsored funds, the PI should notify the Finance Office **before** any purchases are made for the fabrication. All components must be identified to allow monitoring of total cost calculations. If the fabricated equipment total cost will exceed $5K, then the equipment will be capitalized upon completion and tracked as described above. Individual components that meet the definition of "equipment" should be itemized and tracked, as well, though they may be included under the property record of the primary piece of fabricated equipment when it is a permanent installment.

Disposition. When original or replacement equipment acquired under a Federal award is no longer needed for the original project or program or for other activities currently or previously supported by a Federal

awarding agency, the PI should request disposition instructions from the Federal awarding agency. 2 CFR 200 disposition requirements are as follows:

> Items of equipment with a current per unit fair market value of $5,000 or less may be retained, sold or otherwise disposed of with no further obligation to the Federal awarding agency. At ACU, depreciation will be managed, monitored, and calculated by Financial Operations according to the Property and Equipment Memo.
>
> Except as provided in §200.312 Federally-owned and exempt property, or if the Federal awarding agency fails to provide requested disposition instructions within 120 days, items of equipment with a current per-unit fair-market value in excess of $5,000 may be retained or sold. In such cases, the federal awarding agency may be entitled to a share of the sales proceeds, according to calculations set in 200.313.
>
> ACU may transfer title to the property to the Federal Government or to an eligible third party provided that, in such cases, ACU is entitled to compensation for its attributable percentage of the current fair market value of the property.

Supplies.

At the completion of the project, the PI should determine the value of any residual, unused supplies. If there is a residual inventory of unused supplies exceeding $5,000 in total aggregate value upon termination or completion of the project or program and the supplies are not needed for any other Federal award, ACU must retain the supplies for use on other activities or sell them, but must, in either case, compensate the Federal Government for its share. The amount of compensation must be computed in the same manner as for equipment, as detailed in 200.313.

Export Controls and Fly America

Export Controls

The Federal Government sets certain restrictions on interactions with foreign countries. In research, the primary concerns exist in the following areas: collaborations with foreign partner, visiting scholars/enrolled students from controlled nations, travel to controlled foreign countries. If a PI is planning to collaborate with a foreign partner or student either here, abroad, or remotely, please contact ORSP **before** any engagement occurs.

Fly America

The Federal Government sets certain restrictions on the types of airlines that can be used for federally-funded travel. If the PI or another individual on the grant is planning to fly to a foreign country, please notify ORSP **before** plane tickets are purchased or any travel occurs. For reference, the NSF Fly America policy (from the NSF Proposal and Award Policies and Procedure Guide) is available as Appendix K.

ORSP, in collaboration with Risk Management and the International Office, will guide PIs through export control and Fly America concerns and processes.

Salary, Wages, and Fringe

Salary and wages are allowable on external awards for personnel who are essential to the conduct of the project. Their role must be clearly allocable to the award either through hours worked or percent of total effort. This section outlines what is and is not allowable and how salary/wages should be charged to a grant. It is the responsibility of the PI to ensure that salaries/wages are properly established, paid in a fashion that corresponds with effort expended, and is documented in a manner that satisfies federal regulations for effort documentation. It is also the responsibility of the PI to ensure that effort allocated is appropriate to the award commitment and pay received. Time & Effort is further outlined in the respective policy.

General Pay Principles

In general, external awards will pay the salaries/wages of personnel who are essential to the conduct of the project. The pay allowable is the proportionate **share** of the salaries/wages for the employee's effort on the sponsored project. Sponsors view the employee's entire work effort as a whole when determining these proportions, regardless of number of hours worked or when the work is done. In other words, sponsoring agencies do not consider work done on "personal time" as excluded from this whole. Thus, all work done that contributes to the employee's role at ACU and on the sponsored project contributes to 100% of their work effort. The sponsoring agency will pay the proportion of the employee's base salary or wages that represents the proportion of the effort dedicated to the sponsored project.

For employees on a 12 month contract, they should apportion their effort between ACU and sponsored activities and allocate their salary/wages accordingly. This should be calculated on a semester by semester basis and adjusted as appropriate. Faculty on 9 month contracts should see the sections below for academic year salary versus summer salary.

Employees should develop a mechanism for tracking their effort allocation. PIs are responsible for ensuring that all employees are tracking their effort and for storing this documentation to make available upon request. Non-exempt employees naturally track their effort through payroll reports of hours worked. Exempt employees may use the T&E calculator tool available on the ORSP website.

Federal regulations generally allow a 5% margin of error for effort relative to % salary paid. Deviations from this should be adjusted, particularly when the sponsor contributed a greater proportion of the salary than allowable. Significant reductions in effort (25% or 3 months leave or greater) by key personnel must be reported to the agency.

For hourly employees, PAFs should be submitted for the new position and fund. For exempt employees, the PI should meet with ORSP and Finance to establish a mechanism of payment.

Academic Year Salary

For faculty on a 9 month appointment, salary allocation should follow the policy above. Faculty should determine the amount of their total effort that is/will be dedicated to the sponsored project and apportion that percentage of their base salary to the award. This should be done on a semester basis, as effort may vary from one semester to the next.

For Federal awards, course release and/or adjunct costs should not be charged to the award as a direct cost. Course release and adjunct costs are generally considered departmental administrative decisions and

are not allocable to a federal award. Salary share is an allocable cost and will create salary relief for the department to grant course release and hire adjuncts. Course release is a decision to be made between the faculty person and their department.

Though course release cannot be directly charged, effort may assist in determining the need for course release. In general, for a faculty person with a 4/4 load, a single course is considered 20% effort. Course load, then, represents approximately 80% of total effort, with the remaining 20% consisting of other activities such as research/scholarship, service, leadership, committee responsibilities, etc. Therefore, if a faculty person is working on a sponsored award for more than 10-20% of their time, a course release may be necessary.

Some non-federal sponsors do not pay salary, but may allow small stipends, course release costs or adjunct pay. In such cases, the applicant should follow the guidelines of the sponsor.

Summer Salary

Federal regulations allow summer salary for 9 month faculty. Summer pay for 9 month faculty may not exceed 3/9 of the IBS (effectively annualizing the salary), when effort is 100% for 1 FTE and time is not committed elsewhere (including ACU activities and vacation). Because of these other commitments, it is recommended that summer pay not exceed 2-2.5/9 of IBS.

Summer salary must be based on the faculty person's IBS. External summer salary does not change the faculty person's contractual IBS. Summer salary is also not eligible for retirement contributions, leave accrual, or salary incentive payments.

Summer salary should be calculated based on # of months worked, FTE worked, and % effort. For example, summer salary should be calculated as IBS x 1/9 x #months x FTE x % effort.

Institutional Base Salary Limits

Institutional Base Salary (IBS) refers to an employee's contracted salary rate. For 9 month faculty, this is the salary provided in their appointment letter for the 9 month academic year. For other employees, it consists of the salary paid over 12 months. IBS generally does include any additional pay received for appointments including but not limited to Chair, Director, and Dean. IBS does NOT include one-time supplemental payments for activities outside of the employee's job description, course overload, incentives and bonuses, and other stipend payments.

The base salary of any employee **shall not be increased by virtue of funding from a grant or contract, federal or non-federal**. Increases on grant-funded employee salaries must be reported to and approved by the VPR.

Some funding agencies limit the amount of IBS that can be used to calculate grant pay. In such cases, ORSP will work with the PI to determine the salary cap and the amount of salary that may be charged to the grant.

Examples of Pay Allocation

EXAMPLE 1
PI is on a 9 month contract with an IBS of $60,000. PI commits to 25% effort for 4 months in the fall, 10% effort for 4 months in the spring, and 0.5FTE at 100% effort for 2 months in the summer.

Fall salary allocated to grant is $6667 (IBS x 1/9 x 4 x 0.25)
Spring salary allocated to grant is $2667 (IBS x 1/9 x 4 x 0.1)
ACU pays the remaining $50,666
Additional summer salary that may be charged is $6667 (IBS x 1/9 x 2 x 0.5)

EXAMPLE 2
PI is on a 9 month contract with an IBS of $60,000. PI commits to 25% effort for 2 months in the fall and then works for 4 more months in the spring at 25% effort. During the summer, the PI works for 2 months @ 1FTE, dedicating 75% effort to the project and 25% effort to other teaching and research responsibilities.
Fall salary allocated to grant is $3333 (IBS x 1/9 x 2 x 0.25)
Spring salary allocated to grant is $6667 (IBS x 1/9 x 4 x 0.25)
ACU pays the remaining $50,000
Additional summer salary that may be charged to the grant is $10,000 (IBS x 1/9 x 2 x 0.75)

Fringe Rates & Benefits

When salary is charged to an external award, the following fringe rates should also be charged proportionately.

Position	Annual/AY/Summer	Fringe Rate
Exempt Fulltime	Annual	30%
Exempt Halftime	Annual	30%
Exempt Reduced Fulltime	Annual	30%
Faculty Fulltime 9mo	AY	30%
Faculty Fulltime 12mo	Annual	30%
Faculty Halftime	Annual (12mo) or AY (9mo)	30%
Faculty Reduced Full Time	Annual (12mo) or AY (9mo)	30%
Nonexempt Fulltime	Annual	30%
Nonexempt Halftime	Annual	30%
Nonexempt Reduced Fulltime	Annual	30%
Executives(Dean, VP, President)	Annual	30%
Executives Halftime	Annual	30%
Exempt Parttime	Annual	8%
Faculty Parttime	Annual or AY	8%
Faculty Summer Research (9mo)	Summer	8%
Nonexempt Parttime	Annual	8%

Nonexempt Temporary	Annual	8%
Executives parttime	Annual	8%
Student Lab/Research Assistant	AY (if enrolled FT)	0%
Student Lab/Research Assistant	AY (if NOT enrolled FT)	8%
Student Lab/Research Assistant	Summer (IF enrolled HT)	0%
Student Lab/Research Assistant	Summer (IF NOT enrolled HT)	8%
Any supplemental pay outside of IBS	Annual	8%

Extra Service Pay

Extra service pay is allowable only when it is outside of the employee's regularly work duties and meets the HR policy 111 for Supplemental Payments.

Extra Service Pay must be approved by the employee's supervisor, ORSP, and the Provost Office as meeting the requirements for agency and ACU policy. This should be done at the proposal stage and clearly documented in the proposal budget, but certainly before the work begins. It is at the discretion of ACU to determine if the standards are met. Otherwise, pay must be allocated as part of the IBS during standard appointments and/or summer salary for 9 month appointments. Regardless, Extra Service Pay must be paid at a rate commensurate with the employee's IBS and/or existing University pay structures.

The Federal Uniform Guidance (2 CFR 200) allows for Extra Service Pay only under the following conditions (from 200.430(h)(4)).

- "Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. It is allowable if all of the following conditions are met:
- The non-Federal entity [ACU] establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards.
- The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred.
- The supplementation amount to be paid is commensurate with the IBS rate of pay and the amount of additional work performed.
- The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity."

ACU's policy on supplemental pay is outlined in Policy 111 of the Employee Handbook. In general, supplemental payments are intended to be for sporadic activities outside of one's home department. ("Work that is occasional or intermittent and performed on a part-time basis. Assignments must be infrequent, irregular, or occurring in scattered instances [assignments may not be regular or recurring]. Additional nonexempt duties performed by exempt employees for more than 10% of their work time will not be considered sporadic.") In all cases, the employee's immediate supervisor must give permission for

the activities, and ORSP and the Provost Office must confirm that the activity meets the ACU and Federal policies summarized herein.

It should be noted that for non-exempt employees, supplemental activities for hours worked affect the base calculation for overtime (see below). The activities should be discussed with the employee's primary supervisor and HR to determine how it will affect hours worked and any overtime incurred.

Exempt employees who are engaging in an activity on a regular basis should not request supplemental/Extra Service Pay. Please consult with ORSP and HR.

Extra Service Pay must be approved before payment can be issued, preferably at the point of grant submission. In order to obtain approval, please complete the Extra Service Pay Approval Form (Appendix L). This form must be signed by the employee's supervisor, ORSP, and the Provost, confirming that the requirements of this policy are met.

Overtime

Grants should only be charged for overtime pay when it meets the requirements set forth in ACU HR Policy 211 and there is justification that the overtime was necessary to the conduct of the grant, and the charge is allocated to each pay fund proportionately. Employees and Supervisor may complete the Overtime Pre-approval Form (Appendix M) to document the need and pre-approval.

Emeritus Faculty

Emeritus faculty may be PIs/PDs, Co-PIs or other research personnel on a sponsored award. If the individual is no longer on a paid capacity with the university, their research salary should be calculated based on the last employed base salary, escalated at 2% per year. If the previous salary was a 9 month salary and the emeritus faculty person is working on the project in a 12 month capacity, the salary may be annualized. The amount charged to the sponsored award should be based on FTE, just as other sponsored salaries.

EXTERNAL AWARDS: TIME AND EFFORT REPORTING

POLICY STATEMENT & PURPOSE

ACU receives funds to complete projects and research from external sources, including the federal government. The U.S. government has developed grant accounting policies (2 CFR 200, "The Uniform Guidance"), which are often followed by other funding sources. These policies require that personnel costs be documented in a manner that shows they are accurate, allowable, and properly allocable to the grant. In addition, documentation must reflect all activities for which the employee is compensated, and total compensation cannot exceed 100% of the institutional base salary for each employee. Failure to comply with these standards could have significant impact on ACU. Non-compliance can result in disallowed salary and benefits expenditures, associated decreases in the recovery of facilities and administration costs, penalties, fines and other legal action, damage to ACU's reputation, and impairment of ability to act as a subcontractor on awards held by other institutions.

Abilene Christian University (ACU) monitors and documents efforts expended on externally funded projects, whether federal or non-federal in source, in compliance with "The Uniform Guidance" (2 CFR 200) requirements. All project directors and principal investigators for such projects ("PD/PIs") are required to certify both their effort and that of other persons active on such projects led or supervised by PD/PIs, unless the PD/PIs delegate this task to another individual with sufficient knowledge of the project activities and a reliable means of verifying work performed. Delegation of this certification is only acceptable in rare circumstances, such as extended severe illness or lengthy travel outside the country, and must have received written approval from the chair or head of the applicable department and the Office of Research and Sponsored Programs (ORSP).

All ACU effort reporting shall be completed after-the-fact and as a percentage of an employee's total compensated activity in accordance with 2 CFR 200.430. The effort commitment from the project proposal and award document, the reported effort and the employee's ACU salary and wages (e.g., annual or academic year salary, and additional summer salary as applicable,) will serve as the basis for calculation and verification. Adjustments in compensation will be made, as necessary, in compliance with the federal regulations.

Effort reporting is required for all externally funded projects, whether federal or non-federal in source, following each academic semester (fall, spring, and summer). Reports will be distributed by ORSP following the end of the reporting period and must be signed and returned to ORSP. Reporting periods run from the start of the pay period of a semester to the end of the last pay period irrespective of holidays, vacations, and weekends. Time & Effort certification should be completed within 120 days of the end of the reporting period.

Thank you to Lipscomb University for generously sharing their Time and Effort Reporting Policy for use and adaptation by Abilene Christian University.

APPLICABILITY OF THE POLICY

This policy applies to any ACU faculty, staff, students and organizations that work on an externally funded project, whether federal or non-federal in source, on behalf of ACU.

PROCEDURAL GUIDELINES

ACU effort reporting will occur following each academic semester.

All ACU faculty and staff that have worked on one or more externally funded projects, whether federal or non-federal in source, are to certify their total percent effort at the end of each academic semester. ORSP will distribute the Time & Effort Certification Form (Appendix N) to all PIs following the semester to be certified. PIs should then distribute the form to all exempt personnel who need to certify effort. Non-exempt personnel do not need to certify time, as their payroll records satisfy this requirement. Trainees receiving a participant stipend, likewise, do not need to certify time as their role is educational and does not constitute an agreement for work.

"Total Effort" is considered all activities that constitute part of one's job duties, irrespective of total number of hours worked or activities conducted on "personal time." Thus, total effort of ACU and sponsored activities should always equal 100%.

In rare instances, Extra Service Pay is allowable. Extra Service Pay can only be for activities outside of the job description for the specified employee, as defined in the Faculty or Employee Handbook and applicable appointment/hiring letters. Pay must be consistent with ACU policies on supplemental pay and consistent with the pay structure for the specified employee. Extra Service Pay should be approved prior to initiating the work (Appendix L) and reports must be supported by documentation that the work meets these requirements. Extra Service Pay should be documented separately and include justification. Please see the previous "Costs" section for further detail.

As a guide, ACU generally considers a faculty assignment with a 4/4 teaching load to include 20% effort per course/per semester, leaving 20% effort per semester for scholarship, service, and other duties. Faculty with course releases to work on sponsored projects may use this as a guide to determine the amount of effort that should be committed to the sponsored project.

Effort Calculations

Effort on a given sponsored project may be calculated as the number of hours committed to that project relative to the Total Effort number of hours (which may be more or less than 40 hrs/week). Though exempt employees are not required to log hours with payroll, those paid on sponsored projects should develop some system for determining allocation of time.

For 9 month faculty who do not have other ACU duties during summer months, summer effort should be reported only for the time period worked. Pay should be distributed relative to the summer FTE according to the salary policy in the previous section.

Adjustments

If the actual effort dedicated to the project is more than 5% less than that committed (and pay received), then adjustments are required. Funds must be re-allocated for the affected period to accurately reflect the actual effort given to the sponsored project. Short-term fluctuations in time commitment may occur from

semester to semester and will not be a cause for concern as long as the annual effort commitment reflects that which was proposed for the project. The employee should include an explanation of the fluctuation with their report, including how they intend to make up the difference. If reduced effort is expected in the long-term, then pay distribution should be adjusted by notifying ORSP and the Finance Office.

PIs or other key personnel who expect more than 25% reduction in effort must report this to the sponsoring agency. Please notify ORSP as soon as you become aware of such circumstances.

If the actual effort dedicated to the project is above the amount committed and paid, you may record this as voluntary uncommitted cost share. Such commitments should be approved and supported by the employee's department.

PD/PI Responsibilities in Effort Reporting

Faculty and staff who serve as a PD/PI on an externally funded project, whether federal or non-federal in source, accept responsibility to the sponsor and ACU for stewardship of the project and associated resources. This responsibility includes, but is not limited to:

- Reviewing the award documents upon receipt to confirm that the levels of effort and compensation have been properly represented;
- Directing and monitoring activity on the project in a manner that includes awareness of the time commitments by the project personnel;
- Completing an effort reporting form following each academic semester in which work was done and/or pay was received;
- Certifying effort of grant project personnel by signing the applicable effort reporting forms;
- Seeing that all effort reporting is completed and submitted to the appropriate ACU offices by the deadlines listed in the Policy Statement; and
- Identifying when and where effort committed to projects should be adjusted and working with ACU personnel to make the necessary modifications.

