UNIVERSITY OF GUAM
UNIBETSEDAT GUÅHAN
Board of Regents

Resolution No. 22-05

RELATIVE TO APPROVING THE UNIVERSITY OF GUAM RESEARCH MANUAL

WHEREAS, the University of Guam (UOG) is the primary U.S. Land Grant institution accredited by the Western Association of Schools and Colleges Senior College and University Commission serving the post-secondary needs of the people of Guam and the region;

WHEREAS, UOG must comply with federal and local sponsor requirements for programmatic, regulatory, fiscal, and property stewardship for research activities;

WHEREAS, the Office of Research and Sponsored Programs (ORSP) supports faculty members and eligible University personnel to conduct research activities, and operates to streamline the administration of funded projects and other similar externally funded research by providing information, technical assistance, and guidance on program management throughout the proposal period from pre-award to post-award;

WHEREAS, a manual is needed that provides guidance to research activities undertaken by faculty, students, and employees of UOG that covers, but is not limited to, procedures for ORSP pre-awards and post-awards; principal investigator duties and responsibilities; Research Council membership and function; Committee on Human Research Subjects (IRB), and Institutional Animal Care and Use Committee purposes and responsibilities; conflict of interest disclosures; research integrity and misconduct; intellectual property; and best practices in research compliance to all federal and local regulations;

WHEREAS, ORSP met with the UOG Research Council and Faculty Union who contributed to the final draft of the proposed UOG Research Manual, and was reviewed and endorsed by the Administrative Council on January 12, 2022, and the UOG Faculty Union on January 28, 2022; and

WHEREAS, the enclosed UOG Research Manual was reviewed by the Academic, Personnel, and Tenure Committee and recommends approval of the Manual to the Board of Regents (BOR).

NOW, THEREFORE, BE IT RESOLVED, that the BOR approves the enclosed UOG Research Manual effective the date of this resolution.

Adopted this 24th day of February, 2022.

Liza J. Providio, Chairperson

ATTESTED:

Thomas W. Krise, Ph.D., Executive Secretary

University of Guam Research Manual

Last updated: February 2, 2022

UNIVERSITY OF GUAM
UNIBETSEDÅT GUÅHAN

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University of Guam Policy / Procedure Face Sheet

Policy Type	[ ] Board; [ ] Board-approved; [ ] President; [X] President-approved; [X] Other _BOR___				
Policy/Procedure Manual Name	**UOG Office of Research and Sponsored Programs Procedures, Regulations, and Policies Manual**				
Article No.	II	**Article Title**	Policies of the UOG Board of Regents		
UOG Office of Research and Sponsored Programs Procedures, Regulations, and Policies Manual		**UOG Office of Research and Sponsored Programs Procedures, Regulations, and Policies Manual**			
Approval Authority	President	**Effective**	02/02/2022	**Most Recent Review**	02/02/2022
Responsible Executive	Vice Provost ORSP	**Resolution No 22-05**	02/24/2022	**Date of Next Required Review** (date set by Board)	02/01/2025
Responsible Office	ORSP	**Revision Tracking**	1/28/2022 with Faculty Union; 2/2/2022 confirmed concurrence.		
Policy/Procedure Contact & Website where document is maintained		671.735.3037; mailto:orsp@triton.uog.edu; https://www.uog.edu/policy-procedures-library/			
Who Should Review (not in specific order)		[ ] Creating group; [ ] Unit Administrator(s); [ ] Unit Academic Affairs Committee; [ ] Human Resources Office; [ ] Business Office; [ ] Facilities & Maintenance; [ ] Institutional Safety Committee; [ ] Faculty Senate; [X] Faculty Union; [ ] Student Government Association; [X] Research Council [X] Administrative Council; [ ] Academic Officers Council; [ ] Vice President Administration & Finance; [ ] Senior Vice President & Provost; [ ] UOG Legal Counsel; [X] UOG President; [X] UOG Board of Regents;			
Initiation / Review / Consultation / Approval History		Content original from 2000 RRPM; Content extracted and made into UOG Research Manual; Guidelines Original documents for Graduate Studies, Research and Sponsored Programs, approved by Acting President, Dr. Anita Enriquez - 4/5/2018; Admin Council review and concurrence – 1/12/2022; Faculty Union review and concurrence with changes – 2/2/2022. Preparing for BOR AP&T Committee for 2/16/2022, then BOR on 2/24/2022. Approved by the BOR on 2/24/2022.			
NOTE: All approved changes to policy/procedures need to be made on the hardcopy of this document within 5 workdays and posted on https://www.uog.edu/policy-procedures-library/ within 10 workdays from the date approved.					

University of Guam Research Manual

1. **Policy/Procedure Statement**
   The UOG Research Manual provides guidance to research activities undertaken by faculty, students, and employees of the University of Guam. The Intellectual Property, Misconduct in Research, and Conflicts of Interest policies apply to all research at the University. Likewise, the oversight of the IRB Committee on Human Subjects Research and the IACUC animal protections may apply.

   This Manual also makes available the policy requirements that serve the terms and conditions of pre-award and post awards. By accepting an award, Principal Investigators and the Project Team agree to comply with the requirements in the University Policy Statement. Notices of policy changes published in the UPM or RRPM can supersede information in the UOG Research Manual. ORSP will incorporate these notices into the annual update of this manual.

2. **Reason for the Policy/Procedure**
   To enforce best practices in research, undertaken with integrity, in an ethical fashion, compliant to all federal and local regulations.

3. **Scope of Policy/Procedure and Exclusions**
   All members of the University community are affected by this policy, except minors.

4. **Who Should Read this Policy / Procedure**
   This Policy/Procedure is intended for the personnel responsible for research activities, especially grant management personnel, involved in Pre-award, Post-award procedures, including Principal Investigators (PI), Co-PI, co-investigators (CI), Grant Program Managers, and other grant team members.

5. **Responsibilities**
   Compliance, monitoring, and review
   - Office of Research & Sponsored Programs maintains this manual and is responsible for making sure it is kept updated, posted on the UOG website, and manages the required three (3) year comprehensive review.
   - Research Council has the responsibility to comment and participate in the comprehensive review.
   - The Vice Provost has the responsibility to keep forms current and facilitate compliance with research guidelines and reporting for the University.

   Records management
   - Office of Research & Sponsored Programs keeps this manual.

6. **Definitions**
   There are approximately 70 definitions in this document, specifically listed in the IRB Committee on Human Subjects Research, Conflict of Interest, Research Integrity & Misconduct, and Intellectual Property Policies. These definitions have been included in the UOG/UPM definition glossary.

7. **Feedback**
   University staff and students may provide feedback about this document by emailing orsp@triton.uog.edu

I. INTRODUCTION

The UOG Research Manual provides guidance to research activities undertaken by faculty, students, and employees of the University of Guam. The Intellectual Property, Misconduct in Research, and Conflicts of Interest policies apply to all research at the University. Likewise, the oversight of the Committee on Human Subjects Research (CHRS/IRB) and the IACUC animal protections may apply.

The UOG Research Manual also provides policies and procedures relating to funded research grant awards, sub-awards, contracts, or cooperative agreements for all UOG administrators, faculty and staff involved. Corrections, changes, requests for clarification, or suggestions should be communicated to orsp@triton.uog.edu.

The University of Guam's institutional mission addresses three primary foci: teaching, research, and outreach pertinent to the western Pacific region. While scholarly work, research and the publication of research findings are required for tenured faculty promotion, the University encourages all eligible personnel to seek external funding and engage in projects related to the mission and goals of the University.

The Office of Research and Sponsored Programs (ORSP) supports faculty members and eligible University personnel to conduct research activities in collaboration with the various Micronesian colleges, as well as select public and private agencies locally, nationally, and internationally.

Office of Research and Sponsored Programs

The Office of Research and Sponsored Programs (ORSP) supports faculty members and eligible University personnel to conduct research activities. ORSP operates to streamline the administration of funded projects and other similar externally funded research by providing information, technical assistance, and guidance on program management throughout the proposal period from pre-award to post-award.

ORSP's major priorities are to:

- Support faculty members and University personnel to conduct research activities and to successfully manage existing research and sponsored projects.
- Select public and private agencies locally, nationally, and internationally as grantors.
- Seek external funding and engage in projects related to the mission and goals of UOG.

ORSP is led by the Vice Provost of Research & Sponsored Programs, who reports directly to the Senior Vice President & Provost and advises the UOG President directly on all grants management activities at the University.

UOG must comply with federal and local sponsor requirements for programmatic, regulatory, fiscal, and property stewardship. Therefore, principal investigators (PIs) must comply with the requirements governing each proposal and award. ORSP or the responsible administrator is responsible for verifying PI compliance.

II. ORSP PRE-AWARD PROCEDURES

ORSP will meet with interested Principal Investigators (PIs) to search for grants. Searches can be done through grants.gov, AASCU GRC, or other search engines by grantor agency websites. ORSP aids in the submission of proposals by identifying contribution sources, reviewing budget accuracy, and ensuring compliance of grant applications with university policies and sponsor guidelines. Much of what occurs during the early stages of applying for grant funds affects the University's ability to manage a grant after it is received, therefore discussions and cooperation between the investigators and ORSP is encouraged in developing programs and proposals that receive funding.

- Proposal Preparation – Sponsoring agencies provide guidelines that describe the format and procedure that the proposal must adhere to. Discussions with ORSP in the development phase of the award is encouraged. ORSP can aid with constructing budgets, cost sharing, and other related documents.

- Timeline – In order to ensure that proposals will be submitted to sponsoring agencies by the announcement deadline, please adhere to the following schedule: Final documents and attachments should be submitted no later than three (3) business days before the announced application deadline. Exceptions to the 3-day submission rule will only be granted with the (signed) approval of the Vice Provost of Research & Sponsored Programs; and signed exception must be sought before the 3-day deadline.

- Administrator Authorization – PIs must have the ORSP Transmittal form approved by Dean/Director in order to submit a grant. ORSP Transmittal form can be found in UOG ORSP website. Form can be found at https://www.uog.edu/_resources/files/research/orspfile/2020-orsp_transmittal.pdf

- Letter of Support – All UOG faculty involved in the grant proposal, including PI's and co-investigators, must submit a letter of support from their respective Dean/Director to ensure their approval.

- Proposal Submissions by part-time University Professors and other University Staff – If an individual with a less than full-time position wishes to submit a proposal, a full-time UOG faculty member must also be named as a co-PI or co-investigator. If a staff member wishes to submit a proposal, a full-time UOG faculty member (or administrator) must also be named as a co-PI or co-investigator.

III. ORSP POST-AWARD PROCEDURES

- The Award Instrument – The Award Instrument formally acknowledges the award of funds by an authorized representative of the funding agency. ORSP will notify the principal investigator within two (2) business days of Notice of Award (NOA).

- ORSP Program management of funded projects – ORSP would be the liaison between the sponsoring agency and the project team. ORSP will offer guidance for requesting for additional funding, no-cost extensions, preparing documents, and other grant related needs. ORSP adheres to University of Guam Research Corporation (RCUOG) and the University's fiscal accountability policy for sponsored-projects funds and regulatory compliance with local

and federal policies. Expenditures and financial transactions will be reviewed to make certain that award terms and conditions are met.

- Budget Reports and Financial Reports – The Program Director (PD) or PI are responsible for monitoring the awarded budget. Real-time monthly expenditure reports are available upon request to ORSP. An account availability report summarizes the account's budget and actual activity to show the budget available for future activity. The detailed budget shows the detailed transactions that occurred throughout grant year periods.

- Progress Reports/Final Reports – External funding requires recipients to report periodically on the progress of supported project. Reporting information are included in award documents. PD or PI are responsible for preparing and submitting progress/final reports to grantor agency.

- Time and Effort Reporting – Time and effort provide auditors with proof that grant personnel has devoted the necessary time and effort for respective projects. Time and effort should be submitted bi-weekly for grant hires.

IV. PRINCIPAL INVESTIGATOR DUTIES AND RESPONSIBILITIES

INTRODUCTION

The University of Guam's institutional mission addresses three primary foci: teaching, research, and outreach pertinent to the western Pacific region. While scholarly work, research and the publication of research findings are required for tenured faculty promotion, the University encourages all eligible personnel to seek external funding and engage in projects related to the mission and goals of the University.

The Office of Research and Sponsored Programs (ORSP) supports faculty members and eligible University personnel to conduct research activities in collaboration with the various Micronesian colleges, as well as select public and private agencies locally, nationally, and internationally.

POLICY STATEMENT ON DUTIES

The intent of this statement is to provide guidance with procedures that must be followed in conducting externally sponsored projects or managing campus program accounts through the UOG and to identify individuals and areas within the institution that can provide assistance and answer questions Principal Investigators may have regarding these requirements. As a resource, this statement supplements and does not replace existing policies and procedures of UOG.

A PI (sometimes known as Project Director or Responsible Person) has the responsibility to be aware of all matters contained in this policy statement, to ask questions, to alert the appropriate administrator of any risks or issues related to the program, and request assistance from the ORSP in the undertaking of projects, to effectively train and supervise project personnel about those matters that are appropriate for each employee to know and to adhere to.

PIs operate under the supervision of an administrator, normally, a dean or director. When the PI is a Dean/Director, then the PI will operate under the supervision of their immediate supervisor. It is the PI's duty to continuously exercise responsible judgment in the administration of the project from the inception through the close out. The PI is accountable and responsible to the Dean or Director and Vice Provost of Research & Sponsored Programs for ethical conduct, accuracy of time and effort reporting, and quality performance for the grant or contract.

The first step is to prepare a proposal for a grant, contract, or Request for Proposal (RFP). Any program or proposal that uses any University of Guam resources must have the written approval of the appropriate administrator. Faculty time is a resource, and as such, approval in writing must be obtained from the faculty member's dean or director for participation on a grant or contract. When the proposal is ready, the complete narrative and a budget must be submitted in time for a review by the faculty member's dean or director and the RSP (for form accuracy and budget). Upon their approval the grant or contract may be submitted. If there are questions about submission of grants, please contact the ORSP. For grants, normally a scientific review and scoring summary is provided as feedback. These reviews will be kept at the ORSP for future use.

Once an award has been received, a campus program account will be established at the Research Corporation of the University of Guam (RCUOG) or at the UOG Business Office. The PI is responsible to send a copy of the proposal, the award letter, and any other information to the RCUOG or UOG Business Office. Once a campus program account is established, PIs assume primary responsibility for the technical (or programmatic) conduct, the administration of the funds, and the general management of the project to assure contractual/award terms and conditions are met, all Government of Guam rules (such as procurement) are followed, all RCUOG and UOG policies (travel, etc.) are adhered to and ensure the project stays within budget.

Upon the completion of the project, the PI will submit all final reports. A copy must also be submitted to the ORSP, including copies of all published papers, outcomes or reports produced during the term of the project or using data produced by the project.

GENERAL RESPONSIBILITIES

In conducting a sponsored project, performing work under a contract, or operating under a campus program account, PIs responsibilities include but are not limited to the following:

Ongoing Responsibilities:

- Communicate regularly with ORSP;
- Attend and ensure all staff also attend training sessions offered by the ORSP to ensure up-to-date information on project administration requirements;
- Administer the grant or contract, including time and effort reporting;
- Ensure ethical conduct regarding research and management of the grant or contract;
- Provide technical and academic direction for the grant or contract;
- Supervise staff and others working under the auspices of the grant or contract;
- Ensure accountability to the units involved, including ensuring that a Cross-Unit Load Form at https://www.uog.edu/_resources/files/research/crossunit418.pdf is approved: communicate with home unit and unit housing the grant, communicate with the RCUOG or UOG Business Office and communicate with the ORSP;
- Sign off on all requests for hiring;
- Ensure signatures and routing of documents are done correctly to demonstrate transparent and accessible flow;
- Maintain time and effort reporting and oversee submission of timesheets.

Pre-Award:

- Thoroughly review and follow sponsor guidelines and Request for Proposal (RFP);
- Communicate to the ORSP of PIs intent to submit a proposal and begin completing Forms;
- Prepare a proposal, including a budget, in accordance with sponsor guidelines and applicable laws and regulations;
- Identify any special needs for compliance, any potential conflicts of interest and/or Intellectual Property, IRB requirements;
- Obtain collaboration letters from any anticipated collaborator or consultant on the proposed project;
- Obtain the written approval of the administrative supervisor of any current employee named in the grant or contract;
- Once the PI receives written notification/approval from the ORSP the proposal may be submitted to the sponsor.

Post-Award Responsibilities:

- Notifies the ORSP when the PI receives award notification from the Sponsor and forward the award document to the ORSP for processing;
- Review the award document for technical and administrative accuracy and appropriateness;
- Responsibly oversee, in coordination with RCUOG or UOG Business Office and the ORSP, project funds, including expending funds within the projected period and within designated budget categories, following all RCUOG and UOG policies;
- Complete and submit technical or progress reports according to established time schedules;
- Ensure timely evaluation and review by unit housing grant and the ORSP;
- Maintain Time/Effort reporting for grant activities;
- Maintain business and activity reporting with signature approval by PI, Dean/Director, Legal Counsel, Director RSP, and SVP and President where appropriate.

ELIGIBILITY TO BE A PRINCIPAL INVESTIGATOR

- PIs must be qualified to submit an application, as defined by the appropriate funding agency;
- PIs must have solid commitment to the University, including a desire to serve the University;
- PIs must have a binding relationship to the University community through appointment or contract through at least the period of the grant or contract.

V. RESEARCH COUNCIL

Membership

- Vice Provost, Research and Sponsored Programs
- Vice Provost for Academic Excellence, Graduate Studies & Online Learning
- Dean, University Libraries
- Directors of:
  - Center for Excellence in Developmental Disabilities Education Research and Service (CEDDERS)
  - Marine Laboratory
  - Richard F. Taitano Micronesian Area Research Center (MARC)
  - Water and Environmental Research Institute of the Western Pacific (WERI)
- Associate Director, Western Pacific Tropical Research Center (WPTRC)
- Chairperson, Institutional Animal Care and Use Committee (IACUC)
- Chairperson, Committee on Human Research Subjects/Institutional Review Board (CHRS/IRB)
- One elected faculty member each from the:
  - College of Natural & Applied Sciences (CNAS)
  - College of Liberal Arts and Social Sciences (CLASS)
  - School of Business and Public Administration (SBPA)
  - School of Education (SOE)
  - School of Health (SOH)
  - School of Engineering (SENG)
- Non-voting members:
  - Representative of the Office of Research and Sponsored Programs (ORSP)
  - Representative of the Research Corporation of the University of Guam (RCUOG)
  - Director, Center for Island Sustainability (CIS)

Members are responsible for reviewing and passing on items to their respective schools/colleges as part of a review process for the functions listed below and updates from other units that make impact or influence research activities from their constituents. They are responsible for reporting at each Research Council meeting the most relevant and impactful projects and coordinating submissions to the Annual Research Report.

Functions

The Research Council shall be responsible for providing advisory services to faculty, administrators, and staff of the various research units on campus on matters of funding sources and other research-related concerns; shall stimulate and help faculty members conduct basic and applied research in their area of specialization; and shall provide guidance and links to faculty in strategic planning on facilitating research directions and supporting research programs for the University.

Research-related matters of compliance with federal regulations shall be administered by the Research Council or its designated subcommittees, i.e., Committee on Human Research Subjects and Institutional Animal Care and Use Committee. Other standing committees (Intellectual Property sub-committee) and committees formed on ad hoc basis at the request of the Vice Provost for Research & Sponsored Programs (Conflict of Interest sub-committee or UOG Privacy Board) report their activities to the Research Council.

a. Research Integrity

It is the policy of the University of Guam to foster a research environment that discourages misconduct in all research, research training or research related activities pursued at the University or under the sponsorship of the University.

Misconduct in research means fabrications, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the academic and scientific community for proposing, conducting, exhibiting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

University policies and procedures can be found in Section IX of this Manual, Research Integrity & Research Misconduct Policy. It is the responsibility of all persons at the University involved in research, research training or related research activities to familiarize themselves with university and federal policies and procedures. Copies of 42 CFR Part 93, and 45 CFR Part 689 are federal regulations, readily available online.

b. Human Research

It is the policy of the University that no research involving human subjects be undertaken until those research activities have been reviewed and approved according to procedure s developed by the Committee on Human Research Subjects (CHRS) of the Research Council.

c. Animal Research

The University adheres to the standards for protecting animal research subjects promulgated by the National Science Foundation, the National Institute of Health, and the U.S. Department of Agriculture. An established Institutional Animal Care and Use Committee of the Research Council shall ensure that the University community adheres to these standards.

VI. COMMITTEE ON HUMAN RESEARCH SUBJECTS

It is the responsibility of the University to safeguard the rights and welfare of subjects at risk in any research, development, or related activity in accordance with the Code of Federal Regulations (45 CFR part 46) which governs the protection of human subjects, and which forms a basis of University policy.

Guam Public Law No. 24-326 designates the University of Guam's Committee on Human Subjects in Research as the Institutional Review Board (IRB) for review and approval of research conducted on Guam concerning human subjects.

It is the policy of the University that no research involving human subjects be undertaken until those research activities have been reviewed and approved according to procedures developed by the Committee on Human Research Subjects (CHRS) of the Research Council.

All projects which involve human subjects, and which are conducted at or sponsored by the University of Guam, regardless of the absence or presence of support, and regardless of who else may have revised or reviewed these projects, must receive prior approval from the Committee on Human Research Subjects (CHRS).

Purpose

U.S. Mandate — In the United States, Institutional Review Boards (IRBs) are governed by Title 45 CFR (Code of Federal Regulations) Part 46. These regulations implement provisions of the National Research Act of 1974, for example, defining IRBs and requiring them for all research that receives support, directly or indirectly, from what was the Department of Health, Education, and Welfare at the time, and is now the Department of Health and Human Services (HHS). IRBs are themselves regulated by the Office for Human Research Protections (OHRP) within HHS. IRBs were developed in direct response to research abuses earlier in the twentieth century. Two of the most notorious of these abuses were the experiments of Nazi physicians that became a focus of the post-World War II Doctors' Trial, and the Tuskegee Syphilis Study, a project conducted between 1932 and 1972 by the U.S. Public Health Service on Black men in rural Alabama. Title 21 part 56 has additional requirements for IRBs that oversee clinical trials of drugs involved in new drug applications.