Department Level Responsibilities

Department personnel will manage the effort reporting process within the department that oversees or works on an externally funded project in a manner consistent with ACU's policies and guidelines, including the following:

- Addressing challenges and irregularities in respect to effort reporting with the appropriate offices at ACU;
- Facilitating information gathering and reporting in respect to modifications in effort reported, adjustment of time commitment to projects, personnel changes, grant transfers, or any other alteration to the funded project and its implementation; and
- Approving appropriate designees of a PD/PI in effort reporting, should the need arise, including drafting the memorandum or other form describing the substitution and its necessity.

Office of Research and Sponsored Programs and Accounting Office Responsibilities

The Office of Research and Sponsored Programs and the Accounting Office will collaborate to verify, report on, and store effort-reporting materials.

The Office of Research and Sponsored Programs will be responsible for:

- Distributing and collecting effort reporting forms for all persons working on externally funded projects;
- Maintaining this policy on effort reporting in compliance with federal regulations and informing ACU personnel of the same;
- Answering questions regarding policies, procedures and funder regulations;
- Facilitating timely and accurate effort reporting;
- Reviewing any appropriate documents and forms;
- Facilitating conversations with representatives of funding agencies;
- Approving appropriate designees of a PD/PI in effort reporting, should the need arise, by signing the substitution memorandum from the appropriate department.
- Reviewing effort reporting documentation for completion, accuracy, and compliance with funder regulations;
- Maintaining the records that verify and reports that certify effort on externally funded projects;
- Responding to requests for effort reporting information;
- Modifying effort reporting records and informing funders of changes as necessary

The Accounting Office will be responsible for:

- Working with ORSP to provide any accounting records required, including but not limited to budgetary information, invoices, receipting, and payroll reports.
- Assisting in the reallocation of effort and compensation, as needed.

EXTERNAL AWARDS: GRANT SALARY SAVINGS PROGRAM

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) receives funds to complete projects and research from external sources, including the federal government. When an ACU employee works on a sponsored project during the academic year and receives salary support from the sponsor, budget relief may be created for ACU. In an effort to encourage ACU employees to seek and obtain academic year support on sponsored projects, we offer the Salary Savings Program described herein.

Institutional Base Salary (IBS) refers to an employee's contracted salary rate. For 9 month faculty, this is the salary provided in their appointment letter for the 9 month academic year. For other employees, it consists of the salary paid over 12 months. IBS does include any additional pay received for appointments including but not limited to Chair, Director, and Dean. IBS does NOT include one-time supplemental payments for activities outside of the employee's job description, such as course overload, and other stipend payments.

APPLICABILITY OF THE POLICY

This policy applies to all sponsored projects in which salary is charged to the grant for employees who are otherwise regularly paid by ACU. The policy does not apply to employees whose positions are fully grant-funded or to supplemental salaries, such as summer salary for 9-month academic appointments.

PROCEDURAL GUIDELINES

As outlined in the Cost section of this Handbook, salaries are allowable on external awards for personnel who are essential to the conduct of the project. The pay allowable is the proportionate **share** of the salaries for the employee's effort on the sponsored project. The sponsoring agency will pay the proportion of the employee's base salary that represents the proportion of the effort dedicated to the sponsored project. Salary share is an allocable cost and creates salary relief for the university. In an effort to encourage employees to seek salary support for sponsored projects, we offer the following Salary Savings Program.

The Principle Investigator of a project that creates salary savings may request that a portion of these funds be used for the following standard purposes: 1) Unmet research expenses, 2) Project cost share, or 3) Employee bonuses/incentives. Non-standard requests will be reviewed on a case-by-case basis. The salary savings may be accessed at a sliding rate based on the percent of effort being released, up to and including 80% effort. This sliding scale allows for increasing departmental support and teaching replacement costs as replacement loads increase, while recognizing that releases over 80% often require full staffing replacement. Should the savings generated not be enough to cover teaching replacements after shares

have been distributed, then the college and department would be responsible for finding the additional supporting funds.

Calculations for Eligible Funds

Eligible savings are calculated on a semester basis per researcher and deposited into a dedicated account for the PI to access for approved uses (See Appendix O_Calculator for Grant Salary Savings). Savings include the salary + fringe savings. Eligible savings rates are as follows:

% Effort charged to grant in a semester	% of salary savings available to PI
Up to 20%	20%
21-40%	20% of 1st 20% effort 10% on next 20% effort
More than 40% up to 80%	20% of 1st 20% effort 10% on next 20% effort 5% on any additional effort between 40-80%
Above 80%	20% of 1st 20% effort 10% on next 20% effort 5% on any additional effort between 40-80% No additional returns on effort above 80%

EXAMPLE 1: a 9 month PI's IBS is $60,000. In the fall semester, they receive one course release and allocate 25% of their salary and fringe to an external award, resulting in a gross salary savings of $10,125 ($7,500 salary and $2,625 fringe). The PI is then eligible to access 20% of the first 20% effort (20% of $8100= $1620) and 10% of the next 5% effort (10% of $2025= $202.50) for a total of $1822.50.

EXAMPLE 2: a 9 month PI's IBS is $90,000. In the fall semester, they allocate 60% of their salary and fringe to an external award, resulting in a gross salary savings of $36,450 ($27,000 salary and $9,450 fringe). The PI is then eligible to access 20% of the first 20% effort (20% of $12,150= $2,430), 10% of the next 20% effort (10% of $12,150= $1,215), and 5% of the last 20% effort (5% of $12,150= $607.50) for a total of $4,252.50.

Bonuses/Incentives

PIs may use the eligible salary savings to provide bonus payments to those employees creating the salary savings, consistent with the following guidelines:

1) The employee must charge at least 10% effort for one semester (excluding summer for 9 month faculty). Externally-supported summer salary for a 9 month employee is already annualized beyond the 9 month IBS and does not result in institutional savings, therefore, this effort is not eligible for incentive pay. Any other pay that is not charged to the award and, thus, does not produce salary savings is not eligible for incentive pay.

2) The PI must apply for the incentive during the eligible semester (Appendix P_Salary Incentive Payment Approval Form), and may issue payments at the end of the eligible semester. If approved, a request for one-time payment should be **completed** through Payroll by August 15, November 15, and April 15 to be paid on or about September 1 (summer term for 12 month employees), December 1 (fall term), and May 1 (spring term), respectively. The account from which the payment is charged MUST be an institutional account. These payments cannot be paid from external awards.
3) Payments must include the required 8% fringe for supplemental pay.
4) The request must be approved by the eligible employee's chair, dean, ORSP, and the Finance Office. If the eligible person is the Chair of his/her department, then the request will be reviewed by the Assistant or Vice Provost. Deans and above must have approvals from the Provost and the President. Non-faculty should gain approvals from their supervisor and the head of their unit.
5) The eligible employee must be employed by the University at the time of the payout. Employees who leave the university before incentive pay date will become ineligible.
6) Any incentive payout received is considered a one-time payment. It is NOT to be considered as part of the eligible employee's IBS, for retirement contributions, or for leave accrual.
7) Faculty on renewal leave are not eligible for incentive payments during the semester of leave.
8) The award to which salary is charged should pay all direct costs and maximum F&A (indirect costs) unless the program states in writing that only less than full F&A is allowable. The award should not include voluntary cost sharing or in-kind matching or this may reduce the available eligible funds.
9) The eligible employee must have a satisfactory annual review and be fully compliant with fiscal and administrative management of the award. They must meet award deadlines in a timely fashion.
10) The award must have undergone appropriate institutional routing and approval processes at the time of submission.

Voluntariness

Participation is voluntary by both parties. Salary savings are not an entitlement but made available when beneficial to both parties and funding is available. Program may be modified or terminated by ACU at any time.

EXTERNAL FUNDING: STUDENTS AND TRAINEES

POLICY STATEMENT & PURPOSE

The Uniform Guidance limits the circumstances under which a student can be classified as fellows, scholars, trainees, or interns to awards where the purpose is training and the charge is approved by the agency. Many agencies explicitly disallow stipend payments, and others only allow them if the training is laid out in the statement of work and approved by the agency. This policy outlines the conditions under which a student should be classified as an employee versus a trainee/intern.

APPLICABILITY OF THE POLICY

This policy applies to all students who receive wages or training stipends on external awards.

PROCEDURAL GUIDELINES

Trainees/Interns

Student internships involve training with no expected work effort and are designed to contribute to the educational experience of the student.

If the student's effort is to directly benefit the PI's research, and is not otherwise approved as training in the grant proposal, the student must be classified as an employee and paid wages as such (see Student Employees below).

Trainee stipends should be budgeted in Participant Support: Stipends. The proposal should include a training component in the scope of work/proposal with defined learning outcomes, and the activities should clearly constitute training and not employment based on university and federal policies. The training role should be clearly stated in the grant proposal and budget such that agency approval can be given.

Funds approved for Participant Support must be used in this category. Any rebudgeting must be approved by the agency, so the PI should ensure that the trainee is enrolled as an intern with the university and paid a living support stipend through Accounts Payable.

To enroll an intern, the PI should complete the internship paperwork (Appendix Q, R) and submit this to ORSP with the Request for Payment, W-9, and proof of RCR training (see Responsible Conduct of Research section).

Please note that if a student is listed as an employee (Research Assistant, Student Worker, etc) in the grant budget, they **must** be paid wages as such (described below).

Student Employees

If a student is **not** identified as a trainee/intern in the grant proposal as defined above, then they must be classified as an employee. Students can be classified in two ways:

Student Employees: Students must be enrolled full time in the fall/spring or half time in the summer for student employee classification. They should be budgeted in salaries and wages, paid an hourly wage according to university policies on student employment (e.g., capped at 25 hrs/week), and budgeting 0% fringe rate for the student classification.

Non-student Employees: Students would be classified as "non-student employees" if they do not meet the enrollment requirements stated above for classification as student employee. This condition is most likely to occur during the summer if students are not enrolled at least half time to be classified as student employees. Non-student employees should be budgeted in salaries and wages and paid an hourly wage according to university policies on standard employment. For part-time employment, budget 8% fringe. For full-time employment, budget 30% fringe and offer benefits. This classification requires an FTE be approved for the position.

If a PI wishes to hire a student for full time hours (even if briefly): 1) the student may **not** be enrolled full time, and 2) ACU must offer benefits (and the appropriate fringe rate will need to be charged to the grant). This applies to all semesters including summer, and overtime wages must apply.

EXTERNAL AWARDS: SUBAWARDS

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) receives funds to complete projects and research from external sources, including the federal government. The U.S. government has developed grant accounting policies (2 CFR 200, "The Uniform Guidance") that outline the costs that are allowable or not allowable and establishes requirements for subaward monitoring. ACU is committed to following these regulations for all Federal awards. In addition, non-federal funders may have different or additional requirements. ACU is committed to ensuring financial compliance with all funders.

The procedural guidelines herein address subaward risk assessment, monitoring, and management for awards issued with federal funds. These procedures are designed to satisfy the Uniform Guidance requirements for federal awards. Non-federal awards may have different requirements which must be addressed. Exceptions will be handled on a case-by-case basis based upon ACU policy and interpretations of Uniform Guidance applicability and/or the sponsor's requirements.

Failure to comply with this policy could result in unallowable expenses requiring repayment, impairment in ACU's reputation as a grant recipient, and inability to receive such funds in the future.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are listed as Principle Investigators or Program Directors on an external award with a subaward to another institution. This policy also applies to all offices who handle subaward management, including ORSP and Finance Office.

PROCEDURAL GUIDELINES

Subaward Regulations

The following federal definitions apply to this section:

II. 2 CFR 200.92 *Subaward* means an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.

III. 2 CFR 200.93 *Subrecipient* means a non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

IV. 2 CFR 200.74 *Pass-through entity* means a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

The following federal regulations also apply to this section:

(1) 2 CFR 200.101 The terms and conditions of Federal awards flow down to subawards to subrecipients unless a particular section of this Part or the terms and conditions of the Federal award specifically indicate otherwise.
(2) 2 CFR 200.201 & 332 Fixed Amount Subawards
(3) 2 CFR 200.205 Federal awarding agency review of risk posed by applicants.
(d) In addition to this review, the Federal awarding agency must comply with the guidelines on governmentwide suspension and debarment in 2 CFR Part 180, and must require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.
(4) 2 CFR 200.300 Statutory and national policy requirements.
(b) The non-Federal entity is responsible for complying with all requirements of the Federal award. For all Federal awards, this includes the provisions of FFATA, which includes requirements on executive compensation, and also requirements implementing the Act for the non-Federal entity at 2 CFR Part 25 Financial Assistance Use of Universal Identifier and Central Contractor Registration and 2 CFR Part 170 Reporting Subaward and Executive Compensation Information. See also statutory requirements for whistleblower protections at 10 U.S.C. 2409, 41 U.S.C. 4712, and 10 U.S.C. 2324, 41 U.S.C. 4304 and 4310.
(5) 2 CFR 200.308 Revision of budget and program plans.
(c) For non-construction Federal awards, recipients must request prior approvals from Federal awarding agencies for one or more of the following program or budget-related reasons:
(6) Unless described in the application and funded in the approved Federal awards, the subawarding, transferring or contracting out of any work under a Federal award. This provision does not apply to the acquisition of supplies, material, equipment or general support services.
(6) 2 CFR 200.330 Subrecipient and contractor determinations. Characteristics which support the classification of the non-Federal entity as a subrecipient include when the non-Federal entity:
(1) Determines who is eligible to receive what Federal assistance;
(2) Has its performance measured in relation to whether objectives of a Federal program were met;
(3) Has responsibility for programmatic decision making;
(4) Is responsible for adherence to applicable Federal program requirements specified in the Federal award; and
(5) In accordance with its agreement, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity.
(7) 2 CFR 200.331 Requirements for pass-through entities. All pass-through entities must:
(a) Ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the following information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification. When some of this information is not available, the pass-through entity must provide the best information available to describe the Federal award and subaward. Required information includes:
(1) Federal Award Identification. (i) Subrecipient name (which must match registered name in DUNS); (ii) Subrecipient's DUNS number; (iii) Federal Award Identification Number (FAIN); (iv) Federal Award Date; (v) Subaward Period of Performance Start and End Date; (vi) Amount of

Federal Funds Obligated by this action; (vii) Total Amount of Federal Funds Obligated to the subrecipient; (viii) Total Amount of the Federal Award; (ix) Federal award project description, as required to be responsive to the Federal Funding Accountability and Transparency Act (FFATA); (x) Name of Federal awarding agency, pass-through entity, and contact information for awarding official, (xi) CFDA Number and Name; the pass-through entity must identify the dollar amount made available under each Federal award and the CFDA number at time of disbursement; (xii) Identification of whether the award is R&D; and (xiii) Indirect cost rate for the Federal award.

(2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award.

(3) Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the Federal awarding agency including identification of any required financial and performance reports;

(4) An approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal government.

(5) A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this section, and

(6) Appropriate terms and conditions concerning closeout of the subaward.

(b) Evaluate each subrecipient's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward for purposes of determining the appropriate subrecipient monitoring described in paragraph (e) of this section, which may include consideration of such factors as:

(1) The subrecipient's prior experience with the same or similar subawards;

(2) The results of previous audits including whether or not the subrecipient receives a Single Audit, and the extent to which the same or similar subaward has been audited as a major program;

(3) Whether the subrecipient has new personnel or new or substantially changed systems; and

(4) The extent and results of Federal awarding agency monitoring.

(c) Consider imposing specific subaward conditions upon a subrecipient if appropriate as described in § 200.207 Specific conditions.

(d) Monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved. Pass-through entity monitoring of the subrecipient must include:

(1) Reviewing financial and programmatic reports required by the pass-through entity.

(2) Following-up and ensuring that the subrecipient takes timely and appropriate action on all deficiencies pertaining to the Federal award provided to the subrecipient from the pass-through entity detected through audits, on-site reviews, and other means.

(3) Issuing a management decision for audit findings pertaining to the Federal award provided to the subrecipient from the pass-through entity as required by § 200.521 Management decision.

(e) Depending upon the pass-through entity's assessment of risk posed by the subrecipient (as described in paragraph (b) of this section), the following monitoring tools may be useful for the pass-through entity to ensure proper accountability and compliance with program requirements and achievement of performance goals:

(1) Providing subrecipients with training and technical assistance on program-related matters; and

(2) Performing on-site reviews of the subrecipient's program operations;

(3) Arranging for agreed-upon-procedures engagements as described in § 200.425 Audit services.

(f) Verify that every subrecipient is audited as required by Subpart F—Audit Requirements of this Part when it is expected that the subrecipient's Federal awards expended during the respective fiscal year equaled or exceeded the threshold set forth in § 200.501 Audit requirements.

(g) Consider whether the results of the subrecipient's audits, on-site reviews, or other monitoring indicate conditions that necessitate adjustments to the pass-through entity's own records.

(h) Consider taking enforcement action against noncompliant subrecipients as described in § 200.338 Remedies for noncompliance of this Part and in program regulations.

Subaward Procedures

In order to meet the requirements in the policies above, the following procedures should be followed when a subaward is planned and/or implemented.

When a PI is preparing a proposal with a planned subaward, they should contact ORSP as soon as possible to begin the required risk assessment and management. ORSP will first verify that a subaward (vs contractor) is appropriate based on the definitions in 200.330. At the proposal stage, all proposed subrecipients must complete the Subrecipient Commitment Form (Appendix __) and submit this form to ORSP along with the proposed statement of work, budget and budget justification, F&A rate agreement, fringe rate or documentation of proposed rate, and any other required documentation (e.g., NSF biosketch, explanation of audit findings, etc). ORSP will determine if the subaward is allowable based on the information provided by the subrecipient and the terms of the proposed award.

If the proposal is awarded, the PI should notify ORSP and submit a Subaward Request Form (Appendix __) as soon as possible to begin the subaward procedures. At this time, each subrecipient should complete Subaward Attachment 3B pg 1 and, as appropriate, pg 2 (Appedix __). ORSP will conduct a risk assessment (FDP Risk Assessment Questionnaire) to determine the level of monitoring required and will prepare the subaward agreement for review by legal counsel and negotiation with the subrecipients. PIs shall not engage in any subaward negotiations or execution with the subrecipients.

PI and Finance Responsibilities

1. The PI must review technical performance reports or other specified deliverables in a timely manner. Any issues must be documented, investigated, resolved, and the documentation retained in the grant files.
2. The PI is responsible for formally requesting subaward agreements and amendments by completing and sending the Subaward Request Form to ORSP. Anytime an action needs to be made on a subaward, a Subaward Request Form will need to be submitted.
3. The PI and/or Senior Accountant must ensure that the final technical report and final invoice from the subaward is received within the timeframe specified in the subaward.
4. The PI must verify for each invoice that the work is completed in a satisfactory manner and there is adequate progress compared to costs incurred.
5. The Senior Accountant must review each subrecipient invoice for the following and retain documentation of this review (Subrecipient Invoice Checklist) in the grant's files:
   a. Costs are reasonable, accurate, allowable, allocable, and properly documented.
   b. Costs on a cost-reimbursable project have been charged based upon actual expenses, rather than an allocation of the budget. (For example, billing exactly 1/12 of the budget per month is usually not allowable.)

   c. F&A costs have been calculated correctly.
   d. Cost-sharing requirements are being met and reported regularly throughout the life of the subaward.
   e. Cost-reimbursable invoices identify current period and cumulative expenses.
   f. Fixed price invoices identify deliverables/tasks which are being billed, award amount for each deliverables/tasks, and timeline/due dates (if any) for the deliverables/tasks.
6. If the Senior Accountant or PI become aware of any issues of noncompliance with respect to the subaward terms or if they become aware of an audit of the subrecipient, they will immediately notify ORSP staff of the noncompliance and/or audit to take appropriate action.
7. High-risk subrecipients may be contractually obligated to provide detailed documentation of charges. The PI and Senior Accountant must review all required additional documentation prior to invoice approval. All high-risk subrecipients will require additional monitoring from the PI, Senior Accountant, and/or ORSP.
8. ACU's PI should communicate with the subrecipient 90 days before closeout of the award to ensure that the scope of work is complete and final invoicing is due. ACU's PI should review final invoices, ensure deliverables are met, and collect any final reports due by the subrecipient. All final documents should be submitted to ORSP along with the requested close-out documents.

ORSP Responsibilities

1. Prior to issuing a federal or federal pass-through subaward, ORSP will be responsible for the following:
   a. ORSP shall complete a risk review to determine any measures necessary to appropriately monitor the subrecipient. These may include additional monitoring procedures, additional contract language or inclusion of special terms and conditions.
   b. ORSP shall verify whether the subrecipient has completed a single audit when a risk assessment is completed.
   c. ORSP shall confirm that subrecipient has a DUNS number and is registered on SAM.
2. ORSP will include in the subaward the necessary terms and conditions from the prime award and will also include the CFDA number and title for any federal or federal pass-through subaward. Other identifying information will be included when the CFDA information is unavailable.
3. ORSP will inform the PI and Senior Accountant of the additional terms and conditions included in the subaward or other appropriate actions for high-risk subrecipients.
4. ORSP will provide the PI and Senior Accountant a copy of the fully executed subaward.
5. ORSP will maintain documentation regarding ongoing risk analysis of subrecipients.
6. ORSP must request the subrecipient provide clarification of charges that appear unreasonable, unallocable, unallowable, or unclear. In addition, ORSP or the Senior Accountant may request detailed support for selected invoiced charges from the subrecipient. Examples of detailed justifications or documentation that may be requested are: payroll records, copies of paid invoices, description of services rendered by consultant that are paid by subrecipient, and details of incurred travel charges. For any costs determined to be unallowable, ORSP must notify the subrecipient of the disallowance and request a revised invoice with the disallowed expenses removed.

Subawards above Low Risk

Subawards to recipients who are assessed to be more than low risk will require additional approvals and monitoring, depending on the reasons for the increased risk. This may include, but is not limited to: senior level and legal approvals to enter into the agreement, more detailed invoices, more frequent invoicing, submission of all expense documentation, periodic internal audits, submission of conflict of interest reports.

EXTERNAL FUNDING: RESPONSIBLE CONDUCT OF RESEARCH

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) encourages all students and faculty to complete Responsible Conduct of Research (RCR) training; however, the following policy will apply to all undergraduate and graduate students (and post-doctoral employees/trainees, as applicable) receiving National Science Foundation (NSF) support.

NSF requires that all undergraduate, graduate, and post-doctoral trainees/students who receive support on an NSF grant, whether through stipends or wages, receive RCR training. NSF requires that the Institution have a policy in place at the time of proposal submission to provide the requisite training. It further requires that the Institution verify and certify that training has been met according to Institutional policy. The following resources provide the NSF requirement and FAQ.

NSF RCR Requirement

NSF RCR FAQ

APPLICABILITY OF THE POLICY

This policy applies to any ACU faculty, staff, and students that work on an NSF funded project in which undergraduate, graduate, and post-doctoral trainees/students receive support.

PROCEDURES

(1) All students/trainees receiving NSF support at ACU shall complete RCR training as follows:
   (a) Completion of institutionally approved RCR Modules. Please contact ORSP for modules that meet this requirement.
   (b) Formal and/or informal instruction guided by the Faculty mentor, as written in a submitted training plan. The training plan must include the activities to be completed and the dates of expected completion and be signed by the mentor and the mentee. Once training activities are complete, they should be documented and signed off by both individuals.
   (c) For research involving human or animal subjects, any training activities required by the ACU IRB or IACUC, respectively.
(2) The RCR Modules and Training Plan should be submitted to ORSP prior to any payment/stipend support being provided to the student. When possible, these should be submitted at the time of PAF submission, but no later than during the first pay period.
(3) Once the activities in the training plan are complete, the documentation should be submitted to ORSP immediately. The mentor is responsible for ensuring these activities are completed on schedule and documentation submitted to ORSP.

(4) The Executive Director of Research is responsible for overseeing compliance with this policy. The Director is responsible for ensuring that the RCR Modules completion certificate, an adequate training plan, and subsequent documentation of completion of training plan are located in the grant file.
(5) ACU students and trainees receiving NSF support should complete the RCR Modules upon hire/start of program and prior to receiving grant support.

(6) Hands-on RCR training from the research mentor may be through formal and informal meetings, as well as coursework. ACU allows mentor and departmental discretion in formulating these plans, as needs can vary depending on the discipline and the student's background. The mentor and mentee should work together to develop this plan and targeted completion dates.

To complete the training plan:

- Complete the template to develop your training plan (Appendix S)
- The plan should identify the formal and informal activities that will be conducted to deepen the student's/trainee's understanding of RCR
- The plan should include targeted completion dates for each activity
- Submit the plan, signed by mentor and mentee, to orsp@acu.edu, along with the RCR Modules completion certificate at hire/start of program and prior to receiving grant support.
- When training activities are complete, document completion dates and submit to orsp@acu.edu

If the research involves human or animal subjects, the mentor/mentee should contact ORSP for IRB or IACUC training requirements, respectively.

PD/PI Responsibilities

Faculty and staff who serve as a PD/PI on an NSF funded project, in which undergraduate, graduate, and/or post-doctoral trainees/students receive support, accept responsibility to the sponsor and ACU for ensuring that students/trainees are aware of and fulfill the NSF RCR training requirement. This responsibility includes, but is not limited to:

- Ensuring the student/trainee completes approved RCR modules and submits the completion certificate to ORSP prior to receiving support;
- Working with the student/trainee to develop a mentored training plan and ensuring student/trainee submits this plan to ORSP prior to receiving support;
- Ensuring the activities outlined in the training plan are completed, documented, and documentation is submitted to ORSP;
- When human or animal research subjects are involved, ensuring that the student complies with all IRB or IACUC requirements, respectively.

Office of Research and Sponsored Programs Responsibilities

The Office of Research and Sponsored Programs is responsible for overseeing compliance with the NSF RCR training requirement.

The Office of Research and Sponsored Programs will be responsible for:

- Monitoring the involvement of undergraduate, graduate, and post-doctoral students/trainees on NSF awards;
- Verifying that each student/trainee has completed the RCR Modules and the training certificates are stored in the appropriate grant file;

- Verifying that each student/trainee has a signed RCR training plan on file;
- Verifying that the training plan is documented upon completion and located in the grant file;
- Verifying that any applicable IRB or IACUC requirements are met.

EXTERNAL AWARDS: CLOSE OUT PROCEDURES

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) monitors and documents close out procedures for all scholarly activities funded by external sources, in compliance with federal requirements. All investigators are required to complete close out activities with the Office of Research and Sponsored Programs (ORSP) and the Office of Finance.

These procedures ensure that the various offices on campus work together to determine that award obligations are met, accounting is complete and accurate, and reports are submitted in a timely and accurate fashion. The Principle Investigator/Project Director should initiate close out procedures 90 days before the expiration of the award.

Failure to properly close out an award could result in financial obligations to the agency, difficulty in obtaining repeat funding from the agency, and/or complete disbarment from funding from the agency and/or the federal government.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are listed as Principle Investigators or Program Directors on an external award and are responsible for the design, conduct, or reporting of research and educational programs funded by external sponsors. This policy also applies to all applicable offices who handle close-out procedures, including but not limited to ORSP and Finance Office.

PROCEDURAL GUIDELINES

Procedure

Time Table

Executive Director of Research sends reminder of Close Out and Close Out documents, requirements, and timelines	90 days before expiration
PI initiates Close Out process by submitting Close-Out form (Appendix T) and other requested documents	90 days before expiration
PI notifies ORSP and Finance Office of any intention to buy equipment in final days of award. Discussion and justification is required	90 days before expiration
Executive Director of Research sends reminder and documents progress and/or requests status of progress	60 days before expiration

Executive Director of Research sends reminder and documents progress and/or requests status of progress	30 days before expiration
PI notifies ORSP and Finance Office of any intention to buy significant supplies in final 30 days of award. Discussion and justification is required.	30 days before expiration
Award accounts are finalized, cleared, and closed	Within 30 days after expiration
PI completes final reports and submits to agency (or ORSP submits when required)	30-90 days after expiration, depending on award requirements**
PI and ORSP ensure that **ALL** necessary documentation is loaded into the study Google Drive. Documentation should be sufficient to allow a successful audit in the PI's absence.	90 days after expiration

**While most federal awards allow 90 days for submission of final reports, some agencies have a shorter time window. In such cases, the time line above will be sped-up to ensure compliance with the agency's required timeline.

Roles and Responsibilities

Roles and Responsibilities	**PI**	**Department**	**College**	**ORSP**	**Other (Finance, GC, Provost)**
Ensure all appropriate expenditures have been posted to accounts	X	X			X
The PI and his/her department should work with the Finance Office to ensure that all charges have been posted to the award account and that the PI's financial report aligns with the General Ledger. The PI should review the General Ledger provided at the start of Close Out to ensure that no mistakes have been made, no charges are missing or mis-assigned, and that any errors are corrected before Close Out. The PI should note any charges that are pending or expected to occur in the final 90 days (such as salary payments, etc.).					
Resolve issues related to unreconciled accounts	X	X			X
The PI and his/her department should work with the Finance Office to correct any errors or other issues identified in the above step.					
Ensure that all financial reports have been submitted to sponsor	X			X	X
The PI is primarily responsible for ensuring that reports are submitted and accepted on time. The PI must ensure that the financial report is reviewed and approved by the Finance Office prior to					

submission. The Executive Director of Research will communicate with the PI and monitor agency submission portals as necessary to ensure successful submission of reports.					
Monitor submission of Final Technical Reports to sponsor	X			X	
The PI is primarily responsible for ensuring that reports are submitted and accepted on time. The Executive Director of Research will communicate with the PI and monitor agency submission portals as necessary to ensure successful submission of reports.					
Monitor submission of Final Invention reports to sponsor, when required	X			X	X
The PI is primarily responsible for ensuring that reports are submitted and accepted on time. The Executive Director of Research will communicate with the PI and monitor agency submission portals as necessary to ensure successful submission of reports. The Office of General Counsel will provide assistance with IP concerns, as necessary.					
Monitor submission of Patent reports to sponsor, when required	X			X	X
The PI is primarily responsible for ensuring that reports are submitted and accepted on time. The Executive Director of Research will communicate with the PI and monitor agency submission portals as necessary to ensure successful submission of reports. The Office of General Counsel will provide assistance with IP concerns, as necessary.					
Inactivate award account(s) in financial accounting system					X
The Finance Office, in communication with the PI, should ensure that all award accounts are cleared at the completion of the project. The Finance Office should ensure that any monies due to be reimbursed to the agency are transferred in a timely manner, as required by the agency.					
Maintain official project closeout documents for sponsored projects	X	X		X	X
The PI and his/her department, as well as the ORSP will maintain all required documentation for at least 3 years following submission of final report, or the length of time required by the agency, whichever is **longer**. All documentation should be loaded into the study Google Drive for long-term storage and access by ACU officials in the case of an audit. All documentation should stand alone such that a successful audit could be accomplished in the PI's absence. Should a PI leave ACU during the record storage period, the PI's department should ensure that a copy of all documentation is on file at ACU. The Finance Office will maintain financial records as required by their record storage policies.					

Assessing expenditures

(1) The PI should examine the general ledger provided at Close Out initiation for any incorrect or missing charges. Errors or changes should be coordinated with the Finance Office.

(2) The PI should identify any pending or expected charges in the final 90 days, such as any pending p-card charges, salaries, and F&A.
(3) Major equipment purchases should not be made in the final 90 days and major supply purchases should not be made in the final 30 days. If such purchases are necessary and planned during the close out period, these should be discussed with ORSP and the Finance Office and justified and documented.
(4) Personnel and tangibles

Externally-funded personnel – If the award supports an employee, the PI should determine if the position will be transferred to another account or if the position will end with the award. Human Resources (HR) should be notified when the employee's pay should cease or begin to be drawn from another account. The employee should be notified in writing of any changes to his/her employment status prior to the end of the award period. Please seek guidance from HR for proper termination proceedings.

Equipment – Determine who owns equipment purchased with award funds. If the University has ownership, then the equipment should be inventoried. The ORSP should place a copy of the inventory record in the award file in case of an audit. Equipment must be used, sold, or disposed of according to Uniform Guidance or agency requirements.

Inventions – Inventions and patent issues must be managed according to ACU's intellectual property rights policy and any agency agreements. The PI should file any required reports regarding whether or not any inventions resulted from the award.

Supplies – Federal regulations require institutions receiving federal funds to reimburse the federal government for any inventory of **unused** supplies in excess of $5,000. The PI should inventory any remaining supplies, in sum, and report this to ORSP. Please seek guidance from ORSP on how supply values should be calculated and how reimbursements should be made.

(5) Cost Share – If the award called for cost share, the University must document that the appropriate amount of cost share was achieved. Cost share documents should be added to the report and/or award file.
(6) Sub-awardees – If the award has sub-awards, the sub-awardees should be notified that the award is ending. The sub-awardees should be given a deadline by which to make expenditures, pay invoices, and to make appropriate reports to the awardee. Please coordinate this communication with ORSP and the Finance Office.
(7) Extension – If there are significant funds unencumbered in the award, the PI should consider requesting an extension from the funding agency. Please discuss this option with ORSP.

Closing the award account.

(1) The fund will remain active until 1 month after the end of the award, at which time all charges should have posted. At this point, the fund will enter termination status, which allows the Finance Office to finalize expenditures while limiting any further charges to the account.
(2) Once an account is terminated, the FOAP number should be removed from P-Card and Travel card allocations to avoid further charges to the award account.

(3) The account will be permanently deactived 180 days after the end of the award.
(4) The Finance Office should review indirect costs to ensure they were properly calculated and charged.
(5) In the case of fixed price awards, determine what is to be done with any leftover funds, if applicable. Review award terms to determine what is required/allowed.
(6) Invoices that come in after funds have been returned/redistributed are to be handled on a case by case basis. The PI should initially discuss this with ORSP and their department Chair.

Reporting and record keeping

(1) All required reports and documents must be submitted to the funding agency on or before the due date.
(2) In the event a PI fails to submit reports on time, the University may impose stricter monitoring requirements on future external awards.
(3) Records must be stored for at least 3 years following the submission of the final report or the length required by the funding agency, whichever is **longer**. The ORSP Office maintains a Grant Repository on Google Drive for storage of all necessary award-related documentation. PIs are required to store all necessary documentation in the Google Drive Repository. Remember, documentation should stand alone. The institution should be able to successfully complete an audit based solely on the documentation in the Google Drive folder. These documents should be uploaded throughout the life of the award; however, it is the PIs responsibility to ensure that all documentation is stored in the folder upon close-out.
(4) Records for real property and equipment acquired with Federal funds must be retained for 3 years after final disposition.
(5) If any litigation, claim, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.

Thank you to the CLASP group for providing their Close Out template for development of our own policies and procedures, and to University of Maryland for sharing their Roles & Responsibilities tables.

EXTERNAL AWARDS: FINANCIAL REVIEW & AUDITS

POLICY STATEMENT & PURPOSE

The policy herein is established to ensure that adequate internal controls exist to maintain compliance with financial requirements in the Uniform Guidance (2 CFR 200) and with 34 CFR Sections 80.20 and 71.21 which states, "must provide for accurate current, and complete disclosure of the financial results of each grant project. Fiscal controls and accounting procedures must be sufficient to permit the tracing of funds to a level of expenditures adequate to establish that such funds have not been used in violation of the restrictions and prohibitions of applicable statutes."

Failure to comply with this policy could result in unallowable expenses requiring repayment, impairment in ACU's reputation as a grant recipient, and inability to receive such funds in the future.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are listed as Principle Investigators or Program Directors on an external award and are responsible for budgeting and cost allocation. This policy also applies to all offices who handle grant accounting, including ORSP and Finance Office.

PROCEDURAL GUIDELINES

Record storage

A grant repository folder will be set up in the ACU Google Drive for PIs and administrative personnel to deposit all documents and documentation related to external awards. This includes, but is not limited to, reports, invoices, receipts, student intern forms, and time and effort reports. PIs are responsible for ensuring that all grant-related documents are stored in the grant's Google drive.

Please remember that documentation should stand alone. The documents necessary to complete a successful audit should be stored in the Google drive at all times.

Financial Reports

To ensure that all financial reports align with the general ledger and financial office accounting, and to ensure that all costs charged to the account are allowable, all financial reports to the sponsor must be reviewed and approved by the Finance Office prior to submission.

Reports should be submitted to the Senior Accountant in the Finance Office with sufficient time to review the report and compare to the general ledger for the grant account. The PI is responsible for communicating with the Finance Officer well in advance of the report due date to establish review times needed.

Internal Audits

All awards are subject to internal audit procedures. Internal audits will be conducted on a random selection quarterly. During internal audits, grant-related records will be reviewed for completeness, allowability, and consistency with the general ledger.

PIs must cooperate with any internal audits. If documents are not available in the Google drive or questions arise, the PI should respond as quickly as possible for requests for information.

External Audits

Roles & Responsibilities

(1) PIs must cooperate with any external audits by the funding agency. Documents must be provided as requested and in a timely manner.
(2) The Executive Director of Research will communicate with the auditor, determining what documents are needed and coordinating the request with the relevant offices.
(3) The Senior Accountant in the Finance Office will supply the requested general ledger documents and attach the respective receipts and affiliated documentation.
(4) Management Response decisions will be a collaborative effort between ORSP, Finance, and the Provost Office. The Executive Director of Research will compose the Management Response, to be signed by the Provost and VP of Finance.
(5) Any revision of policy required by the Management Response will be managed by the ORSP Office in coordination with the relevant, affected offices/divisions.

Repayment

In the event that an audit finds that ACU must repay grant funds, a meeting will be held between the Executive Director of Research, the Provost (or designated representative), and the Dean of the college that received the award.

Repayment responsibility will be determined based on the following factors: the grant principle that was violated, the University policies that were in place at the time of the violation, any institutional internal controls that were in place at the time, and the knowledge of the parties involved.

The committee will try to reach a fair and balanced consensus of where responsibility for the violation lies and how repayment should be divided among responsible parties. The committee may determine that the individual, the department, the college, ORSP, and/or the University are singly responsible or that shared responsibility exists.