Functions

This process of review and approval includes the consideration of the methods to be used in the collecting of data, obtaining informed consent, and protecting of the confidentiality of subjects. Since the "risks" to subjects are affected by these procedures, it is the responsibility of the principal investigator to be fully familiar with the Code of Federal Regulations (45 CFR 46) and with all applicable policies, rules and procedures regarding research at UOG.

Guidelines and rationale for the process are available from the Office of Research and Sponsored Programs. A copy of the Code of Federal Regulations 45 CFR 46 is also available from this office. An assurance by the principal investigator that approved procedures will be followed in the conduct of activities involving human subjects is a requirement of the application for CHRS approval process.

The CHRS shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects.

The University's CHRS shall assist other Institutional Review Boards (IRBs) on Guam or at other colleges and universities, as requested, and provide a joint review for any cooperative research projects covered by the Federal Policy and involving more than one institution including the University of Guam. In the conduct of such collaborative research projects, each institutional IRB is responsible for safeguarding the rights and welfare of human subjects and compliance to the Federal Policy. The CHRS may enter into a joint review arrangement, rely upon the review of the other IRB, or make appropriate arrangements to avoid duplication of efforts and oversight.

Scope

IRBs are most commonly used for studies in the fields of health and the social sciences, including anthropology, sociology, and psychology. The purpose of an IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. To accomplish this purpose, IRBs review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research. The chief objectives of every IRB protocol review are to assess the ethics of the research and its methods, to promote fully informed and voluntary participation by prospective subjects who are themselves capable of making such choices and to maximize the safety of subjects once they are enrolled in the project.

Applicability

Guam Public Law No. 24-326 designates the University of Guam's Committee on Human Subjects in Research as the UOG-IRB for review and approval of research conducted on Guam regarding human subjects. University IRB determinations are made consistent with the Title 45 CFR (Code of Federal Regulations) Part 46 and where appropriate adopting guidance policies and procedures from other institutional review boards. The policies and procedures set forth in this manual are applicable to all faculty, staff, employees, and students at the University who propose to use human subjects in research, development, and related activities including research for which investigational devices or drugs are used (Office of Research Support and Compliance, n.d.).

The IRB has jurisdiction and oversight responsibilities over human subject research in which the University is engaged. Specific examples would include but not be limited to research:

1. For which the University receives funding.
2. Conducted by or under the direction of faculty, students, or staff of the University in connection with their institutional responsibilities.
3. Conducted by or under the direction of any faculty, students or staff of the University using any property or facility of the University.

The University requires research investigators who are not its employees or agents:

1. To obtain the collaboration of a University faculty member.
2. To ensure all PIs (internal and external to the institution) comply with all relevant
    a. IRB determinations.
    b. Federal and state regulatory requirements.

c. Human subjects' protection standards.

Definitions:

Definitions Applicable to All Sections of the CHRS-IRB Manual
As provided in 45 CFR 46 with elaboration, should a question or conflict arise, the definition as provided in the federal guidelines will prevail. This expanded definition is offered to clarify "generalized research."

Alternate: An individual appointed to serve in the same capacity as the primary member(s) for whom the alternate is named, who substitutes for the member at a convened meeting when the primary member is not in attendance.

Assent: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b)). Assent is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g. a child or cognitively impaired person) to participate in research." (IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_glossary.htm).

Children: Children are defined as "persons who have not attained the legal age for consent (18 years of age) and cannot legally provide "consent" to treatment or procedures under the applicable law of the jurisdiction in which the research will be conducted." Children includes any person under the age of 18.

Conflict of Interest: A conflict of interest includes financial interests of the IRB member, or immediate family members (spouse, domestic partner, and dependents) as well as non-financial issues, or members closely associated with the investigators on the study being reviewed, or other studies. This includes involvement in the design, conduct, or reporting of the research study.

Cooperative Research: Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

Exempt Research: 45 CFR Subtitle A §46.104 provides the guidelines for exempt research.

(1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily
   i. be ascertained, directly or through identifiers linked to the subjects;
   ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to

the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) Exempt Research

i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not

i. applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Human Subjects: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Minimal Risks: 45 CFR references minimal risks as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-Human Subject Research (NHSR): This type of research refers to the use of data about individuals when that data is obtained (1) neither through intervention or interaction with the individual, (2) nor private and individually identifiable.

Research: A systematic investigation, i.e., the gathering and analysis of information, designed to develop or contribute to general knowledge, or to solutions to an applied problem that is not

specific (a) to teaching a University class within which the data are collected, or (b) to the duties of a University committee whose work directly serves the interests of the faculty, staff, or students from whom data are solicited.

Student means any individual who is enrolled as a student at The University of Guam.

Quorum is defined as a majority of the voting members. In the case of the Institutional Review Board (IRB), a quorum will consist of at least 51% of the voting IRB members. All members present have equal voting power. At meetings of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum.

General Policies and Standard Operating Procedures:

Membership

The Committee on Human Research Subjects (CHRS) shall constitute the University's Institutional Review Board (IRB) for human research subjects. The CHRS shall be comprised of at least five (5) members appointed by the President upon the recommendation of the Vice Provost of Research & Sponsored Programs and Senior Vice President & Provost.

An effort will be made to appoint members so that the CHRS will be sufficiently qualified: through the experience and expertise of its members; the diversity of their racial and cultural backgrounds; and their sensitivity to community attitudes. CHRS member qualifications should insure respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

At least one (1) member shall be a person whose primary training and research concerns are in nonscientific areas; for example, lawyers or members of the clergy. At least one (1) member shall be a person who is not otherwise affiliated with the University or part of the immediate family of a person who is affiliated with the University. When research is reviewed involving a category of vulnerable subjects, e.g., prisoners, children, individuals institutionalized as mentally disabled, the CHRS shall include at least one member who has as a primary concern the welfare of these subjects.

(Reference to above sections sourced from Title 45 CFR Applicable §46.107IRB membership)

Term of appointment

Ex-Officio Non-voting member

The Vice Provost of ORSP shall serve ex-officio, as a non-voting member.

CHRS-IRB Chair

The Chair shall be recommended by Vice Provost ORSP to the UOG President via the SVP & Provost based on expertise and experience from among current and former IRB members. Each IRB Chair serves a three-year term of service (with renewable terms of one to three years). The Chair of this committee shall receive a one-quarter load allocation per semester.

CHRS Members
Other CHRS members shall be appointed for two (2) years, renewable and for staggered terms. The CHRS shall not consist entirely of men, entirely of women, or entirely of members of one (1) profession.

External Reviewers
The UOG CHRS-IRB in consultation with the Vice Provost of ORSP may designate an alternate external reviewer to serve as an adjunct reviewer if the board requires expertise beyond the current capacity of the sitting members.

The UOG CHRS-IRB may invite individuals with competence or expertise in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB, such as special or vulnerable populations. These individuals serving as external reviewers may not vote with the IRB (45 CFR Subtitle A§46.107 IRB Membership).

Alternate IRB Members
The UOG CHRS-IRB in consultation with the Vice Provost of ORSP may designate an alternate member to replace a primary member on the board. Alternate members should have the experience, expertise, background, professional competence, and knowledge comparable or qualified based on the member being replaced. If in the event, the primary member is a sitting chair, the chair may recommend to the Vice Provost of ORSP a replacement that can come from current board appointees or recommend a new appointment should any sitting member decline the chair succession.

Conflict of Interest
To avoid conflicts of interest, a CHRS member shall not participate in the CHRS' review of any project in which the member is involved as a researcher or subject.

CHRS-IRB Training
All IRB members, alternates, and support staff will receive human subjects protections education related to federal regulations and guidance, and policies and procedures for IRB review processes. Minimal initial training in human subjects protection that include (e.g., Collaborative Institutional Training Initiative Modules, National Institute of Health Modules as appropriate).

CHRS-IRB Member Roles and Responsibilities

CHRS-IRB Chairs
The IRB Chairs have primary responsibility for the following:

- Providing leadership to the CHRS-IRB to help ensure the rights and welfare of human subjects participating in the research reviewed by the IRB
- Conduct convened meetings and reviewing and approving the minutes documenting IRB discussions and findings
- Leading discussions with Principal Investigators and/or administers to resolve controversial and/or procedural matters relating to research approval
- Signing CHRS-IRB correspondence communicating and documenting IRB decisions
- Delegate review responsibilities as necessary and applicable.
- Maintain current knowledge of and assuring compliance with relevant regulations, laws, and policies related to human subjects
- Regularly consult with the Director of the ORSP and staff on IRB issues and concerns
- Prepares CHRS-IRB reports

CHRS-IRB Members
IRB member responsibilities include all the following:

- Attend convened meetings and participate in the review discussions and actions
- Provide timely written comments on research undergoing IRB review, when required
- Work with Principal Investigators to resolve matters relating to research approval and participate in educational efforts for investigators and new IRB members
- Review and provide comments when designated by the IRB chair to perform a review
- Serve as a primary or secondary reviewer to communicate and prepare approval determination recommendations

IRB Functions and Operations
In order to fulfill the requirements of this policy the CHRS-IRB shall:

- Have access to meeting space and sufficient staff to support the CHRS IRB review and recordkeeping duties;
- Maintain current records of IRB members and period of appointments and reappointments; area of expertise and representation;
- Establish and update review procedures for conducting reviews of research and reporting its findings to the investigator and the institution;
- Conduct ongoing reviews of research studies;
- Ensure prompt reporting should approved study procedures change;
- Address any unanticipated problems involving risks to subjects or others; (Source: 45 CFR 46 §46.108)

CHRS-IRB Review of Research
An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption.

An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f).

Continuing Review. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances: (i) Research eligible for expedited review in accordance

with §46.110; (ii) Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); (iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. (2) [Reserved] (g) An IRB shall have authority to observe or have a third party observe the consent process and the research.
(Source: 45CFR 46 §46.109)

Principal Investigator Responsibilities
Principal Investigators are responsible for ensuring that all forms and documents are filled out completely and included in the application packet. The following are the PI responsibilities and are not all inclusive:

- Submit protocols for IRB review and approval of proposed research activities prior to commencing the research activities.
- Employ sound study design and approval of proposed research activities prior to commencing the research activities.
- Ensure the rights, safety and welfare of the research subjects are upheld and protected.
- Disclose all conflicts of interest.

Investigator Responsibilities for Completed Study
Investigator upon completing all human subject interactions, data collection and analysis of the CHRS-IRB approved research plan should address the following:
- Submit a closeout report
- Address all approved methods related to data collected, reporting to research subjects or other conditions noted in the application.

Co-investigator or PI Roles and Responsibilities
- In addition to the roles identified for the Principal Investigator, identify the specific roles of the co-investigator
    - Interaction with subjects
    - Working with de-identified data
    - Working with identifiable data
    - Other- Include any other information that helps explain roles of the research team

Revisions to CHRS-IRB Research
Guidelines to modify an ongoing CHRS-IRB approved research:
- Submit a request to the CHRS-IRB and receive an CHRS-IRB approval before implementing the proposed modification.
- Expedited reviews can be allowed for revisions involving minor changes in previously approved studies (45 CFR 46.110(b)(2)).