INTELLECTUAL PROPERTY POLICY

ABILENE CHRISTIAN UNIVERSITY

REVISED NOVEMBER, 2003

1.0 Introduction

1.1 Abilene Christian University (ACU) recognizes and encourages development of new and useful devices and processes, publication of scholarly works, and development of computer software as an integral part of the processes of learning, service, and research. ACU acknowledges that faculty, staff and students regularly prepare, usually through individual effort and initiative, articles, pamphlets, courseware and software (including mediated courseware and software for instructional technology in the classroom), and other scholarly and technological works (hereby termed "intellectual property") that may be subject to the provisions of copyright law and may generate royalty income for the authors, inventors, or creators. Publication, manufacture, or production may also result from work supported either partially or completely by the institution. Given the increasing number and variety of works created at ACU, the ownership of and rights to the intellectual property has presented an exigent situation.

2.0 Purpose Statement

2.1 The purpose of the **Intellectual Property Policy** (hereby the name of this document) is to define the ownership and rights of the "creators" or the "originators" (including full-time and part-time faculty, staff and students) and "the University" ("the University" being Abilene Christian University) and to provide policies and an administrative body to govern those policies.

2.2 This **Intellectual Property Policy** seeks to foster the creation and dissemination of knowledge while defining individual and institutional rights and the distribution and sharing of revenues and other benefits that result from the creation and commercialization of intellectual property.

3.0 Terms and Definitions:

3.1 **Intellectual property** can be either an invention or an expressed idea that can be bought, sold, bailed or licensed. This "property" can be protected by patents, copyrights, trade secrets and trademarks. These protections are used to prevent others from the unauthorized manufacture, copying, use or sale of the property in tangible form. Inventions are novel and unobvious and can be protected by patents when practiced. Expressed ideas consist of literature, music, art, software, etc. When these ideas are expressed in a tangible medium, they can be protected by copyright.

3.2 A **copyright** is granted by the United States government to the author or creator of the "original works of authorship." A copyright is used largely for the "creative arts," text and software. Copyrights are granted for the term of the life of the author and an additional 50 years. Once assigned, a copyright

enables a work to be the sole property of the author. The copyright allows either the author or persons deriving rights for the author, to rightfully withhold others from copying or otherwise using the work without permission. A copyright is automatically secured when the work is created or "fixed" in a tangible medium. No publication or registration or other action in the Copyright Office is required to secure copyright registration; however, it is required that a copyright be registered before a lawsuit is brought.

3.3 The proper **copyright notice** consists of three things: 1) The letter "c" in a circle © called the "copyright symbol") or the word "copyright", or the abbreviation "Copr.;" 2) The year of the first publication; and 3) The name of the copyright owner. An example of the proper copyright notice is: Copyright © 1999 Abilene Christian University

3.4 **Copyrightable materials** include but are not limited to literary works such as books, journal articles, tests, glossaries, bibliographies, study guides, laboratory manuals, syllabi, tests, and proposals; lectures, musical or dramatic compositions, unpublished scripts, computer programs, CD-ROMs, maps, blueprints, textual materials, pictures, graphics, sculptures, art works, motion pictures, videos, films, filmstrips, charts, transparencies, and other visual aids, live video and audio broadcasts, programmed instructional material; research notes, research data reports, and research notebooks and other works produced in the university environment.

3.5 **Fair use** is a use of copyrighted material which is permitted by law even though no express authorization is granted by the copyright owner as long as the use is for purposes such as criticism, comment, news reporting, teaching, scholarship, or research. Demonstration of such a purpose is not, by itself, sufficient to sustain a claim that the use is "fair." Fair use determinations are made on the basis of the following four statutory factors: "1) the purpose and character of the use; 2) the nature of the copyrighted work; 3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and 4) the effect of the use upon the potential market for the value of the copyrighted work." (See Section 107, U.S. Copyright Act, 1976).

4.0 Policy Statements:

4.1 Policy on establishing **The University Committee on Intellectual Property** (UCIP): The University Committee on Intellectual Property will be established and will be responsible for making policy recommendations to the Provost for dealing with copyrights and related mechanisms for the protection/exploitation of intellectual properties.

4.1.1 The UCIP will consist of three members: the Assistant Provost for Research, the University Counsel, and a third member designated each year by the Assistant Provost for Research and chosen from the University Research Council. The Assistant Provost for Research will also choose on a case-by-case basis a fourth person who has knowledge about an area in question to serve as an ad hoc member.

4.2 Policy on **authority and responsibility** of UCIP: The committee shall have the following authority and responsibility with respect to intellectual property:

4.2.1 To develop and recommend University policy to the Provost dealing with intellectual property, including the revision of this document.

4.2.2 To hear and make recommendations to the Provost on disputed ownership of copyrightable materials.

4.2.3 To hear and make recommendations on disputed equities of the University, the creators and other parties associated with the intellectual property concerned.

4.2.4 To make recommendations to the Provost for the sharing of royalties between the University and the creator of the intellectual property in which the University has a proprietary interest.

4.2.5 To promulgate such guidelines and procedures as may be necessary for the implementation of this policy, subject to review and approval of the Provost.

4.2.6 To review all disclosures of copyrightable materials. Such review, when possible, should occur prior to submission of such information to any other party. Exceptions to this practice must be approved by the chairperson of the committee and by the author of the copyrightable materials.

4.2.7 To review as appropriate, agreements on copyright matters that may be entered into as a prerequisite to University participation in a sponsored project or receipt of a grant or contract.

4.2.8 To establish deadlines for the disposition of copyrightable materials.

4.2.9 If a decision is made by the University not to pursue an interest in created materials, to advise the appropriate administrators on the assignment of the University's rights to copyrightable materials.

4.3 Policy of **applicability**: This Intellectual Property Policy applies to all full-time and part-time employees of the University. Students attending the University are covered by this policy under two circumstances: 1) when they are in an employment relationship that involves the creation of intellectual property and 2) when they are assisting in a project managed by faculty or staff of the University.

4.3.1 Otherwise, student works created in fulfillment of academic requirements belong to the student. However, by enrolling in the institution, the student gives the institution a nonexclusive royalty-free license to mark, modify or retain the work as required by the institutional process. Institutional policies or course syllabi should identify how intellectual property created by students will be treated. The institution shall not have the right to use the work in any other manner without the student's consent.

4.4 Policy on **"nominal use"**: nominal use of University resources shall mean use that is customary or usual given the employee's appointment and academic assignments. For example, the use of office, computer, photocopier, telephone, office supplies, secretarial assistance, and other assigned resources in the ordinary support of his or her responsibilities and assigned activities is considered to be nominal. University personnel may make such nominal use of University resources and devote office time in carrying out a range of professional activities. Furthermore, the University recognizes that ownership of any intellectual property resulting from such activities rests with the developer(s) along with the rights to any income generated, as long as university resources are used in this nominal (or customary) fashion,

and the time involvement of the developer(s) of the intellectual property in questions does not compromise the individual's (s') core responsibilities in teaching, research, and service.

4.5 Policy on **"substantial use"**: Substantial use of University resources shall mean use of university facilities, equipment, personnel and an employee's own time beyond nominal (or customary) as described above. Substantial use of resources occurs when creation of the work or intellectual property in question requires use of University resources beyond those allocated to individuals in support of assigned responsibilities and activities within their respective departments or colleges. Such usage may occur as a result of actions of the personnel involved, may occur when specific assignments are given to personnel, or may occur in situations where contracts or other obligations are involved. The University will retain title to all intellectual property that involves substantial use of University resources. However, the university grants authors permission to assign copyright for purposes of publishing scholarly materials, such as journal articles and chapters in books.

4.5.1 The following examples generally define substantial use when they are applied, singly or in combination, in support of a revenue-producing work. It is the responsibility of the dean, director, or equivalent supervisor to evaluate situations and determine whether or not substantial use of resources has occurred. Faculty members or other employees also have an obligation to promptly notify their supervisors when they believe their work will involve more than nominal use. Furthermore, such notification must be accomplished before the execution of an assignment of rights with the University Committee on Intellectual Property. The following are examples of substantial use:

4.5.2 Extended use of time and energy by the developer(s) in creation or promotion of a work which results in a reduction in the levels of teaching, scholarship, or other assigned university activities, and the developer's (s') anticipated instructional load in these areas is at a level significantly lower than normal;

4.5.3 Greater than customary or nominal use of University facilities such as laboratories, studios, equipment, production facilities, or specialized computing resources in direct support of development of the work in questions;

4.5.4 Extraordinary University funding in support of the work's creation, publication, manufacture or production;

4.5.5 Direct assignment or commission from the University to undertake a creative project as a part of the developer's regular appointment;

4.5.6 Substantial use of funding from gifts to the University to support creation of the work(s) involved;

4.5.7 Production of the works under specific terms of a sponsored research grant or contract;

4.5.8 Use of specifically designated University funds to support media production. Such use and support will require negotiation and agreement by the developer(s) and his/her (their) respective supervisors as to the ultimate management and financial considerations concerning the resulting work as intellectual property. Whenever possible, such use and support will be identified in advance of or during the project, by the developer(s) and his/her (their) respective supervisors.

4.6 Policy on "**work-for-hire**" or "**made-for-hire**": Except as herein provided, the University shall obtain the entire right, title, and interest in and to any work or intellectual property made by any faculty or staff member of the University: (a) with a substantial contribution by the University of facilities, equipment, materials, funds, or information, or of time or services of other University employees during working hours, or (b) which is made in consequence of the official assigned duties of the creator or originator.

4.6.1 For the purpose of this policy, it shall be deemed that a work or intellectual property has been "made-for-hire" if the employee is employed or assigned to: (a) invent, improve, or perfect any art, machine, design, manufacture, or composition of matter, (b) conduct or perform research, development work, or both, (c) supervise, direct, coordinate, or review University financed or conducted research or development work, or both, or (d) act in a liaison capacity with agencies or individuals engaged in such research or development. This assignment, however, does not preclude the sharing of royalties or other payments with the employee in accordance with this policy.

4.6.2 The University claims no interest in the work or intellectual property if University facilities, services, funds, or time have not been used. An example would be works or intellectual properties resulting from pursuance of a hobby, not related to the employee's University activities, and conducted off-campus.

4.6.3 Copyrights – In order to encourage creative efforts by the faculty and staff, the University will exercise its rights as an employer under the concept of "work-made-for-hire" only when: (1) the materials subject to copyright represent an assigned duty of a member of the faculty or staff of the University, and/or (2) substantial use of University facilities and resources is made in the production of the materials.

4.6.4 In any case, where the contribution of the University, as measured by the foregoing criteria, is de minimis and is insufficient to equitably justify the requirement of assignment to the University of the entire right, title, and interest, the University shall reserve an exclusive, irrevocable, royalty-free license in the copyrightable work with those in power to grant licenses for all University purposes.

4.7 Policy on **Exception**: In the event that an originator or creator of some work or intellectual property desires to take exception to the policies on nominal use, substantial use and/or work-for-hire (policies 4.3, 4.4 and 4.5) that originator or creator may do so based on the following criteria and process.

4.7.1 The originator or creator has to present in advance a strong and persuasive rationale based on extraordinary considerations in writing to the University Committee on Intellectual Property prior to assuming ownership of the copyright on the work or intellectual property.

4.7.2 The approval of such request will require an official consent of the UCIP.

4.7.3 In exceptional cases, the creator or originator would be obligated to provide remuneration to the University for expenses incurred through the use of University facilities during the development of the work or intellectual property. The remuneration will be paid back in terms to be agreed upon by the creator or originator and the UCIP.

4.8 Policy on **Revenue Sharing**: Where the University has an equity position in an intellectual property, the creator and the University will share equally in any income received by or on behalf of the University from royalties, front-end payments, or incentives, after any expenses incurred by or on behalf of the University to protect, market, or develop the intellectual property have been repaid to the University. In this context, the "University" shall be understood to include all those units (e.g., departments, centers, etc.) which have contributed materially towards development of the intellectual property. The University's share of royalties or other income shall be divided commensurate with involvement of the University units during development. In usual practice, division of the University's share shall follow recommendations of the UCIP and shall typically include an assignment to the employee's primary unit (e.g., departments, centers, etc.) equal to at least 10 percent of the total income as defined above. The remaining portion of the University's share shall be used to maintain an environment supportive of employee activities in development of intellectual properties.

4.9 Policy on **Use by Non-owners**

4.9.1 Where the University is the owner of intellectual property created by an originator, the University agrees to grant the originator a non-exclusive and irrevocable license in relation to the intellectual property.
4.9.2 Where an originator is the owner of intellectual property created in the course of employment with the University, the originator agrees to grant the University a non-exclusive and irrevocable license in relation to the intellectual property.

4.9.3 Where the intellectual property arises from the work which has been specifically commissioned by the University, or which has been produced for teaching or administrative purposes, the University's license includes the right to adapt the subject matter of the intellectual property.

4.9.4 Where a license has been granted the license must not: (a) commercially exploit the intellectual property, or assign the license, or grant a sub-license, without the consent of the University, such consent not to be unreasonably withheld; or (b) do anything which would jeopardize the protection or enforcement of the owner's intellectual property rights.

4.10 Policy on **Reporting or Disclosure**: All materials in which the University may have a proprietary interest under any provision of this policy shall be promptly reported in writing by the University personnel concerned, through their department heads, to the UCIP. The purpose of this disclosure is to determine whether, and to what extent, the University has a proprietary interest in the materials. This report shall include a full and complete disclosure of the subject matter of the materials concerned and identity of all persons participating in the development.

4.11 Policy on **Ownership of Intellectual Property:** The Copyright Act (P.L. 94-553) provides that, when a copyrightable work is produced by one person who has been employed by another for that purpose, it is the employer and not the actual creator or originator that is the copyright proprietor. In the academic setting, complex issues can arise as to whether the faculty or staff person produced the copyrightable work in the course of his or her employment. Generally, the courts have placed a heavy burden of proof on the employee to establish the copyright was not a product of his or her employment.

4.12 Policy on **Dispute Resolution**: Should any issues develop as to the ownership of the intellectual property involved, the UCIP shall make a finding as to ownership and shall report for final resolution such findings to the Office of the Provost. The parties involved shall be entitled to appear before the Committee and to present evidence with respect to the disputed ownership. The Committee's determination shall be made in writing and shall contain a statement of the basis for its decision.

4.12.1 The Provost, on his/her own motion or at the request of any interested party, may review any determination of the Committee. The Provost may affirm, modify, or reject any determination of the Committee.

4.13 Policy on the **Right of Appeals**: The creator or originator of an intellectual property covered by this policy shall have the right to appeal application of the policy regarding ownership, equity, classification, sharing of royalties, disposition, management, or exploitation of a copyright, or any procedure relating thereto, to the UCIP.

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*See Appendix U for Intellectual Property Agreement & Intellectual Property Disclosure Form

RESEARCH MISCONDUCT

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) strives to create a climate that promotes faithful adherence to high ethical standards in the conduct of research, scholarship, and creative activities without inhibiting the productivity and creativity of the academic community.

The policies and procedures herein are written to comply, when applicable, with the Federal Policy on Research Misconduct, published in Federal Register: December 6, 2000 (Volume 65, Number 235). According to the Federal Policy, the following definitions apply:

Research Misconduct Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

A *Finding* of research misconduct requires that: There be a significant departure from accepted practices of the relevant research community; and the misconduct be committed intentionally, or knowingly, or recklessly; and the allegation be proven by a preponderance of evidence.

Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

The *Research Record* is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

Research Misconduct is a major breach of the relationship between a faculty member, staff member, or student and the institution. In order to maintain the integrity of research projects, every investigator must keep an auditable record of experimental protocols, data, and findings. Coauthors on research reports of any type must have a bona fide role in the research and must accept responsibility for the quality of the work reported.

Any inquiry or investigation of allegations of misconduct in research must proceed with *timeliness* and with due regard for the reputation and rights of all individuals or entities involved. *Timeliness* means reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases (if any), with allowances for extensions where appropriate, to provide confidence that the process will be well managed. When funding agencies require specific timelines, these will be followed under the advisement of the Executive Director of Research.

This policy is developed in part based on the Federal Policy on Research Misconduct, published in Federal Register: December 6, 2000 (Volume 65, Number 235) and the NSF Research Misconduct policy. Thanks also to Angelo State University and University of Wisconsin-Parkside for generously sharing their Research Misconduct Policy for use and adaptation by Abilene Christian University.

The university will take reasonable steps to assure that the persons involved in the evaluation of the allegations and evidence have appropriate expertise and that persons involved in the procedures are neither biased against the accused person(s) nor have conflicts of interest.

The university will take reasonable steps to protect complainants who make allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Whistleblower protections are posted in the Employee Handbook (421).

The university will take reasonable steps to ensure the integrity of research, the rights and interests of research subjects and the public and the observance of legal requirements or responsibilities.

The purpose of this policy is to outline and delineate the procedures of the university with regard to the conduct of research and scholarly activity.

This policy is also established to satisfy the requirements for reporting and managing allegations of misconduct related to federally- and non-federally funded scholarship and publication.

APPLICABILITY OF THE POLICY

This policy and the associated procedures apply to any person paid by, under the control of, or affiliated with Abilene Christian University, such as scientists, trainees, technicians and other staff members, faculty members, students, fellows, guest researchers, or collaborators. The policy and associated procedures will normally be followed when an allegation of possible misconduct in research is received by an institutional official.

PROCEDURAL GUIDELINES

Definitions

Allegation means any written or oral statement or other indication of possible research misconduct made to the Provost or designee at Abilene Christian University.

Complainant means a person who makes an allegation of research misconduct.

Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur because of prior or existing personal or professional relationships.

Good faith allegation means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is unjust and malicious or is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

Inquiry means gathering information and initial fact-finding to determine whether the allegation has substance and if an investigation is warranted.

Investigation means the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies.

Respondent means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

Procedure

(1) Initial allegations, whether oral or written, must be reported to the Provost or designee. Allegations may also be reported anonymously according to the Institution's Whistleblower Policy.
(2) When allegations involve federally funded research, the Provost or designee shall immediately notify the Executive Director of Research, who will advise on requirements and timelines of the involved agency.
(3) The Provost or designee shall informally review any allegation of misconduct in research and scholarship and determine whether the allegation warrants initiation of the inquiry process according to the policies and procedures for misconduct in research and scholarship, or whether other policies and procedures, such as those relevant to employment grievances, should be invoked. If the Provost or designee determines that the allegation provides sufficient information to warrant research misconduct follow-up, the complainant will be asked to put the allegation in writing, if it has not already been so done. If the reporting individual chooses not to make a formal written allegation but the Provost or designee believes that reasonable cause exists to warrant an inquiry, the inquiry process shall be initiated.
(4) Even if the individual against whom the allegation is made (hereafter referred to as the respondent) leaves or has left the university before the case is resolved, the university may pursue an allegation of misconduct to its conclusion.
(5) Confidentiality During the Inquiry, Investigation, and Decision-Making Processes. To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know. Records maintained during the course of responding to an allegation of research misconduct are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation. Records will be stored securely and shared only on a need-to-know basis.