Expiration of IRB Approvals and Renewals
If a research study expires before a CHRS-IRB approval is obtained, the investigators must stop all research activities involving human subjects to that study (45 CFR 46.103(b)).
Guidelines for renewal within the approval period may be submitted to the CHRS-IRB for consideration if there are no substantive change other than a study period extension.

Should a study exceed the (1) year study period, the PI will be required to submit a new application for review.

Use of Computer and Internet Based Human Participant Survey Research
Social Networking Sites or Mobile Devices for Human Participant Research
All studies, including those using computer and Internet technologies*, must:

1. Ensure that the procedures fulfill the principles of voluntary participation and informed consent;
2. Have appropriate safeguards addressing human participants privacy or confidentiality of information;
3. Address possible risks to participants, including psychosocial stress and related risks *(*Source: https://www.irb.cornell.edu/policy)*

CHRS-IRB Administrative Functions:

Convened Meetings
At a minimum, the CHRS-IRB meetings are held on the last Friday of the month during the FAÑOMNÅKAN and FANUCHÅNAN semesters. No meetings are held during the Finakpo or Tinalo' intersession period.

Quorum
For convened meetings, the necessary number (i.e., more than half) of the IRB members listed on the membership roster are present.

Teleconference or videoconference
Any member may participate by teleconference or videoconference, provided the member has received all materials before the meeting and can equally participate in the discussion.

IRB Meeting Minutes
All documents and files, meeting agendas and minutes are maintained in a secure location.

Meeting agendas and minutes are required only for convened meetings of the membership.

IRB Reports
CHRS-IRB Application Summary Report. The summary report represents a profile of all applications submitted for review during each semester. This report is presented during convened meetings and submitted to the Research Council.

Approval Letters and Documents:

Approval Letters
Applications that have been reviewed during convened meetings or assigned to a lead reviewer, the Chair finalizes all reviews with the issuance of an approval letter or a conditional approval letter. Final approval letters represent that the committee and or the assigned lead reviewer(s) have reviewed the application and recommended approval. This includes applications that have been reviewed during convened meetings. The second type of approval letter involves a committee review and or a lead reviewer(s) requiring additional clarification or information. The Chair will issue a conditional approval letter requesting the additional information or clarification as noted during the review. The PI receiving a conditional approval letter is required to address the stipulated conditions and submit an updated application denoting the amendments. The Chair then determines if the conditions have been met and then issues a final approval letter.

Duration of approval Letters
Approval letters are effective up to one year from date of issuance.

Research Project Time Extension.
Should the project extend beyond a 1-year period, the PI is required to submit an extension request prior to the expiration date of the approval period.

Amendment/Revisions to an IRB approved Study

Request for Modifications:

Should a PI encounter a situation during the active period of an approved research, the PI may submit a request to make modifications or procedures regarding change in the research or any part thereof. Any proposed modifications or changes to the research, will require informing the IRB committee of those changes. The IRB will review the amended procedures prior to implementation.

Reporting Study events and unanticipated problems
If a concern or situation regarding or relating to the research arises, the PI should contact the CHRS-IRB Chair or representative immediately for consultation or assistance to address the research concern.

CHRS Application Information:

Minimum Application Information
The Principal Investigator will be responsible to completely filled-in the current **Application for Approval of Studies Involving Human Subjects** (available from ORSP), with all sections of the form completed with specific and detailed information

1. Identify project team members and roles, Co-investigators
2. Select review type
   - Identify the appropriate basis for review type
3. Identify any collaboration roles
4. State the objective of the research study and summarize relevant background knowledge
5. What is the research question or questions to be addressed?
6. Research design (i.e., quantitative/qualitative, mixed methods, multi-phase, etc.)
7. Importance of knowledge to be obtained as a result of this research.
8. Identify any conflict of interest.
9. Define the target population
   - Age range
10. Describe the population of human subjects to be recruited.
11. Number of subjects
12. Describe the process as to how a subject may withdraw from the study if they no longer want to participate.
13. Recruitment procedures
14. Summary of data collection procedures
15. Compensation-Payments to Research Participants
16. Course Credit
17. Privacy, Confidentiality & Security
    - List all identifiers that will be collected during the study

18. How is the privacy of the subject protected?
19. Describe provisions for data security and access control
20. Describe Data security storage
21. Accompanied by at least **two** (2) copies of the research abstract/prospectus and methodology;
22. All surveys to be used in the study;
23. Content of flyers to be used in participant recruitment
24. Cover letter;
25. Forms for informed consent and/or assent and the process for protecting confidentiality of subjects;
26. If the application packet is being considered by another IRB, include that application and approval letter;
27. For theses or dissertations, attach the methods section only and not the entire dissertation or thesis proposal;
28. For dissertation or thesis from another university, that IRB must give approval first and the approval letter must be included; and if applicable,
29. For **exempt** status, must be submitted to the Office of Research and Sponsored Programs. If it is clear that the proposal involves more than minimal potential risk to human subjects, the Chairperson of the CHRS shall require from the investigator one (1) copy of the entire proposal, less any appended materials not necessary to the understanding of the project, to aid in the review process.
30. Supplemental Forms: Audio Recording Consent Form
31. Monitoring/Verification of Compliance- An IRB shall conduct monitoring and continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f).
32. Contacts for Questions, Concerns, Complaints or Input should be addressed to the CHRS-IRB Chair or the IRB designated representative

CHRS-IRB Student Class Project Guidelines

Student Class Project Criteria

Research qualifies for the designation of student class project if: It is an activity designed as part of a course requirement for purposes of learning research methods and; The results and data will not be presented, posted, or published outside of the classroom.

IRB Approval Not Required

- A student class project does not meet the definition of human subject research because the project is intended only for classroom purposes. The student cannot use the project for any presentation, conference, publication, thesis, dissertation, or report outside the course for which it is assigned. If the class projects (individual or group) that are designed for or relating to teaching purposes only, then the IRB approval is not required.

IRB Approval Required

- If student class assignments are intended to collect information systematically or to publish or disseminate data meet the federal regulatory definition of research.

- Independent research projects that collect data through interaction with living people or access to private information requires an IRB review. The student must submit an

IRB application if they intend to use the project outside the classroom. This application must be approved before the student starts the project.

Vulnerable Populations

Inclusion of Vulnerable Populations in Research Proposal

When some or all of the subjects that will be enrolled in a research study are likely to be vulnerable to coercion or undue influence, such as pregnant women, prisoners, children, and decisionally impaired adults, additional safeguards must be included in the study to protect the rights and welfare of these subjects. Plans for implementing additional safeguards must be described in the application to the IRB (45 CFR 460 Subpart B).

In addition to the responsibilities prescribed for the IRB under 45 CFR Part 46, Subpart A, the IRB shall follow special procedures with respect to pregnant women, fetuses, neonates of uncertain viability, prisoners, and children as specified in Subparts B, C, and D. Inclusion of other vulnerable populations as research subjects is considered by the IRB and is discussed in further detail in this section.

Determination Guidance

Should situations arise that are not clearly covered in any of the sections provided the CHRS-IRB shall defer to the applicable safeguards under 45 CFR 46 as needed.

Source:
https://research.utexas.edu/ors/human-subjects/policies-and-procedures/
Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

IRB Review of Research Activities

Human Subjects Determination

Activities that meet the institutional definition of Human Subjects Research (HSR) require IRB review.

Types of Review:

Exempt Review

Proposed projects involve no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Certain categories of HSR can be determined to be exempt as long as they meet prescribed ethical criteria including the requirement for informed consent, minimal risk study procedures and considerations for participant privacy and data confidentiality. Any significant changes to an exempt project will need to be submitted to the IRB to ensure that the exempt determination still applies.

(Reference to above sections sourced from Title 45 CFR Applicable §46.104 Exempt research)

Expedited Review
Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research will be reviewed for compliance with the applicable regulations permitting expedited review (45 CFR 46.110).

Expedited Review Period
The review is generally completed within two weeks of receipt of the materials, and the review recommendation is sent to the Chair for final approval and or for further review and processing.

An IRB may use the expedited review procedure to review the following:

a) CHRS-IRB Reviewer determines that the study involves more than minimal risk;
b) Minor changes in previously approved research during the period for which approval is authorized; or
c) Under an expedited review procedure, the review may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the CHRS-IRB. In reviewing the research, the reviewers may exercise all the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).
d) Advise the CHRS-IRB members of research proposals that have been approved under the procedure.
(Source: 45 CFR 46 § 46.110)

Full Board Review
Studies that do not qualify for exempt or expedited review and/or present greater than minimal risk to participants must be reviewed at a fully convened IRB meeting. The full board meets once per month. Due to the frequency of full board meetings, the OIRB website lists deadlines for submission in order for items to be on the meeting agenda.

Examples of full board studies include but not limited to the following:

- Research in prisons
- Studies administering drugs or alcohol
- Research involving invasive interventions (e.g. biopsies, tDCS)
- Research including high risk or vulnerable populations

Approval Notification
The CHRS-IRB will notify investigators in writing of its decision to approve the proposed research activity, the risk level assigned, the consent requirements, approved documents and the continuing review within the final approval letter. A PDF file copy of the approval letter and approved documents will be forwarded to the investigator.

Administrative Review
Minor changes to study documents such as grammar corrections, addition or removal of project team members, phone number changes, etc. and study closures are reviewed administratively by OSRP staff.

Functions. It is the responsibility of the University to safeguard the rights and welfare of subjects at risk in any research, development, or related activity in accordance with the Code of

Federal Regulations (45 CFR part 46) which governs the protection of human subjects, and which forms a basis of University policy.

Authority of the University of Guam CHRS-IRB and Administrative Procedures and Support

The IRB board is responsible for ethical and regulatory oversight of research that involves human subjects and adheres to the Code of Federal Regulations (CFR) Title 45, Part 46 (Protection of Human Subjects). Guam Public Law No. 24-326 designates the University of Guam's Committee on Human Subjects in Research as the UOG-IRB for review and approval of research conducted on Guam regarding human subjects.

Applicable Regulations and Laws

Procedures.
All projects involving research with human subjects, as defined in 45 CFR 46:102(f), require review by the CHRS. When it is not clear whether a project constitutes research as defined in 45 CFR 46:102(f) and therefore requires review, the investigator should seek assistance from the CHRS or Vice Provost of Research & Sponsored Programs (ORSP). A decision will be made which rules that a research project is either **exempt** from review, or that it requires an **expedited** or **full** review under the provisions of 45 CFR 46. In the case of a revision to a previously approved research project involving human subjects, investigators have the responsibility to bring this revision to the attention of the CHRS and the same criteria for review will apply.

Requirements by Category:

Research Involving Children
Other applicable guidelines include provisions found under Subpart D–Additional Protections for Children Involved as Subjects in Research.
Research involving Children as subjects must meet one of the following categories:

- 45 CFR 46-401-409

Assent: "Assent," is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g. a child or cognitively impaired person) to participate in research." (IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_glossary.htm). Assent is required from subjects who are either: 1) minors between the ages of 7 and 17 years; or 2) subjects 18 years or older who are intellectually or emotionally impaired and not legally competent to give their informed consent. Note that children below the ages of 7 years are generally not asked to provide assent. Minor subjects who are able to read and understand the informed consent document (parent's permission form) may provide assent on that form with a separate signature line; however minor subjects (age 7 or older) who are too young or intellectually immature to read and understand the parent's permission form should be given the opportunity to provide written assent on a simplified assent form. Also, adult subjects (18 years or older) who are not legally competent to give their informed consent should be given the opportunity to provide written assent on a simplified assent form.