Inquiry

(1) The purpose of an inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant a formal investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.
(2) If the Provost or designee determines that an allegation has merit, he or she will immediately initiate the inquiry process and notify the complainant and the respondent. The Provost or designee will appoint a Fact Finder to conduct the inquiry and notify the respondent of the Fact Finder's identity. The respondent may submit a written objection to the appointed Fact Finder based on bias or conflict of interest within 5 working days of the respondent's receipt of the notice, and the Provost or designee will determine whether to replace the challenged Fact Finder with a qualified substitute.

(3) Upon completion of an inquiry, the Fact Finder will decide whether there is sufficient evidence of possible misconduct to merit further formal investigation. The outcome of the inquiry will be conveyed in writing to the Provost or designee and shared with the respondent. The written report should include the name and title of the Fact Finder, the allegations, a summary of the inquiry process used, a list of research records reviewed, summaries of any interviews, and a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted. General Counsel should review the report for legal sufficiency. The respondent shall be given the opportunity to respond to the report, in writing, within 10 days of receiving the report.
(4) If the Provost or designee determines that the outcome of the inquiry indicates a need for formal investigation, the Provost or designee shall notify both the respondent and the complainant in writing. Under certain circumstances, as defined by the applicable federal regulations, the institution may be expected to notify the sponsoring agency or funding source prior to the initiation of an investigation.
(5) If the Provost or designee finds that an allegation is unsupported but was submitted in good faith, he/she will take no further action, other than informing all parties. If it is found that the allegation was not made in good faith, the Provost or designee may proceed with actions in accordance with university performance and disciplinary procedures (see Adjudication in Section I below).

Formal Investigation and Determination

(1) A formal investigation will be initiated when the Provost or designee determines that the inquiry findings warrant such an investigation. The purpose of the formal investigation is to explore the allegations further and to determine whether misconduct in research and scholarship has been committed, by whom, and to what extent.
(2) The Provost or designee will, after a decision to proceed with an investigation, and after consultation with relevant administration, appoint an Investigating Committee of no less than three persons who are without conflict of interest and have appropriate expertise for evaluating the information relevant to the case. The Provost or designee will notify the respondent of the proposed committee membership, and the respondent may submit a written objection to any appointed member of the Investigation Committee based on bias or conflict of interest within 5 working days of the respondent's receipt of the committee membership. The Provost or designee will determine whether to replace the challenged member or members with a qualified substitute.
(3) The Investigation Committee will review the charge, the inquiry report, relevant records and testimony, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality. The committee should make every attempt to interview all individuals involved in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations. Interviews should be recorded or transcribed.
(4) Upon completion of the investigation, the committee will submit to the Provost or designee a full written report that details the Committee's findings and recommendations. The committee shall find no academic misconduct unless a majority of the members conclude that the preponderance of the credible evidence substantiates the allegations(s). The report should describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any actions taken by the institution (see Adjudication in Section I below). The respondent shall receive a copy of the report and permitted to comment, in writing, within 10 days of receiving the report.

(5) Nothing herein shall prohibit the university from instituting disciplinary proceedings against the respondent under university policy.

Adjudication-- recommendations are reviewed and appropriate corrective actions determined

(1) Finding of Absence of Research Misconduct-- All research sponsors and others initially informed of the investigation will be informed in writing that allegations of misconduct were not supported. If the allegations are deemed to have been made in bad faith, the Committee will report those findings to the Provost or designee who will determine if any administrative action will be taken against the complainant according to University conduct policies (Performance Improvement 430; Faculty Handbook Termination Proceedings). If the allegations, however incorrect, are deemed to have been made in good faith, no additional measures are indicated and efforts will be made to prevent retaliatory actions. In publicizing the finding of no misconduct, the university will consider whether public announcements will be harmful or beneficial in restoring any reputation(s) that may have been damaged.
(2) Finding Research Misconduct-- The Provost or designee shall consider the recommendations of the committee and shall be responsible for recommending actions to the Provost. The Provost will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions.
(3) In addition, the Provost Office, in coordination with the Executive Director of Research and Legal Counsel, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, funding agencies or other relevant parties should be notified of the outcome. The Executive Director of Research is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.
(4) The university should take action appropriate for the seriousness of the misconduct, including, but not limited to, one or more of the following, subject to existing university policies:
    (a) Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
    (b) Restitution of funds as appropriate;
    (c) Disciplinary actions in accordance with the university's operating policies and procedures (e.g., Performance Improvement, Faculty Handbook Termination Proceedings). The potential actions may include, but are not limited to, the following: Letter of warning; Ineligibility of the employee for grant applications or supervision of students; Suspension; Non-renewal of appointment; and/or Dismissal

Appeal

The respondent may appeal the findings and recommendations following the University’s appeal procedures outlined in Policy No. 530 Complaint Procedures

Record Retention

The Provost or designee will keep all records related to the Inquiry, Investigation, Resolution, Actions, and Appeals for three years after completion of the case or, in the case of an externally funded project, for the duration of the funding agency’s minimum records retention period, to permit later assessment of the case by the Office of Research Integrity or other authorized federal agency personnel.

HUMAN SUBJECTS RESEARCH: IRB STATEMENT OF PRINCIPLES

Abilene Christian University is comprised of a community of scholars who are committed to the highest level of integrity and ethical conduct in their work. This commitment grows out of the distinctive Christian character of the institution and its members. Respectful of the biblical doctrine of the creation, members of the ACU community are expected to engage in their scholarly activities with due regard for all the created order, both human and non-human. As a teaching institution, the research activities of the faculty and staff serve as exemplars for the students who observe and learn from these activities.

In order to ensure ethical behavior in the conduct of scholarship and research, the University has established this Institutional Review Board policy. This document is meant to ensure that research practices minimize risk to subjects and that potential benefits from research activities are maximized. This document articulates procedures that assure the human subject participation is based on equitable selection of subjects, and that participation in human subject research is non-coercive and based on the principle of informed consent.

The procedures described in this document are designed to conform to state and federal requirements for the protection of human subjects. While such conformity is necessary for receiving external funding, the rationale for developing and implementing this document is primarily an expression of the Christian commitment of the institution and its faculty, staff and students.

HUMAN SUBJECTS RESEARCH: IRB ORGANIZATION AND COMPOSITION

POLICY STATEMENT & PURPOSE

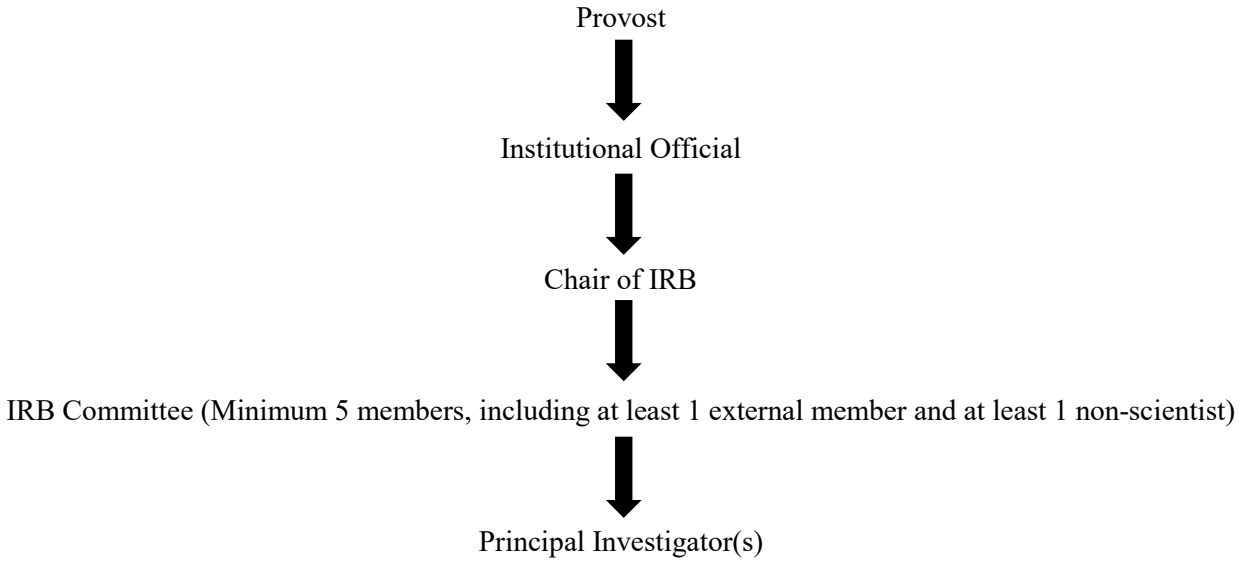
This policy and the following procedures outline the composition of the Abilene Christian University Institutional Review Board (IRB), including but not limited to the number of members, their qualifications, how they are selected, and their tenure. Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to all current and prospective members of ACU's IRB, as well as any administrative units involved in the nomination, selection, and/or oversight of IRB members and activities.

PROCEDURAL GUIDELINES

The lines of authority and responsibility for administering the research program involving human subjects and ensuring compliance with the policies outlined in this handbook are:



Abilene Christian University Institutional Review Board members will be appointed by the Provost or designee. The Provost may appoint up to the maximum allowable by the Faculty Senate.

The Chair shall be the Director of the Office of Research and Sponsored Programs. The Chair will be notified of all decisions made by the IRB and will report those to the Institutional Official, as appropriate.

The Institutional Official shall be the Vice President of Research.

Criteria for Membership

The Provost or designee, considering advice from the Deans, will appoint IRB members using the following criteria, which were adapted in accordance with federal regulations 45 CFR 46 and 21 CFR 56 to safeguard the rights and welfare of human subjects in research:

1. Each IRB will consist of at least five members with varying backgrounds to promote complete and adequate review of human research activities commonly conducted by the institution. The maximum size of the IRB is set by the Faculty Senate who determines the number of faculty members who may be assigned to IRB service.
2. Each IRB will be sufficiently qualified through the experience, expertise, and diversity of the members, including consideration of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. No IRB will consist entirely of men or entirely of women. Qualified persons of both sexes will be considered so long as no selection is made to the IRB only on the basis of gender.
4. Each IRB will consist of members of various professions including at least one scientist, at least one nonscientist, and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is currently affiliated with the institution (community member). Members will be full-time tenured or tenure-track faculty members, with the exception of the individual representative who is not otherwise affiliated with ACU.
5. Alternate members may be appointed, in keeping within the maximum set by Faculty Senate. Alternates may replace any member in a full board meeting, when alternates are needed to meet quorum. Alternates may also be assigned exempt and expedited reviews as needed.

Replacing members

When a vacancy occurs on an IRB, the chair of the IRB shall contact the Dean of the appropriate university college/school/division and request a nomination to fill the vacancy. The nominee's name and current curriculum vitae should be returned to the chair. Once the nomination has been returned, the Provost or designee will review the credentials.

The Office of Research and Sponsored Programs (ORSP) staff will review the functions and responsibilities with the nominee to ensure that the nominee fully understands the time commitment needed for service on this committee.

Once the nominee has agreed to participate as a member of the IRB, a recommendation for appointment may be sent to the Provost or designee, indicating whether to appoint the nominee as a full committee member or an alternate and the term of service with the IRB.

Once appointed, the IRB member will complete the following forms and submit them to the ORSP:

1. Disclosure of Significant Financial Interest (annually)
2. Non-disclosure agreement (annually).

Length of Term/Service and Description of Staggered Rotation

The standard length of service for an appointed IRB member is five years. Usually, no more than one fifth of membership may be considered for replacement each year. If a member resigns prior to the end of his/her term, a nominee may be appointed to complete the original term or may be appointed to a full term.

During the first year of the IRB member's initial term, the IRB chair may assign a senior committee member to serve as a mentor for the new appointee. This mentor will assist the new member, when requested, in preparing for committee meetings, contacting investigators for additional information, and working through any problems noted with the IRB submission, before the scheduled IRB meeting.

Near the end of the five-year term, the ORSP staff will inquire as to whether or not the appointee wishes to continue to serve. If the IRB member wishes to continue to serve on the IRB, the ORSP staff will submit a request to the Provost or designee for the member to remain on the committee. The ORSP staff, in consultation with the Provost, may extend an invitation for a committee member to remain for an additional five years for a total of no more than 10 years. Once the extended term (10 consecutive years) is complete, the member may not be nominated to be a voting member of the IRB for a period of three years.

IRB Member Training and Continuing Education Requirement

All new members should complete training as directed by the chair of the IRB prior to beginning their work with the board. Continuing Education must be done annually through online modules, local training, and/or external training.

Functions and Responsibilities

Each IRB member shall:

(1) Protect the rights and welfare of human research subjects.
(2) Determine that subject risks are minimized. IRB members will ensure that the investigators:

   (a) use procedures which are consistent with sound research design and which do not expose subjects to risk, and
   (b) whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes.

(3) Determine that risks to the subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB member should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB member should not consider possible long-range effects of applying knowledge gained in the research.
(4) Determine that selection of subjects is equitable. In making this assessment, the following should be taken into account:

   (a) the purpose(s) of the research and the setting in which it is conducted; and

(b) special problems of research involving vulnerable populations (such as children, prisoners, pregnant women, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons). The IRB member should be particularly cognizant of these circumstances.

(5) Determine whether the informed consent is adequate, and if not, request clarifications and changes in the consent form to adequately explain the purpose of the research, the risks and benefits entailed therein, and to contain all other federally or locally mandated elements.
(6) Determine that the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
(7) Determine that the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
(8) Ensure additional safeguards are in place to protect the rights and welfare of vulnerable populations.

Members and Alternates may be asked to serve as Exempt and/or Expedited Reviewers, if the IRB determines that a research request qualifies for such review as defined by HHS.

Removal

When a committee member consistently fails to attend IRB meetings or fails to meet expectations, the ORSP staff and the Provost or designee will meet with the committee member to determine the cause. If the IRB member indicates an inability to continue to function effectively as an IRB member, the ORSP staff or the Provost/designee will request assistance from the Dean and/or department chair in obtaining a replacement member to serve on the IRB.

HUMAN SUBJECTS RESEARCH: IRB MEETINGS

POLICY STATEMENT & PURPOSE

This policy and the following procedures outline the procedures for scheduling and conducting Abilene Christian University Institutional Review Board meetings and notifying members of the scheduled meetings and itinerary. Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to all current members of ACU's IRB, as well as any administrative units involved in the scheduling, planning, and/or conducting of IRB meetings.

PROCEDURAL GUIDELINES

Scheduling & Notification

IRB meetings are generally scheduled once per month during the academic year, on an as-needed basis. Full Board meetings may be called during the summer if a full board request is submitted and quorum can be met.

When Full Board submissions have been received, the Chair will notify the Committee that a meeting will take place, schedule a time when a quorum may be met, and distribute the submitted protocols, meeting agenda, and any other applicable materials including minutes from the previous meeting.

The IRB must meet at least once per semester, regardless of whether any full board submissions are received.

Conducting Meetings

The Chair will call the meeting to order and take roll. The IRB Administrator will record the minutes and ensure quorum is met throughout, including the presence of at least one nonscientist. The Chair will moderate the meeting and ensure that the agenda is followed, which may include: reviewing and voting on previous minutes, reviewing and voting on submitted protocols, discussing any administrative business, training, and closing of meeting.

ACU IRB meetings are closed and confidential. Principal Investigators or other guests will not be permitted to attend the meeting unless they receive an invitation from the Chair and sign a non-disclosure agreement. The Chair will make every effort to ensure that the Committee is prepared to reach a decision on a protocol at the meeting, to avoid tabling a protocol for insufficient information. The Chair will solicit

questions and comments from the Committee and request responses from the Principal Investigator prior to the scheduled meeting. The Principal Investigator may also supply a telephone number for contact during the meeting should any other unresolvable issues arise.

If at any time quorum is broken, either due to fewer than ½+1 members present or due to lack of a non-science member, the IRB Administrator will notify the Chair and the Chair will halt the meeting until which time quorum can be restored. If quorum cannot be restored within a reasonable break, the Chair will close the meeting and reschedule.

Alternates may replace any member in a full board meeting, when alternates are needed to meet quorum.

At the conclusion of the meeting, the IRB Administrator will complete the minutes, the Chair will review, and the Committee will vote to approve or modify at the following meeting.

HUMAN SUBJECTS RESEARCH: IRB PROCEDURES INITIAL REVIEW

POLICY STATEMENT & PURPOSE

If participants or researchers are ACU faculty, staff or students and the research -- whether external or internal -- involves human subjects, the project director or principal investigator (PI) must submit a Research Review Request to the Institutional Review Board (IRB). He or she must obtain approval **before** beginning the research. If the PI has received IRB approval from another institution with which he or she is affiliated, the IRB application and approval should be attached to the email submission of the completed ACU Research Review Request (see Section "Other" at the end of this document). This policy and following procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, whether on-campus or off-campus, as part of their duties or studies at ACU. This policy also applies to any non-ACU researchers who wish to use ACU faculty, staff, students, or organizations as research subjects.

PROCEDURAL GUIDELINES

Requirements for Review

Any research study that involves human participants must be reviewed initially and periodically by the IRB, unless the study qualifies for **exempt status** under very specific conditions. These requirements are to ensure that human participants are treated in an ethical manner that respects their rights and welfare. ACU's IRB policies and procedures are based on the federal regulations outlined in the "Common Rule" (45 CFR 46). The Common Rule outlines a set of policies and procedures for all IRBs that oversee studies receiving federal funding or operating under a Federalwide Assurance. Because of this, many IRBs have adopted these policies and procedures for their general practice. The ethical guidelines outlined in the Common Rule are the standard for human research ethics today.

The Common Rule defines ***Research*** as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, projects that are not systematic investigations (such as case studies) or are not designed to contribute to generalizable knowledge (such as class projects, program evaluations, or community service) may not require IRB oversight.

Human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information." Studies that do not involve human subjects also may not require IRB oversight.

Any study that meets both of the above definitions must receive IRB review and approval **before** enrolling any participants and beginning the work, even if that study may qualify as "Exempt" status (See Exempt Section below). Studies that do not meet either of the above definitions do not require review; however, researchers may wish to have an external reviewer make that determination for assurance and/or for publication purposes (See Non-Research and Non-Human Research below). When in doubt, the investigator may submit an application to the ORSP office to determine whether the study qualifies as research or human subjects research.

Investigators should use the tools on the IRB website and the Department of Health and Human Services (DHHS) website to determine whether to complete the non-research/non-human research, exempt, expedited, or full-board application forms. However, ultimately, the ORSP Office or an IRB member will make the final determination as to the level of IRB review required.

Training Requirements

Prior to designing or conducting research in which there are human participants, it is important that all investigators and faculty advisors (when applicable) have sufficient training and knowledge with regard to pertinent federal regulations and ethical guidelines. Researchers should have training in Responsible Conduct of Research and Human Subjects Research at minimum every 4 years. All training modules are accessible via CITI. Upon completion of required training, investigators should save the Certificates of Completion to provide the IRB documentation of their training. If investigators have completed alternative training modules, please contact ORSP to ensure the training meets the required objectives.

Non-Research and Non-Human Research

Any study that does not meet the definitions of ***Research*** and/or ***Human Subjects*** as defined above is not within the purview of the IRB. However, at times such judgments may be difficult for the Principal Investigator to make with confidence. At other times (or in addition), proof of IRB review may be required by another entity (e.g., the study site, hosts of a meeting, a journal, etc.). In such cases, it may be beneficial for another person, not involved in the study, to make the determination of Non-Research or Non-Human Research.