Child Assent
The IRB is responsible for deciding whether child assent is required in proposed research activities. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (45 CFR

46.402(b)). Child assent is required, except in the following three circumstances described at 45 CFR 46.408(a):

1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
3. The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d).

Source: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html
(Reference to the above sections sourced from Title 45 CFR 46 Subpart D. Protection of Human Subjects- Protections for Children involved as Subjects in Research)

Parental Permission & Assent Forms

Children less than 5 years of age
A simple oral explanation of the study should be offered to the child before study-related procedures are conducted. A signed Parental Permission form is required as well.

Children between the ages of 5 and 12 years
Informed voluntary assent should be obtained without pressure from parents or investigators. The protocol review package should include an example of the explanation to be offered to the child.

Children between the ages of 12 and 16 years
Investigators should submit a permission form for parents and a separate assent form for the child (i.e., at about a 6th grade reading level) to read and sign. An assent form should be written as simply as possible and cover the following points:

- What the study is about
- Why he/she qualifies for the study
- The voluntary nature of the study
- The procedures that will be done
- Potential benefits & potential risks
- An assurance that he/she will be treated the same whether or not he/she agrees to join the study
- An invitation to ask questions
- Assurance that he/she may withdraw from the study after discussing it with his/her parents

Children between the ages of 16 and 18 years
Investigators should submit both Parent Permission and Child Assent forms, written in language that is easily understandable for both the parents and the child (i.e., at 8th grade reading comprehension level), which covers the following points:

- What the study is about
- Why he/she qualifies for the study
- The voluntary nature of the study
- The procedures that will be done
- Potential benefits & potential risks

- An assurance that he/she will be treated the same whether or not he/she agrees to join the study
- An invitation to ask questions
- Assurance that he/she may withdraw from the study after discussing it with his/her parents

CHRS Administrative Procedures and Support

Role of the Administrative Support Staff:
Applications submitted to the CHRS-IRB will be reviewed in the order they are received. The CHRS-IRB staff will conduct a preliminary review of the submission packet to determine:

a. The completeness of the packet;
b. To request clarifications and/or additional materials to provide the reviewer with a complete application addressing regulations and institutional requirements.

Maintain and archive all CHRS-IRB Research Applications, Archival of approval letters, Reports and all administrative records in accordance with applicable retention policies and procedures as set forth by the UOG and or applicable provisions under Title 45 CFR 46

Report of CHRS Activities and documentation including the following:

1. Copies of all research proposals reviewed, approved sample consent forms, progress reports submitted by the PI's and reports of injuries to subjects.
2. Minutes of IRB meetings, detailing attendance at the meetings, actions taken by the IRB, the vote on actions, the types of support on actions (for, against, abstaining), basis for requiring changes in or disapproving research; written summary of discussions of issues and their resolution.
3. Records of continuing review activities,
4. Copies of all correspondence, communications between the IRB and the investigators.
5. Rationale for expedited reviewers determination

Maintain and updates to the following

1. UOG-CHRS-IRB Website
2. Provide announcements and updates on CHRS-IRB matters
   a. Notices of meetings
   b. Submission deadlines
3. Provide updates to the CHRS-IRB application forms, review protocols as approved by the CHRS-IRB convened board.

Archival and Storage of CHRS PI Data Series and Reports

1. File Retention Policies for the CHRS-IRB Committee
   - Records required by this policy shall be retained for at least 3 years
   - Records relating to research shall be retained for at least 3 years after completion of the research.
2. The UOG-CHRS-IRB may maintain the records in printed form, or electronically.
3. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.
   (Source: §46.115 IRB Records)

Principal Investigator Responsibilities

CHRS Application Information.

1. A completely filled-in **Application for Approval of Studies Involving Human Subjects** (available from ORSP), with all sections of the form completed with specific and detailed information;
2. Accompanied by at least **two** (2) copies of the research abstract/prospectus and methodology;
3. All surveys to be used in the study;
4. Cover letter;
5. Forms for informed consent and/or assent and the process for protecting confidentiality of subjects;
6. If the application packet is being considered by another IRB, include that application and approval letter;
7. For theses or dissertations, attach the methods section only and not the entire dissertation or thesis proposal;
8. If it is a dissertation or thesis from another university, that IRB must give approval first and the approval letter must be included; and if applicable,
9. The rationale for **exempt** status, must be submitted to the Office of Research and Sponsored Programs. If it is clear that the proposal involves more than minimal potential risk to human subjects, the Chairperson of the CHRS shall require from the investigator one (1) copy of the entire proposal, less any appended materials not necessary to the understanding of the project, to aid in the review process.
10. Supplemental Forms: Audio Recording Consent Form

Elements of Informed Consent

The following elements should be a part of any and all informed consent forms for studies involving human subjects:

1. A statement that the study involves research, an explanation of the purposes for the research and the expected duration of the subject's participation, a description of the procedures to be followed and the identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subjects.
3. A description of any benefits to the subject or to others which may be reasonably expected from the research.
4. A disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A disclosure of appropriate alternate procedures or courses of treatment, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimum risk, an explanation as to whether compensation for medical treatments is available if injury occurs and, if so, what they consist of, or where further information can be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research, and an explanation of the research subject's rights and whom to contact in the event of research related injury to the subject.
8. A statement that the participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9. Any additional costs to the subject that may result from the participation in the research. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
10. The approximate number of subjects involved in the study.

Assent

"Assent," is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g. a child or cognitively impaired person) to participate in research." (IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_glossary.htm). Assent is required from subjects who are either: 1) minors between the ages of 7 and 17 years; or 2) subjects 18 years or older who are intellectually or emotionally impaired and not legally competent to give their informed consent. Note that children below the ages of 7 years are generally not asked to provide assent. Minor subjects who are able to read and understand the informed consent document (parent's permission form) may provide assent on that form with a separate signature line; however minor subjects (age 7 or older) who are too young or intellectually immature to read and understand the parent's permission form should be given the opportunity to provide written assent on a simplified assent form. Also, adult subjects (18 years or older) who are not legally competent to give their informed consent should be given the opportunity to provide written assent on a simplified assent form.

The following should be included on the written assent form:

1. Study title
2. Study purpose – provide a brief explanation of the purpose of the study.
3. Procedures – describe what the subject is being asked to do
4. Withdrawal privilege – describe how a subject can stop participation later even if he/she agrees to start
5. Voluntary participation – include a statement that the subject does not have to participate
6. Confidentiality – indicate that the experimenter will not tell anyone (parents, teachers) what the subject says or does in the study
7. Signature lines – include a signature line for the subject and for the investigator. Be sure to include a date line as well.

Central Institutional Review Board and University of Guam Privacy Board

The University of Guam CHRS/IRB also serves as the "UOG Privacy Board". Please see Appendix "?" for more information.

References

https://www.govinfo.gov/content/pkg/CFR-2018-title45-vol1/pdf/CFR-2018-title45-vol1.pdf
https://research-compliance.umich.edu/operations-manual-part-3-hrpp-policy
http://irb.unm.edu/
https://www.irb.cornell.edu/policy/
https://research.utexas.edu/ors/human-subjects/

VII. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

PURPOSE

The University of Guam Institutional Animal Care and Use Committee (IACUC) is responsible for overseeing the use of animals and animal facilities, and for the review of basic science and biomedical research, teaching, and extension activities involving animals conducted at, or in association with The University of Guam. Members of the IACUC are appointed by the Vice Provost of Research & Sponsored Programs on behalf of the President and SVP & Provost of the University of Guam.

The IACUC ensures that animal care and use is in compliance with all federal, territory, and local regulations. The basis of compliance is determined by the Federal Animal Welfare Act and Animal Welfare Regulations (AWAR), the Institute for Laboratory Animal Research (ILAR) Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, the Public Health Service (PHS) Policy on the Care and Use of Laboratory Animals, the Food and Drug Administration (FDA) Good Laboratory Practices, and other applicable regulations.

The IACUC is the principal advisory source on humane care and use of animals within the University and, as such, the appropriate body for reviewing and investigating concerns or complaints involving the appropriate care and use of animals. The Committee has the authority to negotiate modifications, suspend or terminate animal use that is not in compliance with these regulations.

The Committee shall review the University animal program semiannually, inspect all University animal facilities, and review and approve the care and use of all animals as described in animal use protocols. The Committee shall recommend to the designated Director of Research & Sponsored Programs changes or improvements to the University animal program or facilities necessary to maintain a high-quality animal use program that is in compliance with all appropriate regulations.

As stated in the PHS Assurance Document, the IACUC shall:

- Review the institution's program for humane care and use of animals at least once every twelve (12) months.
- Inspect all the institution's animal facilities, including satellite facilities at least once every twelve (12) months.
- Review concerns involving the care and use of animals at the institution.
- Make written recommendations to the appropriate Director of Research & Sponsored Programs regarding any aspect of the institution's animal program, facilities, or personnel training in their respective areas.
- Review and approve, require modifications, or withhold approval of protocols for the use of animals.
- Review and approve, require modifications, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
- Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of protocols related to the care and use of animals or of modifications required to secure IACUC approval.
- Be authorized to suspend the use of animals.

MEMBERSHIP

The IACUC must be qualified through the experience, expertise, and diversity of its members to maintain oversight of the use of animals, animal facilities, and to provide review of basic science and biomedical research and teaching animal use conducted under the auspices of the University.

All members shall be appointed by the Director of Research & Sponsored Programs, or whomever has been appointed as the Authorized Official by the President of the University of Guam. The Committee will be composed of a Chairperson and at least two (≥ 2) other individuals, both from the following: a Doctor of Veterinary Medicine, a faculty member actively involved in animal research, one individual whose primary vocation is nonscientific in nature, and/or one public member nonaffiliated with the University who represents the general community. Of these, one individual will be elected as Vice-Chairperson. An individual who meets the requirements of more than one of the categories may fulfill more than one requirement. Excluding the laboratory animal veterinarian(s), no more than three members shall be from the same department.

As deemed necessary, the Committee may also call on consultants, with a special expertise in areas of interest to the Committee.

Officers and Responsibilities

- The **Chairperson** of the Committee is appointed by the Vice Provost of Research & Sponsored Programs in consultation with the President and Senior Vice President of Academic & Student Affairs. The Chair must be an individual with previous research involving vertebrate animals. The Chair shall preside over IACUC meetings, approve minutes, and upon agreement with the IACUC Committee members, approve animal research protocols. Approval letters from the IACUC Committee Chair may be issued to the Applicant via email, but in signed .pdf form, which is co-submitted to the Office of Research & Sponsored Programs, who will keep a copy of all IACUC records for the University.
- The **Vice-Chairperson** is an IACUC member elected by the IACUC committee. His or her role is to represent the IACUC when the IACUC Chair is unavailable or cannot function as Chair. As such, the Vice-Chairperson can convene and administer an IACUC meeting, attend administrative meetings, and direct IACUC inspections when the IACUC Chair is unavailable. Also, the Vice-Chairperson can act as Chair when there is a conflict of interest declared by the Chair. Examples of conflicts include review of protocols submitted by the Chair.
- An **attending veterinarian** shall serve as a voting member of the IACUC for an indefinite term. It is the responsibility of the veterinarian to provide veterinary review of protocols and to oversee the adequacy of all aspects of animal care and use for all animals. The attending veterinarian may appoint another veterinarian to the IACUC. The appointed veterinarian will be called the “alternate veterinarian” and will serve as a proxy voting member of the committee when the attending veterinarian is not in attendance or is otherwise unavailable. The alternate veterinarian will have delegated responsibilities for all activities involving animals, including protocol review, animal use program responsibilities, and care of animals when the attending veterinarian is unavailable due to either planned or unplanned circumstances.