Investigators who require review of Non-Research or Non-Human Research studies may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair who will review the materials submitted and determine if the study meets the requirements for the non-research/non-human research designation. The Chair may also designate an IRB member or alternate to make this determination. If the requirements are met, the researchers will receive a letter from the IRB Office stating this designation and exempting the study from further IRB oversight. Researchers will be notified that should the details of the study change such that it no longer qualifies for this designation, the researchers should contact the IRB again.

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

Exempt Research

An exempt study is human-subjects research which does not require ongoing IRB oversight. The determination of Exempt status **must** be made by the IRB Office or a designated IRB reviewer, not by the researcher/s. Exempt research is defined by 45 CFR 46.104. The study must be minimal risk and fall into one of 8 categories. Briefly, those categories are research involving 1) standard educational practices in an educational setting; 2) minimal risk surveys, tests, interviews, or observations; 3) benign behavioral interventions; 4) existing data or specimens that are either publically available or deidentified; 5) public benefit programs supported by a federal agency; 6) taste and food quality; 7) Storage or maintenance for secondary research for which broad consent is required; 8) Secondary research for which broad consent is required. Further detail and stipulations for these categories may be found on the DHHS website. These exemptions do not apply to studies using prisoners as participants. Exemptions involving children are allowable with certain restrictions.

Investigators who require review of Exempt Research may submit an application to the IRB Office using the applicable forms for this review. The Chair or IRB Administrator will assign an IRB member or alternate to make this determination. If the requirements are met, the researchers will receive a letter from the IRB Office stating this designation and exempting the study from further IRB oversight. Researchers will be notified that should the details of the study change, such that it no longer qualifies for this designation, the researchers should contact the IRB again.

Some of the exempt categories may require a limited review. In such cases, the researcher should complete the limited review section in order to satisfy the requirements in 45 CFR 46.111(7) and/or (8).

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

Expedited Review

An expedited review is one conducted by a single IRB member, as opposed to being discussed at a convened meeting of the entire IRB (See Full Board Review Section below). The expedited reviewer may request clarifications and revisions and may approve the research. An expedited reviewer cannot fail to approve a study. In such a case where an expedited reviewer does not feel he/she can approve the study, even with revisions, the study must be brought to full board review.

Expedited research is defined by 45 CFR 46.110. The study must fall into one of 7 categories. Those categories are described in full on the DHHS website and, briefly, include 1) Qualifying clinical study of drugs or medical devices; 2) Qualifying collection of blood samples; 3) Collection of biological samples by noninvasive methods; 4) Noninvasive data collection using procedures routinely employed in clinical practices; 5) Research involving data or samples that were collected for nonresearch purposes; 6) Voice, video, digital, or image recordings; 7) Research on individual or group behavior or using surveys or interviews that don’t otherwise qualify for exemption.

Studies approved by expedited review must still follow the IRB’s policies and procedures for informed consent, amendments, reporting unanticipated problems or deviations, and inactivating a study, as described in other sections of this Handbook.

Investigators who require an Expedited Review may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair or IRB Administrator who will

review the materials for completeness. If items are missing or there are questions about the application, the IRB office may contact the investigator for further information before continuing the review. Once the application package is determined to be complete, the IRB Office will forward a copy to the primary reviewer within 1 week of the completed proposal being received. The primary reviewer will review the protocol and make a determination within 2 weeks of receipt.

A list of all studies approved via expedited review will be submitted to the full IRB committee at the end of each academic semester.

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

Full Board Review

Full board review is considered the default type of review. The other classifications and review types (e.g., exempt and expedited) represent special cases with specific parameters that must be met.

Investigators who require a Full Board Review may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair or IRB Administrator who will review the materials for completeness. If items are missing or there are questions about the application, the IRB office may contact the investigator for further information before continuing the review. Once the application package is determined to be complete, the IRB Office will forward a copy to the primary reviewer. The primary reviewer will then confirm the designation and call the protocol to full board review. If the Chair, or designated reviewer, determines that the study meets the requirements for another review type, the appropriate review will be recommended and forwarded as appropriate.

A protocol that was submitted on an expedited request form may also be called to full board for two reasons: 1) The IRB Office or IRB reviewer determined that the study did not, in fact, meet the criteria for expedited review, or 2) the reviewer did not feel that he/she could approve the study, even after revision. 45 CFR 46 does not permit disapproval of a study under expedited review, but instead requires that it go to full board for consideration. Note that if a reviewer believes that a study that otherwise qualifies for expedited review is more than minimal risk and needs full review, the burden of proof is on the reviewer to justify this claim.

ACU's IRB will meet a least once a semester and monthly, as needed. The PI and Point of Contact named in the protocol will receive notice of full board review and the date assigned for review.

The Chair will make every effort to ensure that the Committee is prepared to reach a decision on a protocol at the meeting, to avoid tabling a protocol for insufficient information. The Chair will solicit questions and comments from the Committee and request responses from the Principal Investigator prior to the scheduled meeting. The Principal Investigator may also supply a telephone number for contact during the meeting should any other unresolvable issues arise.

Review Process, Potential Actions, and Requests for Changes

Review Process

The IRB must determine that 9 criteria, when applicable, are met in order to approve a human subjects research study:

1. The risks to subjects have been minimized by: a) Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and/or b) Using procedures already being performed on the subjects for diagnostic or treatment purposes
2. The risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
3. The selection of subjects is equitable, considering the purposes of the research, the setting in which it will be conducted, and any special problems related to vulnerable populations (such as children, prisoners, pregnant women, mentally disabled person, or economically or educationally disadvantaged persons).
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by §46.116 (which includes conditions under which waivers or alterations may be granted).

   The general requirements of consent cannot be altered. These are: participants must be given sufficient time; language must be readable on an appropriate level, free of technical language, and free of exculpatory language; participants must be given reasonable information in order to make a decision; and the format must be a concise presentation of key information to facilitate understanding

   Consent must include: 1) a statement that this is research and the purpose of the research; 2) descriptions of the procedures involved and the frequency and duration of participation; 3) descriptions of the risks and benefits anticipated; 4) any alternative treatment that may be available instead of the research treatment, if applicable; 5) any efforts that will be made to protect privacy and confidentiality; 6) if there will be any treatments or compensations made in the event of an injury; 7) whom to contact for questions, issues regarding welfare and rights, and in the event of an injury; 8) a statement that participation is voluntary, and the participant may decline to participate or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled.
   In some cases, additional statements may also need to be added when appropriate to the study, including: 1) the possibility of unforeseen risks; 2) any situations whereby the investigator may withdraw the participant; 3) any costs that the participant may incur; 4) any natural consequences that may occur if the subject withdraws (e.g., withdrawal side effects of a study medication); 5) if any findings that occur during the study may affect the participant's willingness to participate and how that will be communicated; 6) the number of participants to be enrolled; 7) A statement that biospecimens may be used for commercial profit and whether the subject will or will not share in the profit; 8) A statement regarding whether clinically relevant results will or will not be shared with subjects and if so, under what conditions; 9) disclosure if biospecimens will be used for whole genome sequencing; 10) a statement informing participants if their data MAY or WILL NOT be stripped of identifiers and used in future research without consent; and 11) if technology will be used capable of generating identifiable private information/biospecimens, a statement including this in the description of research.

   The IRB can grant an alteration or waiver of the consent procedure in certain cases. The research has to be minimal risk, cannot be practicably carried out without the alteration, and the alteration must not adversely affect the rights and welfare of the participants. In cases like deception, the researchers are often required to provide the participants additional information at the end of their participation.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 (which includes conditions under which waivers or alterations may be granted).

Documentation of informed consent is a general requirement for all studies, either requiring a signature on the full consent form or a short form confirming that the consent process was done orally. However, there are conditions under which the IRB can waive this requirement. The first condition is when breach of confidentiality is the primary risk of the research and the consent document is the only identifier. The second is when the research is minimal risk and involves no activities that would otherwise require consent documentation. Finally, waiver of documentation of consent can be granted if the participant or their legal representative is a member of a community for which signature is not the cultural norm. This waiver must be justified and include a method of documenting consent.

6. The research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects, when more than minimal risk and when appropriate.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
8. When Limited Review is required by 45 CFR 46.104(d)(7) for Broad Consent, the IRB need not make the determinations above, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained; (ii) Broad consent is appropriately documented or waiver of documentation is appropriate; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
9. If some or all of the subjects are vulnerable populations likely to be susceptible to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

These requirements are further detailed in 45 CFR 46, which the reviewers will utilize to determine if the conditions for approval are met. In addition to the regulations in 45 CFR 46, the IRB also has to consider other laws and regulations, for instance HIPAA and FERPA laws related to medical and educational records, respectively.

Potential Actions

During an Expedited Review, the reviewer may take the following actions: 1) Research approved; 2) Approved with requested modifications; 3) Requests for further information/modifications before a decision can be made; 4) Recommend that the proposal be reviewed by the full IRB.

During a Full Board Review, the Committee may take the following actions: 1) Approve as submitted; 2) Approve with minor modifications; 3) Table- Request further information/clarification and resubmission of the proposal; 4) Not approved as submitted/ Request Major Modifications for: a) Inadequately observing the Standards for Utilizing Human Subjects in Research; or b) Excessive use of specific groups or classes that may have recently participated in other research. A simple majority will constitute decision of action on the proposal, after a full deliberation of controverted issues. If minor revisions are required, the committee will identify who will be responsible for confirming that the revisions meet the requirements. This may be the Primary Reviewer assigned, the Chair, or another designated reviewer. If major revisions are required, the protocol will be brought back to full board at a later meeting. This meeting will be assigned once the revisions have been received by the IRB Office.

Researchers will be notified, in writing, of the decided action and any requests for changes (see below). Researchers are notified of their responsibilities on the Signature and Assurance Form which must be submitted with the application. In addition, upon final approval, researchers are reminded of their responsibilities in the approval letter.

Requests for Changes

During any of the review procedures, the Chair, designated reviewer, or IRB Committee may request changes in order to bring the protocol in line with the policies set forth in this Handbook and 45 CFR 46. In such cases, the researchers will be notified in writing of the requested changes. It is recommended that requested revisions be completed within 2 weeks of notification and resubmitted to the IRB Office.

For exempt determinations: Once the IRB Office has received the edits, the Chair, or designated reviewer, will determine if the revisions meet the requirements of this policy and 45 CFR 46.

For expedited reviews: Once the IRB Office has received the edits, the protocol will be returned to the reviewer for final determination. The reviewer is provided another 2 weeks for this final review.

For full board reviews:

Approved with Minor Revisions: If the study was approved with minor revisions, the committee has a set of small revisions requested that do not require a reconvening of the full board once those changes are made. The Chair, primary reviewer, or other designated reviewer will review the revisions once submitted, and if they are in line with what the committee has requested, the approval letter will be provided to the PI.

Tabled/Request for Further Information: The IRB reviewers strive to have all questions answered prior to convening the full board. However, if a question arises during the meeting, and the research team is not available to answer the question, the study may have to be tabled until a later meeting after the additional information has been gathered. In such cases, the request for more information will be made in writing. The protocol will be assigned to a later meeting and the research team notified of the date and time.

A study may also be tabled if the IRB meeting fails to establish or maintain quorum. If quorum is not met at any point, all deliberations and voting must cease until quorum can be established or reestablished. The IRB strives to schedule meetings at times when quorum can be met and maintained, but if quorum is lost, the IRB may have to reschedule study discussions to a later meeting. In such cases, no further information may be required. The researchers will be notified in writing of the situation, as well as the rescheduled date and time.

Not approved as submitted/ Request Major Modifications: A study is not approved when it requires substantial revisions in order to meet the criteria for approval and/or the revisions requested by the committee will require a reconvening of the full board in order to review. When a study is not approved, the PI will receive in writing the reason(s) for the decision and a statement regarding any revisions that may be required or requested. The researcher(s) may choose to address said reasons with a revision of the protocol and resubmit. The study will always go back to full board review in these cases. Upon resubmission, the researchers will be notified of the date and time of the meeting during which the

protocol will be reconsidered. The IRB has the final determination on disallowing a particular study. Such a decision cannot be overturned by institutional officials.

In some cases, multiple revision iterations may be required if the revisions bring up new issues. No research may be initiated on any proposal that was returned for revisions or has not been approved by the IRB.

Establishing an Effective Date and Expiration Date

Effective Dates for new protocols will be the date on which the designated reviewer or IRB Committee confirms final approval to the IRB Office. If a protocol is approved without changes, the effective date is the date of the meeting or initial decision. If a study is approved with minor revisions, the effective date will be the date on which the designated reviewer confirms that the revisions are sufficient to meet the requirements of this policy and 45 CFR 46. For protocols that are tabled or require major revisions, the effective date will be the date of the meeting at which it is finally approved or if further revisions are required, the date upon which the designated reviewer confirms the revisions are sufficient to meet the requirements of this policy and 45 CFR 46.

The expiration date, when required, will be one year after the effective date, except when the IRB determines that a protocol must be reviewed more frequently than once per year. The Committee shall take this under consideration when 1) the protocol is more than minimal risk, and 2) potential risks are Serious and Likely. The Committee will consider the number of serious risks, the degree of severity, and the degree of likelihood when determining how frequently to review a high risk protocol. The greater these variables, the more frequently the IRB should review the protocol. The Committee may elect to review a protocol as often as necessary to ensure the protection and welfare of human subjects, including but not limited to every 6 months, quarterly, or monthly. Likewise, if the committee determines that risks are greater than originally anticipated, they may elect to increase the frequency of review. Such changes will be communicated, in writing, to the researchers.

Researchers will be notified in writing when their protocol is approved. This notification will include the expiration date for the study and the PI's responsibilities following approval.

Appeals

If the researcher(s) disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office. The appeal should state the actions being disagreed with, reasons for the disagreement, and any proposed resolutions. The Chair will review the appeal and contact the researchers, if necessary, for further information. When appropriate, the Chair will communicate the request to the designated reviewer or full committee to determine a resolution. The final decision of the IRB will be communicated to the researchers in writing.

HUMAN SUBJECTS RESEARCH: IRB PROCEDURES CONTINUING REVIEW

POLICY STATEMENT & PURPOSE

All studies that were previously approved by full board review and that continue beyond the expiration date assigned at approval must undergo continuing review until inactivated. As per 45 CFR 46, reviews must be completed, at minimum, once per year for on-going studies. Studies with a high degree of risk may be reviewed more frequently at the IRB's discretion. Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by full board review. This policy also applies to any non-ACU researchers who received approval from ACU's IRB.

PROCEDURAL GUIDELINES

Principal Investigator Responsibilities

It is the Principal Investigator's responsibility to ensure that his/her ongoing studies do not expire or have a lapse in approval. Researchers are notified of this responsibility on the Assurance Form and the protocol approval letter.

Review Process, Potential Actions, and Requests for Changes

Review Process

The IRB Office will contact researchers approximately 60 days prior to expiration to notify them of the pending expiration and their responsibilities to file a Continuing Review Request. Researchers will be informed which documents to submit and the timeframe within which to submit them. The Continuing Review Form and any other applicable forms, as directed, should be submitted to the IRB Office approximately 30 days prior to the expiration date. Just as with the initial review, the IRB must determine that the same 9 criteria are met in order to approve a human subjects research study.

The Continuing Review documents will be submitted to the full board following the full board procedures described in previous sections. Committee members will be informed of the pending expiration date and their right to access all study-related documents upon request.

If a reviewer feels that an expedited study requires continuing review, the burden of proof is on the reviewer to justify this need at the time of initial review. Continuing Review for Expedited studies will follow the Expedited procedures described in previous sections.

Studies that were originally approved by full board will also undergo full board review at renewal unless one or more of the following conditions applies according to 45 CFR 46:

1) The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects.
2) No subjects have been enrolled and no additional risks have been identified.
3) The remaining research activities are limited to data analysis.
4) The research is not conducted under an investigational new drug application or investigational device exemption and where the expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Continuing reviews will be conducted in the same manner outlined in the previous sections.

Potential Actions & Requests for Changes

Potential Actions and Requests for changes are the same as with an initial review:

During an Expedited Review (only when documented and required), the reviewer may take one of the following actions: 1) Research approved; 2) Approved with requested modifications; 3) Requests for further information/modifications before a decision can be made; 4) Recommend that the proposal be reviewed by the full IRB.

During a Full Board Review, the Committee may take the following actions: 1) Approve as submitted; 2) Approve with minor modifications; 3) Table: Request further information/clarification and resubmission of the proposal; 4) Not approved as submitted/ Request Major Modifications for: a) Inadequately observing the Standards for Utilizing Human Subjects in Research; or b) Excessive use of specific groups or classes that may have recently participated in other research.

Researchers will be notified, in writing, of the decided action and any requests for changes. The procedure for requesting changes is the same as that outlined in the previous sections. When a Continuing Review is approved with modifications, the new expiration date will apply and the study may continue.

If the researchers disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office in accordance with the procedures outlined in the previous sections.

Determining Continuing Expiration Date

Continuing Review dates and new expiration dates are set in the same manner previously described, except when the review occurs within 30 days of the original expiration date. In such cases, a fixed expiration date may be used. Researchers will be encouraged to submit Continuing Review requests approximately 30 days prior to expiration in order to maintain the fixed expiration date.

Lapses in Approval

If a study expires before being re-approved by the IRB, all research activity on that protocol must halt immediately. The only exception is if it is determined that it is in the best interests of the participants who are already enrolled to continue the activities of the study. The decision may initially be made by an investigator and perhaps by a physician, but as soon as possible, the Primary Investigator should submit a request that the IRB approves. The decision may be made by the IRB Chair or another member of the IRB.

Such an instance still requires that the IRB approve a continuing review before new participants can be enrolled in the study.

Whenever lapses occur, the IRB should document the reason for the lapse and steps planned/taken to prevent future lapses. The IRB will notify the researchers when a study has expired with instruction to halt all activity on the protocol.

External Verification

45 CFR 46 requires that the institution have procedures for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. This section outlines when such verification is required, the procedures for conducting such verification, and the actions that may be taken when such changes have been identified.

Situations in which external verification may be required include:

- Studies with unusual levels/types of risk
- Studies in which noncompliance is suspected or when concerns have been raised that material changes have been made without prior IRB approval
- Studies in which one or more researchers has a history of noncompliance
- Studies in which complaints have been made by participants or others
- During internal auditing of study-related records and procedures
- Any other situation in which the IRB Chair, Institutional Official, and/or convened IRB Full Board determine that external verification is necessary

An external verification process may be initiated by the Institutional Official, IRB Chair, or convening of the full IRB board. Any person may report suspicions/concerns of noncompliance to the Institutional Official or IRB Chair. Reports should detail what activity is suspected or any issue of concern and any evidence available. The confidentiality of the individual filing a report will be protected to the extent possible, and there will be no repercussions for filing a report in good faith. Upon receipt of such a report, the IRB Chair and Institutional Official will review the report and determine if external verification is needed.