- **Various University officials and specialists** may be asked to serve as nonvoting ex-officio members of the IACUC.

Terms and Appointment
Given the current, low volume of UOG IACUC Protocol applications (<10 new proposals per annum), all voting members of the Committee, as well as the Chair, are appointed for an indefinite period of time by the Vice Provost of Research & Sponsored Programs, via memorandum addressed to the Officer. It is recommended that if the protocol submission rate increases to ≤20 per annum, then an amendment to include UOG Faculty that satisfy the criteria of Article III in the member appointment process.

If a Committee member wishes to leave the Committee, either temporarily or permanently, they must do so in writing addressed to the Vice Provost of Research & Sponsored Programs prior to ceasing Responsibilities. When requesting for temporary replacement, the Committee member may suggest one (1) faculty eligible to serve as a temporary proxy voting member (as per Article III) to be considered by the Vice Provost of Research & Sponsored Programs.

Responsibilities of Members
The IACUC recognizes that University research scientists must conduct their research in a timely and responsible fashion. Therefore, to facilitate research while assuring animal welfare, the Committee must conduct its business as efficiently as possible.

This can only be accomplished when all Committee members participate fully in Committee activities.

Committee members should make every effort to attend and actively participate in all regularly scheduled meetings, promptly conduct complete reviews of assigned protocols, and participate in facility and program reviews. Committee members must also recognize the sensitive nature of Committee activities and maintain confidentiality.

All IACUC members are expected to:
- Complete the online Collaborative Institutional Training Initiative (CITI) modules on research involving animals. Required modules include:
  1. Working with the IACUC
  2. Working with the IACUC - Refresher Course
  3. Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
  4. Essentials for IACUC Members
- Attend regularly scheduled meetings of the IACUC. Three or more absences from scheduled meetings per year (except under documented extenuating circumstances) are unsatisfactory.
- Review protocols and all other documents included in the meeting packet prior to scheduled Committee meetings.
- Members may elect to participate in program review and animal facility inspections or may be assigned.
- Maintain confidentiality about Committee activities.

The efficient operation of the IACUC depends on the full participation of its members. The name of any member who exhibits repeated unsatisfactory performance shall be submitted to the IACUC Chair. The Chair shall provide necessary documentation to the Vice Provost of Research & Sponsored Programs, or his/her designated representative, who shall make the final decision regarding dismissal from the Committee.

REGULARLY SCHEDULED MEETINGS

The IACUC shall schedule regular quarterly meetings during the Academic Calendar Year. The meeting may be cancelled if the IACUC has no current business and may be rescheduled in extenuating circumstances.

Emergency meetings and/or expedited reviews may be called by the Chair if required.

It is the University's policy that at least one (1) non-scientific committee member be present in order to conduct IACUC business.

Voting

A motion may only be passed at a convened meeting of a quorum of the IACUC if it receives the affirmative vote of a majority of the quorum present. A quorum means a simple majority of the members of the Committee. A tally of the numbers of members who vote for, against, or abstain from voting shall be recorded. Any minority views shall also be recorded in the minutes. All Committee members with the exception of the Authorized Official who serves in an Ex-Officio manner and the alternate veterinarian when the attending veterinarian is in attendance are voting members of the Committee.

Conflict of Interest

An IACUC member should not vote on protocols in which he/she, their student, spouse, or child is listed as a participant. The member may provide information to the Committee, if the Committee so desires.

However, the Chair shall excuse the member during these deliberations if no further information is required, or if another Committee member requests such action and before a vote is taken.

Sub-committees

The IACUC Chair may appoint sub-committees, as deemed appropriate, to facilitate the business of the Committee. All members of sub-committees shall consist of members in good standing. Sub-committees shall report directly to the IACUC with recommendations or reports. No actions may be taken by the subcommittee without prior approval of a majority of the quorum at a convened IACUC meeting.

PROTOCOL REVIEW PROCEDURES

The Federal Animal Welfare Act and Animal Welfare Regulations (AWAR), the Institute of Laboratory Animal Resources (ILAR) Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, and the Public Health Service Policy on the Care and Use of Laboratory Animals shall be used as basis for reviews.

A. Principal Investigators (PI)

The principal investigator conducting research, teaching, or extension/outreach involving live vertebrate animals shall submit a typed and signed protocol for the use of live vertebrate animals, with the two-page application cover form (contained in Appendix B) attached. Protocols requiring full review received less than five (5) working days before the scheduled IACUC meeting shall be reviewed the following scheduled meeting.

Animals may not be procured by the University of Guam or its Affiliates, regardless of fiscal support, until the protocol has been approved by the IACUC. Activities involving animals may not begin until the PI is notified in writing that the protocol has been approved. Research findings from data obtained prior to UOG IACUC protocol approval may not be included in peer-reviewed publications or any other method of public dissemination under the auspices of The University of Guam or its Affiliates.

Only those persons listed on the protocol are authorized to: maintain, care, and/or use animals or animal facilities; or conduct basic science, biomedical research, extension, outreach, or teaching activities involving animals conducted at, or in association with The University of Guam. Additions and/or substitutions to this participant list require a protocol amendment, and subsequent approval.

B. IACUC Committee Chair

The completed protocol application is submitted to the IACUC email account and is initially reviewed by the Office of Research & Sponsored Programs to ensure that all the components of the application have been completed. Once the application has been verified complete, The Office of Research & Sponsored Programs submits the new application to the IACUC Committee Chair and requests for the application to be reviewed. The IACUC Chair will then conduct an initial review and will work with the PI to identify additional information necessary for the IACUC reviewers. Once complete, the Chair shall electronically distribute the application to all Committee members for official review. The Chair will include a synopsis of their initial review and his/her position on the approval of the application. If the Chair deems that a formal meeting is needed to discuss an application(s), they shall inform and electronically distribute all pertinent documents at least five (5) days in advance of the next scheduled meeting in preparation for Committee discussion. If upon review the protocol is incomplete or unclear, the IACUC Committee Chair notifies the principal investigator of the clarifications/modifications that are required.

C. Veterinarian

The attending veterinarian, or the alternate veterinarian is his/her absence, will perform the veterinary review and present any concerns regarding the research either to the Committee at the scheduled IACUC meeting, or directly to the Chair via email.

D. Protocol Review

All research, instruction, and extension activities involving animals should be brought to the attention of the IACUC.

D. 1. Exemptions

There are areas of research are exempt from IACUC protocol submission and review. Investigators do not make the determination that animal use is exempt from an IACUC protocol submission. The IACUC Committee Chair determines if a protocol is eligible for exemption or requires Full Committee Review (FCR). Using animals in teaching situations does not automatically exempt the activity from IACUC review and approval.

Some areas that may be exempt include but are not limited to: work with invertebrates not listed as Protected Species; observational field research involving no manipulation; and research on vertebrate eggs, commercially obtained tissues, or tissues from colleagues with approved animal protocols in place at their facility, and others.

If the Chair deems that a protocol qualifies for exemption, each IACUC committee member is provided with a copy of the cover page and the non-technical summary. Copies of the complete protocol shall be made available to all IACUC members upon request, and any committee member may request a full committee review within 5 days of receipt. If no requests for FCR are requested within 5 business days, the IACUC Committee shall issue a letter of exemption to the PI for that specific activity or area. The exemption letter is only valid for that specific situation. If the investigator changes or modifies the activity, then it is subject to reexamination by the IACUC, and the exempt status may change and necessitate a protocol and review.

The Chair does not have the authority to disapprove a research project. **Disapproval can only be done by a majority vote of a quorum at a convened meeting of the IACUC**.

D. 2. Full Review Committee

If full committee review (FCR) is required, full copies of the protocol are electronically submitted to all Committee members, who are given at least 5 business days to the review the application. The Committee may discuss the proposed research project(s) electronically and determine if approval can be given or if modifications are needed before approval can be granted. A quorum of the Committee must respond before further action is taken. If the research project is ready for approval, an approval vote by the majority of the quorum present is required.

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the PI will be notified by the Chair that a revised protocol that includes all of the requested information is required to secure approval. The IACUC Committee Chair will communicate the required modifications directly to the researcher. Upon receipt, the revised protocol will be resubmitted to the IACUC Committee for review and approval.

Protocols are approved for a maximum of three years, although the PI will need to undergo annual review every twelve (12) months. After three years, the PI will rewrite and resubmit the protocol for review.

D. 3. Procedures to Request an Expedited Review of Protocols

Under unusual circumstances a PI may request an Expedited Review. An Expedited Review may be requested when any of the above review activities have to take place sooner than would occur under the normal review processes. This process must be justified beyond a convenience for the PI.

The Expedited Review (ER) process follows these steps:
Written Request – A completed protocol application to the IACUC must be submitted. In addition, the PI must formally request, in writing, an expedited review along with a clearly articulated justification for its need.

Determination – Upon receipt of an Expedited Review request, the IACUC Chair, the Veterinarian and another member of the IACUC will determine if the request has merit and notify IACUC and the PI of the determination. If the request for Expedited Review is not granted, the review activity will take place via the standard procedures.

Emergency Meeting/Expedited Review – If more than one ER request has merit and is granted, the IACUC Chair may either convene an emergency meeting of the IACUC, or request an expedited, Full Committee Review. The application and other relevant materials will be given to all IACUC members prior to the meeting. The proposal will then be reviewed in the Full Committee and undergo normal voting procedures.

E. Protocol Approval and Duration

If approved, an approval letter from the IACUC Committee Chair will be emailed to the principal investigator and the Director of the Office of Research & Sponsored Programs. The PI must countersign the issued permit and submit an original copy to the Office of Research & Sponsored Programs. No IACUC permit is valid until a signed copy is filed with ORSP.

Any proposal for animal use approved by the IACUC may be subject to further approval by the Director of the Office of Research & Sponsored Programs. However, the Director may not approve activities involving the care and use of animals that have not been approved by the IACUC.

Protocols are approved for a maximum of three years (≤ 3 years), or the remaining fiscal duration of a grant/contract, whichever is shorter. The PI will need to submit a report and undergo annual review every twelve (12) months.

It is important that the PI rewrite and resubmit the protocol for review at least four (4) weeks prior to its expiration date. No vertebrate animals may be procured, housed, or used for any University purpose on, or after the date of a protocol's expiration, and must immediately be removed from the University in a manner in compliance with all federal, territory, and local regulations. No exemptions or extensions may be granted for expired research protocols involving animals – all previously-authorized personnel must cease and desist until the PI is notified in writing that a protocol has been reapproved.

F. Authorized Personnel

Only those persons listed on the protocol are authorized to: maintain, care, and/or use animals or animal facilities; or conduct basic science, biomedical research, extension, outreach, teaching, or any other activities involving animals on University property, or in association with The University of Guam. Additions and/or substitutions to this participant list require a protocol amendment, and subsequent approval.

G. Procedures for the Annual Review of Protocols

Approved protocols must be reviewed at least annually. Therefore, at least four (4) weeks prior to the anniversary date of an approved protocol, the Office of Research & Sponsored Programs shall send to the principal investigator an Annual Review of Protocol for Use of Live Vertebrates Form (Appendix C) indicating that the annual review form must be completed and submitted to the IACUC Committee Chair before the first day of the anniversary month.

The annual reviews are approved by the IACUC Committee Chair on behalf of the Committee and will be listed on the agenda and minutes of the next quarterly meeting.

Annual reviews consisting of minor changes may be approved by the Chair or the Vice Provost of Research & Sponsored Programs with veterinary consult. Significant changes require a revision in writing and will be reviewed at the next convened meeting.

H. Procedures for the Review of Modifications of Approved Protocols

H. 1. Significant Changes

Significant changes to an IACUC-approved protocol must be reviewed and approved by the IACUC Committee before they occur. UOG interprets significant changes to mean those that have the potential to impact the health and well-being of experimental animals or authorized personnel substantially and directly. Examples of significant changes include, but are not limited to changes:

- from non-survival to survival surgery
- resulting in greater pain, distress or degree of invasiveness;
- in species;
- in study objectives;
- in Principal Investigator;
- in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in increases in animal numbers greater than 10% of the originally approved number; and
- that impact personnel safety.

Proposed significant changes require FCR and approval prior to initiation.

H. 2. Administrative Changes

UOG interprets administrative changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the experimental animals and personnel. Examples of non-significant changes include, but are not limited to changes:

- that correct typographical errors and/or grammar;
- in the funding source;
- in update contact information;
- in personnel (other than the PI); and
- in the use of a new vivarium housing location.

Proposed administrative changes may be approved by the Chair or Vice Provost of Research & Sponsored Programs with veterinary consult prior to initiation.

PROGRAM AND FACILITIES REVIEW

The IACUC shall review the Animal Care and Use Program and all UOG IACUC authorized animal facilities, as defined in the PHS Policy and the Animal Welfare Act, at least once every twelve (12) months. A sub-committee of the IACUC may conduct the inspection, but any member wishing to participate may not be excluded and the program review and inspection report must be reviewed and approved by a majority of a quorum of the Committee and include any minority views.

The sub-committee conducting the review and inspection must include at least two members. The sub-committee shall use the ILAR Guide for the Care and Use of Laboratory Animals as a standard for evaluating all laboratory animal facilities. Other guidelines and recommendations will be used as appropriate. The Guide for the Care and Use of Agricultural Animals in Research and Teaching shall be used as a standard for the non-PHS supported research and teaching activities involving production agricultural animals.

Program Review and Site Inspection Report
After review and inspection, a written report (including any minority views) shall be submitted to the Vice Provost of Research & Sponsored Programs. The report shall contain a description of the extent of each facility's adherence to the Federal Animal Welfare Regulations and shall distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, in the judgment of the IACUC and the appropriate Director of Research & Sponsored Programs and in accordance the Animal Welfare Regulations, may be a threat to the health or safety of the animals and personnel. The IACUC shall include a plan of action with specific dates for correcting any deficiencies. Any failure to adhere to this plan that results in a significant deficiency remaining uncorrected shall be reported within 15 business days through the Director of Research & Sponsored Programs to United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Office for Protection from Research Risks (OPRR) and any federal agency funding that activity.

ANNUAL REPORTS

A. USDA, Regulatory Enforcement of Animal Care
Annual reports shall be prepared by the IACUC according to the provisions of 9 CFR 2 (Subpart A, 2.36). The reports are submitted to APHIS on or before December 1.

B. PHS
Annual reports shall be prepared by the IACUC according to the requirements of the PHS Animal Welfare Policy (IV., F.) at least once every 12 months. Reports will be submitted to OPRR on or before January 31.

TRAINING

A. Committee Members
Committee members shall review these bylaws, the Animal Welfare Regulations, the PHS Policy, and other documents, as well as copies of individual policies developed by the IACUC regarding specific animal use issues. Committee members will complete the Collaborative Institutional Training Institute (CITI) courses including:
1) Working with the IACUC
2) Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
3) Essentials for IACUC Members

In order to stay current with the ever-changing regulatory environment, Committee members will be required to complete the CITI Working with the IACUC – Refresher course at a minimum of once every three (3) years.

B. Scientists, Research Assistants, and Animal Technicians
All scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment and use must be qualified to perform their duties. All scientists, research technicians, animal technicians, and other personnel will be required to take the CITI Working with the IACUC Basic Course and any other modules that can be identified at the time of protocol submission that align with their specific research project.

In order to stay current with the ever-changing regulatory environment, all scientists, research technicians, animal technicians, and other personnel involved in animal care and use will be

required to complete the CITI Working with the IACUC course at a minimum of once every three (3) years.

NONCOMPLIANCE

A. Procedures for Reporting Non-compliance
Everyone involved in animal care and use at the University shall be made aware of the procedures for reporting non-compliance. These procedures will be posted in all laboratory facilities and on the UOG IACUC webpage.

B. Procedure for Reporting Noncompliance with Laboratory Animal Care and Use Guidelines
Concerns or complaints regarding animal usage within The University of Guam should be brought directly to the attention of the people involved whenever possible. If the concern or complaint cannot be handled directly, it may be handled in one of two ways:

- If an emergency exists, the Veterinarian should be contacted immediately.
- If the situation is not an emergency, the concern or complaint should be submitted to the Office of Research & Sponsored Programs or the IACUC Chair. The Chair will assign an ad hoc committee consisting of at least two members to investigate the concern or complaint and prepare a report for the IACUC. The IACUC will review the concern or complaint during the next regularly scheduled meeting. The IACUC will determine what action will be taken and the Chair will notify the principal investigator of such action.

A written reply to those primarily involved and to the Vice Provost of Research & Sponsored Programs will follow each written concern or complaint submitted to the IACUC. No facility employee, student, IACUC member or laboratory personnel will be discriminated against, or be subjected to any reprisal for reporting suspected noncompliance. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with an approved protocol or the applicable provisions of the Animal Welfare Act.

C. Suspension of Activity
If the IACUC suspends an activity due to continuing significant deficiencies in animal care and use, the Vice Provost of Research & Sponsored Programs in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report the action with a full explanation to USDA, Regulatory Enforcement of Animal Care, OPRR, and any agency funding that activity.

D. Investigator Appeal
The principal investigator of any activity that has been disapproved or suspended by the IACUC may appeal that action to the IACUC and request another review based on the correction of misinformation or additional information not available at the time of the initial review.

AMENDMENTS

The IACUC may recommend amendment of these bylaws by a two-thirds vote at any meeting at which a quorum is present, providing that all IACUC members receive notification of the pending vote 10 working days prior to the meeting. Amendments will be subject to review by the Research Council and Vice Provost for RSP, and recommendation for Board of Regents Approval.

VIII. CONFLICTS OF INTEREST DISCLOSURES

A. PURPOSE

The University of Guam (University) is committed to promoting identification, disclosure, and elimination or management of conflicts of interest in operations of the University and activities of its employees. This includes institutional and individual financial, scholarly, and organizational conflicts of interest, as well as conflicts of commitment. These procedures are intended to delineate the process for addressing conflicts of interest and commitment

B. DEFINITIONS

1. ***UNIVERSITY OF GUAM POLICY MANUAL (UPM***) is the new hub for all policies and manuals at UOG and is in alignment with the BOR/Faculty Union Agreement. The UPM is focused on items within the legal and operational purview of the University's nine member Board of Regents including: UOG Legal Authorities; UOG Board of Regents; Finance and Business Practices; Colleges, Schools, Research Units, and other educational Units; Administrative Support Units; Shared Governance; Academic and student Policies; Employment Policies: Employee Roles, Policies, and Expectations; Administrator Policies; Faculty Policies; Staff Employment Policies; Student Employees Policies; and Contractor Policies.

2. ***AWARDING COMPONENT*** refers to the organizational unit of the agency that funds the *Research.*

3. ***COMPELLING CIRCUMSTANCES*** are facts that convince the *University* that an individual with a *Significant Financial* or other *Conflict of Interest* should be permitted to conduct the activity (e.g., *Research*) in spite of a conflict. Circumstances that may be evaluated (when applicable) include:
   a) Nature of the *Research*/activity,
   b) Unique *Investigator* expertise, or unique institutional resources (e.g., equipment, facilities, personnel),
   c) Magnitude of financial or other interest and the extent to which such interest is related to the *Research*/activity,
   d) Magnitude of financial or other interest and the extent to which such interest is related to the *Research*/activity,
   e) Magnitude of financial or other interest and the extent to which such interest is related to the *Research*/activity,
   f) The degree of risk to human subjects that is inherent in the *Research* protocol,
   g) Unique access to particular patient populations, and
   h) Extent to which the interest is amenable to effective oversight and management

4. ***CONFLICTS OF COMMITMENT*** arise when non-University activities of an *Employee* are substantial and overly demanding of the *Employee's* time and attention and interfere with the *Employee's* obligations and responsibilities to the University.

5. ***CONFLICTS OF INTEREST*** refers to situations in which an employee's financial, professional, or other personal interests may influence, or appear to influence, the employee's judgment in fulfilling his or her responsibility to the University. Conflicts of interest may also include institutional or individual financial, scholarly, and organizational conflicts of interest, as well as conflicts of commitment.

6. ***CONFLICTS OF INTEREST COMMITTEE (COIC)*** consists of faculty, staff and administrators appointed to review and provide advice on management or elimination in cases concerning potential or real *Conflicts of Interest* or *Commitment*. Committee members are appointed by the *Senior Vice President & Provost (SVP&P).* The *SVP&P* will consider all nominations from the University's Faculty Senate and will make the final selection of committee members in accordance with institutional policy and these procedures.

7. ***CONTRACTOR*** means "an entity that provides property or service under contract for the direct benefit or use" of the University. CFR 45 Part 94 Section 94.3.

8. ***DEANS and DIRECTORS*** refers to lead administrators of Schools, Colleges, and Organized Research Units within the University system.

9. ***DECIDING OFFICIAL*** refers to the Executive administrator. Unless otherwise designated by the University's President, the President will serve in this capacity.

10. ***DISCLOSURE*** refers to:
    a) Notifying the appropriate Senior Administrator of any personal potential or actual Significant Financial or other Conflict of Interest or Commitment.
    b) Providing a public statement as to the existence of any personal Significant Financial or other Conflict of Interest that may exist.
    c) Notifying funding agencies of any personal potential or actual Financial or other Conflict of Interest.

11. ***EMPLOYEE*** means any person possessing either a full-time or part-time appointment at the University, whether compensated or not, also refers to positions of the Research Corporation of the University of Guam (RCUOG), postdoctoral fellows, and some students or trainees.