If an external verification is initiated for any of the above reasons, the following process will be followed:

- The IRB Chair will convene a committee of at least 3 members. This committee may be comprised of IRB members, other ACU faculty or administrative staff, or non-ACU consultants. The committee shall not be comprised of any member of any of the researchers' departments or other individuals who may have a conflict of interest.
- The committee may review the IRB records for the affected study and the researchers' study records and may observe the conduct of study procedures (such as obtaining consent, running study trials, etc., to the extent that such observance will not materially affect the outcome of the study).
- The committee will determine if the study is being conducted in accordance with the filed IRB protocol and will prepare a report of these findings. The report shall be signed by a majority of those conducting the review and submitted to the IRB Chair.
- The IRB Chair and Institutional Official will review the report and determine if there have been any deviations from the IRB protocol.
- In the case of such deviations, a noncompliance report shall be filed (by the investigators, when possible; otherwise by the Chair) and appropriate actions taken in accordance with the policy on noncompliance.

HUMAN SUBJECTS RESEARCH: IRB PROCEDURES AMENDMENTS TO EXISTING PROTOCOLS

POLICY STATEMENT & PURPOSE

For any study that was previously approved by expedited or full board review, any and all proposed changes to the study, no matter how minor (including changes to personnel, methodology, or consent forms), must receive prior approval by the IRB before being implemented (45 CFR #46.108(a)(3)) (except when the change was made to eliminate an apparent immediate hazard to the participants). Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

PROCEDURAL GUIDELINES

Requirements for Review

It is the Principal Investigator's responsibility to ensure that their ongoing studies are conducted in accordance to the approved IRB protocol and that any proposed changes are submitted to the IRB **before** being implemented. Researchers are notified of this responsibility on the Assurance Form, as well as the protocol approval letter.

All proposed changes, no matter how minor, to active non-exempt human subjects research must be reviewed and approved. Changes that do not increase risk to participants, or seek to further minimize risk, can often be reviewed by an expedited procedure. Changes that significantly increase risk to subjects must go to full board review.

In cases in which changes were implemented prior to review, a noncompliance report should accompany the amendment request. In cases in which changes were implemented to eliminate an apparent immediate hazard to the participants, an unanticipated problem report should be filed in addition to the amendment form.

For studies previously determined to be non-research, non-human research, or exempt, amendments to the protocol do not have to be reviewed by the IRB unless the change increases risk or otherwise affects the study status. If the changes to the study may cause a classification change, such that it no longer qualifies for exemption, please submit the amendment for review.

Reviews for Amendments will follow the same policies and procedures as previously outlined. Amendments submitted during the study period do not constitute a continuing review and will not affect or change the expiration date, except in circumstances in which the degree of risk is increased and the IRB determines that more frequent review is required.

If the researchers disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office in accordance with procedures outlined in previous sections.

Administrative Changes

Changes in, addition, or removal of personnel, address or contact changes, and other minor administrative changes may be requested and approved through the IRB Office. Such changes do not require expedited or full board reviews by IRB Committee members. The IRB Chair or IRB Administrator will review the requested change, ensure that the required training is met by all research team members, and issue the approval.

Minor Changes

Minor changes are defined as the addition of minimal risk procedures or change in procedures that does not increase risk category and/or the addition or change in procedures aimed at reducing risk. Such changes may be reviewed by the IRB Chair or a designated reviewer through the expedited procedure previously described.

Major Changes

Major changes are defined as substantial changes to the study design, additional procedures that are more than minimal risk, and/or change in procedures that results in increased risk.

If the study was originally reviewed via the expedited procedure **AND** the proposed changes do not alter that status, then the amendment will be sent to an IRB member for expedited review via the expedited review procedures.

If the study was originally reviewed via full board or the proposed changes alter the status of the study such that it no longer qualifies for expedited status, then the proposed amendment will be reviewed by full board procedures.

HUMAN SUBJECTS RESEARCH: IRB PROCEDURES UNANTICIPATED PROBLEMS AND NONCOMPLIANCE

POLICY STATEMENT & PURPOSE

If a researcher encounters an unexpected event that is probably related to the research and potentially increases the risk profile of the study or if there is a deviation from the approved protocol, no matter how small, the researcher must **report this** to the IRB in accordance with 45 CFR 46.108(a)(4). Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

PROCEDURAL GUIDELINES

Requirements for Review

What Must Be Reviewed

It is the Principal Investigator's responsibility to ensure that their ongoing studies are conducted in accordance to the approved IRB protocol and that any unexpected events or deviations are reported to the IRB in accordance with this policy and 45 CFR 46. Researchers are notified of this responsibility on the Assurance Form, as well as the protocol approval letter.

If a researcher encounters an unexpected event that is probably related to the research and potentially increases the risk profile of the study, there is a complaint from a participant that suggests there may be an increased risk to the study, or there is a breach of confidentiality, the researcher must **report this** to the IRB. In addition, any deviation from the approved protocol, no matter how small, must be **reported** to the IRB. If the reported deviation is a permanent change, it must be accompanied by an **amendment** request form.

For studies previously determined to be non-research, non-human research, or exempt, unexpected events or deviations from the protocol do not have to be reviewed by the IRB **unless** 1) the unexpected event is a serious UPIRSOs (Unanticipated Problems Involving Risk to Subjects or Others), 2) the unexpected event suggests that the risk involved in the study is higher than anticipated and the study may no longer qualify for exemption, or 3) the protocol deviation increases risk or otherwise affects the study status. If any unexpected event or deviation may cause a classification change, such that the study no longer qualifies for exemption, please submit the report for review.

How Quickly Must it be Reported

Unanticipated problems that are serious UPIRSOs should be reported within 7 days of learning of the event, unless the UPIRSO is potentially lethal, then it should be reported within 2 days. Other unanticipated problems should be reported within 14 days of learning of the event. Deviations from the protocol/Noncompliance must be reported following the same timeline as **unanticipated problems**, with the exception that minor deviations that do not affect safety, increase risk, or violate rights and welfare of participants may be reported on the continuing review.

Procedure for Review

Reports of unexpected event or noncompliance will be initially received and reviewed by the IRB Chair. In cases of minor problems or deviations (defined as those that do not increase risk category) and in which it is not a situation of continuing noncompliance, the Chair may make a determination on the report and issue any requirements for compliance. The Chair may also consult with the Institutional Official and/or one or more IRB members in making this determination.

Reports involving serious events or deviations or cases of continuing noncompliance by a single researcher or group of researchers will be brought before the full IRB board. The Chair may consult with the Institutional Official and/or one or more IRB members in making this determination. Reports will be reviewed by full board procedures. Determinations and requirements for compliance will be determined by a majority vote of the members in attendance, having met quorum.

Any person may report suspicions/concerns of problems or noncompliance to the Institutional Official or IRB Chair. Reports should detail what activity is suspected or an issue of concern and any evidence available. The confidentiality of the individual filing a report will be protected to the extent possible, and there will be no repercussions for filing a report in good faith. Whistleblower protections and anonymous reporting options are posted in the Employee Handbook (421). Upon receipt of such a report, the IRB Chair and Institutional Official will review the report and determine if external verification is needed. In such a case, external verification will be conducted as outlined in a previous section, and if a problem or noncompliance is found, a report will be filed and reviewed as outlined herein.

Potential Actions

Researchers should detail in their report any actions they have already taken to correct the problem. The IRB will review these reports to determine if these actions are sufficient. Otherwise, the IRB may require the following corrective actions:

1) A protocol amendment including but not limited to changes in methods/procedures, modification of inclusion/exclusion criteria, changes to safety monitoring plan
2) A revised Consent Form
3) Notification of the problem to current and/or past participants
4) Additional training
5) Requirement of external verification at Continuing Review
6) A temporary suspension on research activities until problems/concerns can be addressed
7) Permanent termination of study activities
8) Removal of a researcher's or group of researchers' privilege to conduct human subjects research at ACU (typically only in the case of serious misconduct or continued noncompliance)

Corrective actions shall be in line with the severity of the reported problem and the degree of risk involved. Such actions will always be taken in the interest of protecting the rights and welfare of the past, current, and future participants. No study may be suspended or terminated unless approved by the majority of IRB members convened at a full board meeting in which a quorum is met. Removal of research privileges at ACU may be recommended by the IRB, but shall not be implemented without the approval of the Institutional Official and the Provost. Regardless of the required corrective actions, at any time, the IRB may determine that it is in the best interests of the participants who are already enrolled to continue the activities of the study.

Findings will be reported to the researchers in writing, including a statement for the reasons for any IRB actions (e.g., suspension or termination). If the researchers disagree with the actions of the IRB or the requirements for compliance, they may file an appeal in writing to the IRB Office.

Institutional and External Reporting Requirements

45 CFR 46.108(a)(4) requires "prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval." In such cases, the Chair of the IRB will prepare a report to the ACU Institutional Official. In addition, when the study is funded by federal sources, falling under ACU's Federal Wide Assurance, the Chair and/or Official will also notify the funding agency and Office for Human Research Protections (OHRP) and prepare any necessary reports as required. In such cases, the agency or OHRP may investigate the report, as well as issue their own suggestions for corrective actions.

When the event is serious, a preliminary report will be submitted to OHRP, when required, within 7 days of being notified of the event. When the event is less serious, but still reportable, a preliminary or final report will be submitted within 2 weeks. A final report will be submitted when the review is complete.

When possible and appropriate, corrective actions will be implemented institution-wide in order to prevent future occurrences of similar incidents.

HUMAN SUBJECTS RESEARCH: IRB PROCEDURES INACTIVATION AND RECORD STORAGE

POLICY STATEMENT & PURPOSE

All studies that were previously approved by expedited or full board review must be inactivated upon completion of the study in order to fulfill record-keeping requirements in 45 CFR 46.115(b). Procedures are developed in order to maintain compliance with federal (45 CFR 46) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

PROCEDURAL GUIDELINES

When Can a Study Be Inactivated

Inactivation should be completed when enrollment is closed, data is no longer being collected, and analysis is complete or involves only de-identified data, in other words, when all human subjects activity has ceased. Note that if the study is federally funded or if you are the lead site on a multi-center trial with active sites, you must keep the protocol open and submit continuing reviews at least annually per your approval letter.

Record Storage

Data and records related to human subjects research must be kept by the research team and the IRB for at least 3 years after the date of inactivation of the study in accordance with 45 CFR 46.115(b). These records are auditable and must be produced in a "reasonable amount of time." Thus, ACU requires that a faculty member keep these records, in some form, on campus. This can be in electronic or paper form, as long as it is appropriately secure and available upon request.

HUMAN SUBJECTS RESEARCH: IRB ADDITIONAL POLICIES RELATED TO HUMAN SUBJECTS RESEARCH

POLICY STATEMENT & PURPOSE

The procedures in this section address additional important concerns or other regulatory requirements related to the use of human subjects in research and non-research studies. Procedures are developed in order to maintain compliance with federal (45 CFR 46, 45 CFR 160 & 162, 34 CFR 99) and institutional regulations.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, and in some cases non-research involving human participants, whether on-campus or off-campus, as part of their duties or studies at ACU. This policy also applies to any non-ACU researchers who wish to use ACU faculty, staff, students, or organizations as participants.

PROCEDURAL GUIDELINES

Non-Research Classifications using Human Participants

45 CFR 46 defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, projects that are not systematic investigations (such as case studies) or are not designed to contribute to generalizable knowledge (such as class projects, program evaluations, or community service) **may** not require IRB oversight. Project leaders who are unsure whether their study fits into this classification may submit an application form to receive a determination by the IRB Office. However, certain issues should be carefully considered when requesting a non-research determination.

Certain activities are specifically named as NOT research, including: Scholarly and journalistic activities, oral history, biography, literary criticism, journalism, historical analysis, certain public health surveillance activities, criminal justice & national security activities

The following activities should be determined on a case-by-case basis: quality assurance and program improvement activities. Some of these activities may still be research, depending on the intent and goals of the project.

45 CFR 46 states clearly that all human subjects research must receive IRB approval **before** beginning the research. Therefore, it is the policy of the ACU IRB not to provide retroactive approval of studies (i.e.,

approving a study after data collection has already begun/been completed). Project leaders should consider their long-term intentions and possibilities when deciding whether their project is for research or non-research purposes. If there is any possibility that you may wish to use your data for research purposes in the future, you should proceed with the appropriate IRB application. This policy applies to prospective data collected for a study. It does not apply to information collected purely for clinical purposes which may or may not be reviewed retrospectively in the future.

Classroom Projects

A classroom project is defined as one in which the purpose is to teach content, not contribute to generalizable knowledge. These projects may be designed to teach research methodology, and so may look very much like research. Such projects do not require IRB approval; however, ACU does require that students follow the ethical guidelines in 45 CFR 46 in the conduct of such projects. Therefore, the following requirements must be met:

Data collected for class purposes 1) cannot be used for research purposes outside of the classroom, 2) must follow all ethical guidelines for human subjects research, and 3) must be destroyed at the end of the class. Course instructors are responsible for ensuring these standards are met. Again, this exemption should be used wisely. Retroactive approval will not be granted. Course instructors should guide students to an appropriate decision as to whether to apply for IRB approval or not. If the student thinks he/she may wish to use the data outside of the course, the appropriate IRB application should be prepared.

Because course instructors are responsible for ensuring that ethical standards are met, they should contact the IRB Office for ethical training requirements.

Quality Improvement/Program Evaluation

Quality Improvement and Program Evaluation studies may or may not be research. The intent of the study and how the project leaders intend to report the results are important. Guidance published by OHRP suggests that the intent to publish, alone, does not make a project research. Likewise, obtaining a non-research designation does not preclude one from ever publishing or reporting the results. However, the intention behind the report does matter. If the intention of the study is **only** to assess the program's ability to meet objectives and/or assess change meant to improve the specific program, then it may be non-research. Project leaders may report their process and findings (e.g., what we did and what we found). However, if the intention is to develop a program or process of change that may be generalizable and applied at other institutions or organizations, then this is research and should go through the IRB.

HIPAA and FERPA in Human Subjects Research

HIPAA

To collect data

Medical records include protected health information (PHI) that is covered by the Health Insurance Portability and Accountability Act (HIPAA). In general, accessing medical records for research purposes requires a consent to access and disclose PHI. Researchers should prepare a HIPAA/PHI consent to disclose form in addition to or as part of the research consent document. In limited cases, a waiver of such consent can be granted if the PHI disclosure represents no more than minimal risk and the research could

not be conducted without the waiver. The researcher will need to justify this need and explain why obtaining consent to access and disclose PHI is not practicable. In all cases, researchers should take care to only look at and collect the minimum PHI necessary to achieve the goals of the research and any personal identifiers should be destroyed as soon as possible.

For participant selection

Sometimes we cannot know from whom to seek permission without accessing the records. In such cases, a waiver of consent requirement can be approved if the PHI disclosure represents no more than minimal risk and the research could not be conducted without the waiver. In all cases, researchers should take care to only look at and collect the minimum PHI necessary to achieve the goals of the research and any personal identifiers should be destroyed as soon as possible.

FERPA

Educational records include private information that is protected by the Family Educational Rights and Privacy Act. In general, accessing educational records for research purposes requires consent, even if the educational information is something the researcher typically has access to (such as a teacher/professor having access to their students' grades). FERPA requires a signed consent in all but very limited situations, even if you just need to view the information for participant selection. A signed disclosure authorization is required unless one of the following conditions are met: 1) You will only be viewing/collecting directory information; 2) The study is for, or on behalf of, the institution to either develop, validate, or administer predictive tests; administer student aid programs; or improve instruction; 3) The study involves only de-identified records, including the removal of all direct and indirect identifiers. Studies on behalf of the institution require a written agreement between the institution and the researcher which includes the stipulations outlined in 34 CFR §99.31(a)(6)(iii). In all other cases, researchers should prepare a FERPA consent to disclose form in addition to or as part of the research consent document.

Authorizations

Authorizations should include : 1) What is being accessed (what protected information will be viewed and/or collected), 2) Who is accessing the information and/or to whom is it being given, 3) Why– for what purpose, and 4) How Long– for how long will access to (or retaining of) identifiable protected information be required. Additionally, it is recommended to include: a statement of the right to refuse or revoke authorization, if any treatments or benefits are conditional on authorization, a statement regarding risk of accidental disclosure.

Ultimately, it is the responsibility of the institution releasing the protected data and the researchers accessing the data to ensure compliance and authorization for the release of protected information. However, ACU's IRB will review HIPAA/FERPA compliance issues and is granted the authority to provide waivers of authorization when the appropriate conditions are met.

Off-Campus Research by ACU Affiliates

ACU researchers who wish to conduct their studies at a different location (another business, organization, or institution) should seek the permission of that site prior to conducting their studies. Prior to approval,

the ACU IRB will request at minimum that researchers contact the site and inquire about their approval process. In some cases, this may only require a verbal or written affirmation. In other cases, a contract or IRB review may be required. It is up to the site to determine what they require in order to grant ACU researchers access to their site and people/potential participants. It is the researcher's responsibility to ensure they are following the policies of that site.

Other academic institutions typically require that external researchers go through their IRB in some fashion. Therefore, ACU researchers conducting studies at other academic institutions will be required to contact the other institution's IRB prior to approval. This will ensure that the ACU researcher is following the policies required by the other institution. It is not sufficient to rely on the approval of a faculty member or administrator at the institution, as these employees may not be fully aware of the institution's IRB policies on external research. The Chair of the IRB or Human Research Protections Officer will typically be familiar with such requirements.

External Research Requests by non-ACU Affiliates

If a researcher from another institution wishes to have access to ACU faculty, staff or students as potential participants and ACU is not engaged, the project leader or principal investigator must submit the appropriate application to the IRB (External Review Request_ACU NOT Engaged). If the PI has received IRB approval from another institution with whom he or she is affiliated, the IRB application and approval should be attached to the email submission of the completed ACU IRB Request. ACU does not guarantee external researchers that access will be granted. Each request is addressed on a case-by-case basis depending on the topic of the research; whether participation by ACU is in the best interest of the institution and our faculty, staff, and students; and/or the IRB has sufficient resources to consider an external review.

Collaborative Research with non-ACU Affiliates

When ACU faculty, staff or students are collaborating with individuals at another institution, the protocol should be reviewed by the IRB of the primary institution and IRB Authorization Agreement entered into by both institutions. Generally, Authorization Agreements are preferred when the affiliated institution has an approved FWA number with the OHRP. Authorization Agreements should be signed by officials at each institution who have the authority to enter into such agreements. At ACU, Authorization Agreement requests are reviewed by the Chair of the IRB and submitted to the Institutional Official for signature. If the partnering institution refuses to enter into an agreement, then both IRBs must review the protocol.

International Research

When ACU faculty, staff or students are conducting research in a country outside of the United States of America, they must abide by the laws of that country. ACU's IRB members are trained in the human subjects research regulations of the USA, and while we try to remain aware of changes abroad, we cannot maintain expertise on all of the laws of each country. Therefore, it is the PI's responsibility to ensure that their protocol is in compliance with the laws of the site country. The PI must seek consultation with an expert in the site country. This must be someone in that country who is an expert

on human subjects research, for example, the equivalent of an IRB Chair. The PI must have their protocol reviewed by this individual and provide written evidence to ACU's IRB that their study meets compliance requirements in the site country. In some cases, the site country will require their own review comparable to our IRB reviews. In such cases, the PI should provide the results of that review to the ACU IRB Chair.

When faculty, staff or students are conducting research in California or Europe, they must abide by the privacy laws in those locations, the California Consumer Privacy Act (CCPA) or the General Data Protection Regulation (GDPR) respectively. The researcher must disclose the location of their research and describe to the IRB reviewer how they are meeting the requirements of these laws.

HUMAN RESEARCH: GIFT CARDS/CASH PAYOUTS

POLICY STATEMENT & PURPOSE

Abilene Christian University (ACU) policy does not allow for the purchase of gift cards with ACU funds. However, we recognize that in rare instances, financial payouts are necessary to the conduct of valid research (i.e. not simply a reward/incentive for participating). In such cases, gift cards or cash gifts may be allowable when specific conditions apply.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees who are involved in Human Subjects Research and wish to provide gift cards (or cash payouts) to research participants using ACU funds (including external grants awarded to ACU/ACU employees).

PROCEDURAL GUIDELINES

Gift cards (or cash payouts) may only be provided using ACU funds when the following conditions are met:

1. The payout is for Human research participants and is necessary to the conduct of valid research (i.e. not simply a reward/incentive for participating).
2. The PI must collect the attached signed form (Appendix V) from each participant who receives a gift card or cash payout providing an assurance that they are not an employee of the University, nor have they received any funds from ACU in excess of $600. This **includes** student employees and interns. The PI must keep the records of the forms for fiscal year + 7 years or 3 years after the close of the study, whichever is longer, and may protect them for confidentiality purposes; however, if ACU is audited by the IRS or other agencies (e.g., OHRP, granting agency, etc.), the forms will be required to be presented.

a. Please note that the IRB consent document template includes language to this effect, “Information collected about you will be handled in a confidential manner in accordance with the law. Some identifiable data may have to be shared with individuals outside of the study team, such as members of the ACU Institutional Review Board [or individuals affiliated with the granting agency].” The PI may edit this language as appropriate to address limits in confidentiality associated with the receipt of gift cards.

3. If an individual reports that they are an employee of the University, have been an ACU employee in the calendar year, or have received/plan to receive more than $600 in any form from ACU in the calendar year, they may not receive a gift card or cash payout. You may, however, request a payment through Accounts Payable for these individuals. In such cases, a W-9 must be collected.

4. Be aware that a Nonresident Alien should not be receiving a Gift card or cash. ACU is liable for any tax for a Nonresident Alien receiving a gift card or cash. Gift cards/cash should not be given when it is known that a participant is a nonresident alien or when the study population is likely to contain a high number of such individuals.
5. No gift cards will be purchased by P-card. The PI must purchase the cards with their own funds and request reimbursement. The attached form (Appendix W) should be submitted to ORSP prior to purchase of gift cards to ensure allowability. Likewise, Accounts Payable will have a form to fill out as part of the reimbursement. If documents are not provided stating all forms are signed, then the gift card will not be reimbursed.
6. The use of gift cards or cash payouts must be part of an IRB-approved human subjects research protocol.
7. If a gift card or cash payout is provided outside of these parameters, then the value of the gift payouts may be added to the employee's gross income in payroll and will be subject to tax.

ANIMAL SUBJECTS RESEARCH

POLICY STATEMENT & PURPOSE

This policy outlines the requirements, composition, and activities of the Abilene Christian University Institutional Animal Care and Use Committee (IACUC). Procedures are developed in order to maintain compliance with federal and institutional regulations.

APPLICABILITY OF THE POLICY

This policy applies to all ACU employees, students, or other affiliates who are involved in Animal Subjects Research. This policy is applicable to all research, research training, experimentation, biological testing and related activities, and teaching, hereinafter referred to as activities, involving live, vertebrate animals at this institution or involving the institution's faculty, staff, or students when represented by the institution. This policy covers only those facilities and components listed below.

POLICY AND PROCEDURES

Institutional Commitment

ACU will comply with all applicable provisions of the Animal Welfare Act (AWA)/Animal Welfare Regulations (AWR) and other Federal statutes and regulations relating to animals, when applicable and required by law.

This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Policy. As partial fulfillment of this responsibility, this institution will ensure that all individuals involved in the care and use of animals for the purposes defined in this policy understand their individual and collective responsibilities for compliance with this Policy as well as all other applicable laws and regulations pertaining to animal care and use.

This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals have Institutional Animal Care and Use Committee (IACUC) approval, in accordance with AWA/AWR.

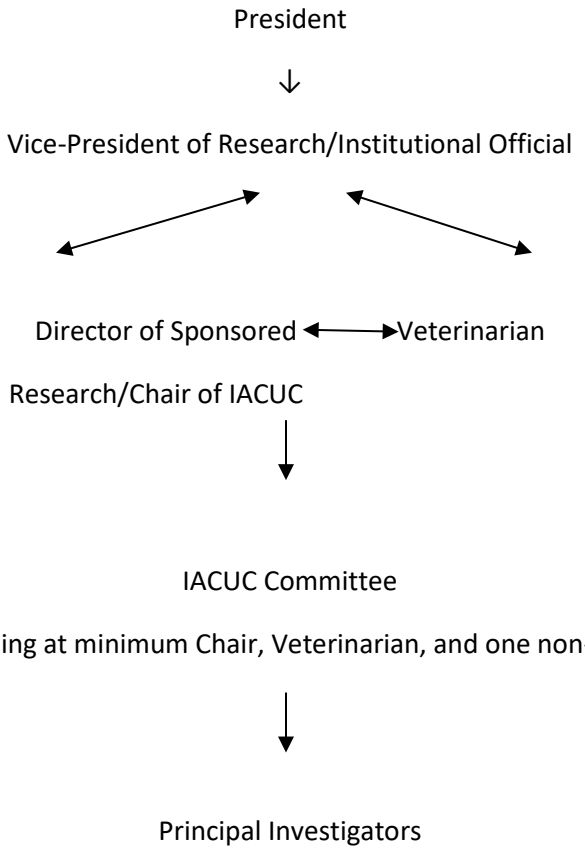
Additional guidance may be sought from the following resources, as appropriate:

(1) "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training."
(2) "Guide for the Care and Use of Laboratory Animals" ("The Guide")
(3) "Guide for the Care and Use of Agricultural Animals in Research and Teaching" ("The Ag Guide").
(4) American Society of Mammalogists Animal Care and Use Guidelines
(5) Ornithological Council Guidelines to the Use of Wild Birds in Research
(6) American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research; Guidelines to the Use of Amphibians and Reptiles in Research

Thank you to Bryn Mawr University for generously sharing their Animal Care Policy for adaptation by Abilene Christian University

Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:



B. The qualifications, authority and percent of time contributed by veterinarian(s) who will participate in the program are as follows:

Dr. Stephanie Carle, D.V.M. is the Veterinarian who participates in the IACUC, contributing time as needed to the functions of the IACUC. Her qualifications are as follows:

Dr. Carle is the full time veterinarian for the Abilene Zoo, demonstrating experience with a variety of animals of captivity and wildlife. She has past experience serving in an IACUC role.

We have established a relationship with Dr. Carle that permits us to avail ourselves of her services on an "as needed" basis rather than in terms of some fixed percentage of her time. Dr. Carle has delegated program authority and responsibility for the Institution's animal care and use program and has access to all animals and protocols.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), is properly appointed in accordance with the AWA/AWR and is qualified through the experience and expertise of its members to oversee the institution's animal care and use program and facilities. The IACUC consists of at least three members, and its membership meets the compositional requirements set forth in the AWA/AWR.

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the documents outlined in II as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

   The chair calls a meeting at least every six months. At least 2 members must be in attendance for review to take place. Prior to the meeting, the Chair reviews the Evaluation Checklist to ensure it is complete and accurately reflects the current animal Program, and distributes the checklist and any other supporting materials to the committee. At the review meetings, guests from relevant departments and Risk Management may be invited to report on all activities involving animals, training, and/or Occupational Health and Safety. All elements of the Checklist are reviewed and discussed. Records are provided to IACUC members, as needed, to determine the status of the program. Deficiencies are noted, timelines for correction discussed, and recommendations for the IO noted. The Chair follows up on any matters of concern with relevant campus personnel.

2. All animal housing facilities/areas will be visited during the semi-annual review. Agricultural facilities housing animals for agricultural purposes will be reviewed, as well. At this time, the ACU Farm will provide assurance that no agricultural animals will be used for purposes other than agricultural uses and/or agricultural research, as defined by the AWA/AWRs.

3. Prepare reports of the IACUC evaluations according to AWA/AWR and submit the reports to the Institutional Official (IO). The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

   Detailed minutes of review meetings and evaluations are taken by the Chair and transcribed for the report. As appropriate, the report is circulated electronically to members of the IACUC for majority signature prior to submission to the Institutional Official and includes any applicable minority views. Any departures from the AWA and the documents outlined in IIE, as appropriate, are included in the report submitted to the Institutional Official. Departures are identified as significant or minor and a plan for correction is included.

   Such departures are discussed with the researcher involved and corrections requested. The IACUC Chair follows up on the corrections that are made. The Chair reports any deficiencies in the program or facilities to the IO. The Chair also meets in person with the IO to review progress towards remediation of deficiencies. When significant deficiencies are not addressed according to the plan, this will be reported to USDA, when required, within 15 business days of the deadline.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

   Any matters arising regarding specific concerns are discussed by the IACUC. In general,

responses to concerns by students or others not involved in any animal research (such as students interested in animal rights issues) are addressed by one-on-one meetings with the department chair or departmental representatives. A written report is submitted to the Institutional official about the IACUC findings and recommendations.

Any persons with concerns regarding animal welfare may bring these concerns in writing or in person to the IACUC Chair. Matters that cannot be resolved by a simple conversation are brought to the full committee for discussion and resolution. Concerns may be reported anonymously, and there will be no repercussions for personnel reporting policy violations. Whistleblower protections are posted in the Employee Handbook (421).

This policy is posted on the Sponsored Research Office Website at Reporting An Animal Welfare Concern. In addition, instructions for reporting concerns regarding animal welfare are also available on that site.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

   Recommendations are developed by the committee and are drafted by the Chair. All proposals are reviewed and approved by members of the Committee, who are free to propose alternative suggestions until consensus is reached. These proposals are sent to the Institutional Official. The Chair also provides liaison with relevant campus offices to assure that recommendations are carried out.

6. In accordance with the AWA/AWR, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of covered activities related to the care and use of animals. The IACUC procedures for protocol review, are as follows:

   Protocols are submitted on a standardized form, consistent with Policy guidelines, for all non-agricultural research and teaching activities involving the use of live vertebrate animals. Protocols are circulated electronically to all committee members and given at least one week to call for a full board meeting. If no call is made, the protocol will be sent to a single voting IACUC member for designated review. This member will be selected by the IACUC Chair. If called to full board, the protocol will be discussed at a meeting of a quorum of voting members. All voting members may ask questions and propose changes as appropriate. The Committee conducts voice votes at meetings, with decisions made by simple majority of voting members in attendance. Possible outcomes include "Approval," "Approval with Clarifications or Modifications," or "Approval Withheld." The Chair communicates to the Investigator in writing either approval, request for clarification prior to approval, request for specific changes, or denial of approval. In the case of requested revisions, the committee will determine at the full board meeting whether revisions can be confirmed by a designated voting member or whether the protocol needs to return to full board meeting. The decision to allow designated review of revisions must be unanimous. The designated reviewer will be assigned by the IACUC Chair.

   Full board reviews may, on occasion, take place electronically, according to guidelines in NIH Notice #NOT-OD-06-052. A meeting may be conducted by real-time conference

call or by videoconference with a quorum of IACUC members to confirm the vote. Members must be given all necessary materials in advance and be able to interact and vote in real time.

If a designated review is assigned, the IACUC member is generally given a two-week period to review and make a decision. Decisions may include "Approval" or "Approval with Clarifications or Modifications." However, a designated reviewer may not withhold approval. In such a case, the protocol must be discussed at a full board meeting.

Guidelines for determining designated review vs. full board:

It is recommended that full board meetings be called for studies involving a high degree or potential for pain, distress, or harm. Such studies may be those involving, but not limited to, survival surgery, radiation sickness, tumor inducement, toxicology, or infectious disease. Designated review may be appropriate for studies involving, but not limited to, non-survival surgery, tissue collection, antibody production, telemetry, or behavioral observation, when appropriate steps are taken to minimize pain and distress.

Committee members with conflicts of interest (for example, those submitting research protocols for review) must recuse themselves from all deliberations on the protocol, other than to answer questions. They may not vote to approve any research activities for which there is a conflict of interest. Consultants may attend meetings and contribute to discussion; however, these individuals do not count toward quorum and may not vote.

No activities covered under this policy may begin until IACUC approval is granted.

7. Procedures to review and approve, require modifications in (to secure approval) or withhold approval of proposed changes regarding the use of animals in ongoing activities as set forth in the AWA. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are similar to those outlined in Section D-6.

Significant changes that require IACUC review include those involving new procedures, changes in pain/distress categories, change in primary personnel (e.g., PI), or changes in species.

Minor, administrative changes, such as changes in non-essential personnel or contact information may be submitted for administrative approval by the IACUC Office.

Minor increases in animal numbers may be administratively approved when the request is no more than 10% of the initial request and a satisfactory justification for the increase is provided. The IACUC Chair may make this determination. At any time, the chair may determine that the request requires IACUC review.

Certain changes may be approved by Veterinary Verification and Consultation (VVC). Such requests must not involve new procedures, but may involve minor changes to already approved procedures, such as the frequency, duration, or number of procedures performed; the type or dose of medication used; or the method of euthanasia. To request a VVC, the researchers should complete a consultation form and submit it to orsp@acu.edu. The request will be sent to the veterinarian who will determine if the requested change is permissible under VVC, conduct the consult, and either approve the request, recommend revisions, or defer the decision to the IACUC.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the AWA/AWR policy. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

   The Chair communicates in writing the approval, request for clarification prior to approval, or request for specific changes to the Investigator, who then submits a revised protocol, if necessary. The investigator must provide requested material in a timely manner before approval of the research protocol. The Chair provides a letter indicating IACUC approval.

   The Institutional Official is informed of IACUC actions through semi-annual reports, and as appropriate, written reports submitted by the IACUC Chair at other times during the year.

9. Conduct continuing review of each previously approved, ongoing activity at appropriate intervals as determined by the IACUC, but not less than annually. The IACUC procedures for conducting continuing reviews are as follows:

   Investigators are notified by the IACUC Chair approximately 6-8 weeks prior to continuing review deadline. Submitted applications are distributed to the IACUC members in the same manner as new applications. Review procedures are conducted in the same manner as described in #6 above.

10. Be authorized to suspend an activity involving animals. The IACUC procedures for suspending an ongoing activity are as follows:

    In the event of a serious breach of guidelines, a special meeting of the IACUC is called to review the incident and determine appropriate responses. The committee shall vote whether or not to suspend research activity; a quorum must be present for this vote to take place and suspension must be by majority vote of those in attendance. Should it be deemed necessary to suspend a research activity, the Chair communicates in writing to the Institutional Official and the Investigator, outlining the details of the breach of guidelines and recommending suspension of research activities until appropriate remediation is completed. The Institutional Official has responsibility to assure that the Investigator abides by the IACUC decision. In addition, the IACUC may determine that a report must be sent to appropriate oversight officials. In such a case, the Chair will draft a report to be sent by the Institutional Official to appropriate authorities.

11. Authorized to determine when a study is exempt from AWA/AWR based on definition provided in Part 1 of the regulations, including studies involving non-covered species or the use of agricultural animals for agricultural purposes. Generally, the IACUC Chair will make this determination. Individual researchers should not make this determination without IACUC consultation and confirmation of exemption. Researchers are still expected to follow standard ethical guidelines for the care and use of animals, even when studies are exempt from AWA/AWR.

Occupational Health and Safety

The risk-based occupational health and safety program (OHSP), for personnel working around or

having frequent contact with animals, is developed in consultation with the University's Risk Management officer. This individual is invited to meet with the IACUC annually to update the committee about new regulations or when changes in current facilities or training are under consideration. The OHSP is based on identification of known hazards and development of procedures to avoid them. Principal investigators have primary responsibility for overseeing the individuals working with and around animals. The Attending Veterinarian is responsible for determining whether the procedures undertaken for animal care are appropriate according to current practice. Finally, the IACUC has responsibility, through regular reviews/inspections, to assure that all components of the OHSP program are consistent with policy.

Known hazards for species frequently encountered by ACU personnel include: 1) bites or scratches from rodents and birds; 2) possible allergic reactions from exposure to animals; 3) exposure to zoonotic diseases; 4) injuries from handling equipment.

Workers must be instructed in issues of personal health and safety, including: 1) the use of personal protective equipment to reduce exposure to allergens; 2) proper handling of animals to prevent bites or other personal injuries; 3) appropriate vaccinations or other preventative measures for protecting against zoonotic disease; 4) and safe handling of equipment.

Personnel are provided with lab coats, gloves and face-masks as appropriate. Workers are instructed not to eat or drink around animals, apply cosmetics or other such activities. They are also required to wash their hands upon completion of work with animals.

Workers are also instructed that in the event of any injury, however minor, they must report the injury to their supervisor for follow-up. Because most workers are students, any injuries would be handled through the campus health center and related services. Faculty and other staff would be eligible for workman's compensation coverage should an injury be work-related.

Workers who have concerns because of pregnancy, illnesses or immunocompromised status will be encouraged to consult with their personal physicians regarding any special actions that must be taken. Where appropriate, workers may be assigned other tasks without penalty.

Training

The training or instruction available to IACUC members, scientists, and other personnel involved in animal research or teaching is as follows:

Researchers are required to complete Animal Research/Working with the IACUC modules through CITI. IACUC members complete these modules, as well as the IACUC member modules. These modules meet the federal requirements for basic training in the humane care and use of animals in research and teaching, in research or testing methods that minimize the number of animals needed to obtain valid results and that minimize pain and distress.

Institutional Program Evaluation

All of this institution's programs for activities involving animals have been evaluated by the IACUC within the last six months and will be reevaluated by the IACUC at least once every six months, in accordance with AWA. Reports have been and will continue to be prepared in accordance with AWA Policy. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the regulations and documents outlined in Section D above. Any departures are identified specifically and reasons for each departure will be stated. Where program or facility deficiencies are noted, the report will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC

evaluation will be submitted to the Institutional Official. Semiannual reports of the IACUC evaluation will be maintained by this institution and made available to outside officials, as required and upon request.

Record-keeping

This Institution will maintain for at least three years:

(1) A copy of this policy and any modifications made to it.
(2) Minutes of IACUC meetings, including records of attendance, activities of the Committee and committee deliberations.
(3) Records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
(4) Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official (Vice-Provost).
(5) Documentation of any IACUC-approved exception to the regulations.

This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

All records shall be accessible for inspection and copying by authorized representatives/officials, as required, at reasonable times and in a reasonable manner.

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