12. ***ENTITY*** means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business, real estate trust, or any other legal body organized for profit or nonprofit purposes.

13. ***EQUITY*** is a financial interest in a business representing an ownership interest, and may include stock, stock options, stock warrants, or any other security.

14. ***HUMAN SUBJECTS RESEARCH*** means a systematic investigation through experimentation, testing, evaluation, or observation performed on a living individual or group of individuals, about whom an *Investigator* obtains: (1) data through intervention or interaction with the individual(s); or (2) identifiable private information. 45 CFR 46.102.

15. ***IMMEDIATE FAMILY*** means the *Employee's* spouse, domestic partner, or reciprocal beneficiary and dependent children.

16. ***INDIVIDUAL CONFLICTS OF INTEREST or INDIVIDUAL FINANCIAL CONFLICT OF INTEREST (FCOI)*** refers to situations in which personal interests, particularly *Significant Financial Interests (SFI)*, cause competing loyalties that compromise, or have the appearance of compromising, an Employee's objectivity in meeting University duties or responsibilities. If an *Employee's* objectivity in designing, conducting, or reporting *Research*, or other scholarly work is directly or substantially biased by *Significant*

Financial Interests or other interests, his/her judgment in the collection, analysis, review and interpretation of data may be compromised, along with the decisions, for example, on the hiring of staff, procurement of materials or equipment, sharing of results, writing of protocols, safety of *Human Subjects* in *Research*, use of statistical methods, and mentoring of students.

a) Examples of potential Financial Conflicts of Interest situations may include the acceptance of income from non- University of Guam sources, Equity, consulting fees, or royalty interest from an outside Entity which relates to the Employee's Institutional Responsibilities; income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; legal partnerships; gifts to the Employee's unit/department; and other forms of payment to the Investigator, Key Personnel, or members of their Immediate Family.
b) Other *Conflicts of Interest* situations may arise when an *Employee*, or a member of his/her *Immediate Family*, has loyalties to another *Entity.*
    i. that may affect decision-making with respect to University teaching, *Research*, or administration;
    ii. that may result in a material, financial or other personal benefit from the use or release of non- public information pertaining to the University.

17. ***INSTITUTION*** means "any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that received, research funding" (CFR 42 Part 50.603).

18. ***INSTITUTIONAL FINANCIAL CONFLICTS OF INTEREST*** may occur when the University, any of its senior management or trustees; a department, school, or other subunit; or an affiliated foundation or organization has a *Significant Financial Interest* in an outside *Entity* that itself has a *Financial Interest* in University *Research* or *Scholarly Activity*. *Senior Administrators* or Regents may also have conflicts when they serve on the boards of, or otherwise have an official relationship with, organizations that have significant commercial transactions with the University. The existence or appearance of such conflict can lead to actual bias, or perception of bias, in the review, administration, or conduct of *Research* at the University.

19. ***INSTITUTIONAL RESPONSIBILITIES*** (modified from CFR 42 Part 50.603) are defined as an *Employee's* professional responsibilities on behalf of the Institution, which may include activities such as research, teaching, consulting, professional practice, institutional committee memberships, or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

20. ***INVESTIGATOR*** may be an *Employee*, project director (PD), principal investigator (PI), co-PD, co-PI, and any other person who shares responsibility for the design, conduct, or reporting of *Research* or other *Scholarly Activity*. Included are clinical investigators who are directly involved in *Human Subjects Research* and share responsibility for obtaining the informed consent of human subjects. "***INVESTIGATOR"*** can also include non-employees such as *Contractors*, sub-grantees, sub-recipients, sub-contractors, or investigators' collaborators, who are expected to adhere to the provisions of this policy if such agreement is established.

21. ***MANAGE*** means taking action to address *Conflicts of Interest (COI)*, and may include reducing or eliminating the *COI*, to ensure, to the extent possible, that the design,

conduct, and reporting of *Research* or other *Scholarly Activity* will be free from bias. CFR 42 Part 50.603 as modified herein.

22. ***OFFICE OF RESEARCH & SPONSORED PROGRAMS (ORSP)*** is the University's administrative office for extramural funded activities under the Vice Provost of Research & Sponsored Programs. ORSP is responsible for developing the infrastructure and policies and procedures to ensure that the University is in compliance with federal, state and sponsor requirements on extramural funded activities.

23. ***ORGANIZATIONAL CONFLICTS OF INTEREST*** means conflicts that arise when the University cannot provide an *Entity* with impartial advice. This arises when technical advice that is given is biased or gives the University an unfair advantage.

24. ***RESEARCH*** means "a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge…" "The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development." CFR 42, Part 50.603.

25. ***SCHOLARLY ACTIVITY*** means "creative work" that is used in teaching, the creation or sharing of knowledge, the *Research* or "discovery*"* of new knowledge, or the development of new technologies, methods, materials, or uses.

26. ***SCHOLARLY OR SCIENTIFIC CONFLICTS OF INTEREST*** means conflicts that arise when a scholar or researcher's impartiality is biased by the potential for professional or personal gain, as in the review and commenting on manuscripts, funding applications, tenure or promotion records, or other publications.

27. ***SENIOR ADMINISTRATOR*** is a member of the University administration above the organizational level of Dean/Director or the equivalent in non-academic units of the University.

28. ***SENIOR/KEY PERSONNEL*** means the PD/PI, and any other persons identified as primary and/or essential personnel by the University in a grant application, progress report, or any other report submitted to a funding agency. CFR 42 Part 50.603.

29. ***SIGNIFICANT FINANCIAL INTEREST***
    a) ***SIGNIFICANT FINANCIAL INTEREST*** [reference 42 CFR §50.603(1); 45 CFR §94.3(1)] refers to anything of monetary value or potential monetary value, to an *Employee* and his/her *Immediate Family*, which is, or appears to be, reasonably related to the individual's *Institutional Responsibilities* with certain exclusions listed below in section CC.2. 42 CFR §50.603(1). *Significant Financial Interest* refers to a financial interest that arose **in the past 12 months** and includes but is not limited to the following:
        i. With regard to any **publicly** traded entity, a significant financial interest exists if the value of any remuneration received from the entity...and the value of any equity interest in the entity, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.,* consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other

reasonable measures of fair market value. 42 CFR §50.603(1.i) & 45 CFR, §94.3(1)(i).

ii. With regard to any **non-publicly** traded entity, a significant financial interest exists if the value of any remuneration received from the entity, when aggregated, exceeds $5,000, or in which the investigator holds any equity interest. 42 CFR§50.603(1) (ii) & 45 CFR §94.3 (1) (ii).

iii. Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests. 42 CFR §50.603(1) (III) & 45 CFR §94.3(1) (iii).

iv. Compensation or payments for service on boards or provision of executive advisory services to non- University of Guam *Entities,* excluded are Federal, State, local government agencies, or *Institutions* of higher education.

b) ***SIGNIFICANT FINANCIAL INTEREST*** does not include:

i. Salary, royalties, or other remuneration paid by the University to its *Employee*. If paid by another *Entity*, total remuneration is less than $5,000 when aggregated for the *Employee* and the *Employee's Immediate Family.*

ii. *Equity* interests arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the *Employee* does not exercise control.

iii. Income from seminars, lectures, or teaching engagements sponsored by Federal, State, local government *agencies*, or *Institutions* of higher education.

iv. Royalties or related remuneration paid by the University including intellectual property rights assigned to the University and agreements to share royalties related to those rights.

v. Income from service on advisory committees or review panels for Federal, State, or local governmental *Entities* or *Institutions* of higher education.

vi. Any ownership interests in the University, related to serving as a recipient under the Phase I Small Business Innovation Research (SBIR). SBIR is the extramural research program for small businesses established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219. CFR 42 Part 50.603, or Small Business Technology Transfer Programs (STTR).

c) Compensation or sponsorship of travel related to *Institutional Responsibilities* which are not reimbursed by a Federal, State, or local government agency, or *Institution* of higher education may be considered to be a *Significant Financial Interest*. *Employees* must disclose such benefits including the following details: purpose of the trip, identity of the sponsor/organizer, cost of travel, destination, and duration. In the determination as to whether there is a *FCOI*, the *Senior Administrator* to whom the *Employee* reports will determine whether additional information is needed.

C. POLICY IMPLEMENTATION AND ADMINISTRATIVE GUIDELINES

1. Disclosure Responsibilities Relating to Conflicts

a) Dissemination of Policy

Senior Administrators are responsible for ensuring that all *Employees* within their respective units are fully informed about UOG Research Policy IX: "Guidelines for Completing Annual Conflicts of Interest" and these procedures, upon initial appointment and reminded annually of the obligation to submit *Conflicts of Interest Disclosure* forms, unless exempt.

b) Conflicts of Interest Disclosure Forms

Forms must be submitted electronically to the appropriate administrative office. *Disclosure* forms will be considered confidential to the extent possible. An individual may be exempt from *Disclosure* depending upon the position to which the individual is assigned. An *Employee* may be exempt only if he or she is not responsible, directly or indirectly, for the design, conduct, or reporting of *Research* or other *Scholarly Activity*. Individuals should consult their immediate supervisors, departmental chairperson, *Dean,* or *Director* regarding exemptions; however, directives are listed below.

i. Individuals required to submit a disclosure form:
   - Persons holding the faculty ranks of professor, associate professor, assistant professor and all persons whose appointments contain such terms as "researcher," "adjunct," "associate," "assistant", "visiting," or "clinical", extension specialist, instructor, lecturer, as well as specialists.
   - Any staff member, student, trainee, postdoctoral research fellow, associate or assistant, and other individuals identified as *Investigators* or *Senior/Key Personnel* by the University. These individuals may be compensated or not and, on behalf of the University, are responsible for or in a position to influence the design, conduct, or reporting of *Research* or other *Scholarly Activity*.
   - All administrators, including Executive and Managerial positions, such as President, Senior Vice President & Provost, Vice Provosts, Deans and Directors.
   - Any individual who acts or appears to act as an agent of the University in using, controlling, or assigning to others the use of University facilities and resources as well as procurement of facilities and resources. Examples are individuals involved in auxiliary services and financial management

ii. Disclosure forms are to be submitted:
   - Within 30 days of initial appointment to a University or Research Corporation of the University of Guam (RCUOG) position.
   - At least once annually thereafter with submission by April 15 each year.
   - At any time when an actual or potential *Conflict of Interest* or *Commitment* arises or when there are changes to, or elimination of a prior conflict
   - **The *Disclosure* statement** (Appendix 2) is the primary vehicle through which actual and potential *Individual Financial* and other *Conflicts* of *Interest* can be identified and resolved through early, open review and discussion
   - New *Conflicts of Interest* situations, relationships and/or activities that give rise to them should be disclosed promptly if not already part of the annual *Disclosure* statement. The *Disclosure* statement serves as a written acknowledgement that the *Employee* has reviewed and is complying with this document, "UOG Research Policy IX: Guidelines for Completing Annual Conflicts of Interest". Accordingly, each *Employee* shall be required to declare explicitly whether he/she does or does not have such personal *Financial* and/or other *Conflicts of Interest*. The failure to report is an unacceptable violation of the "UOG Research Policy IX: Guidelines for Completing Annual Conflicts of Interest".
   - *Senior Administrators* are responsible for the review of *Disclosure* forms for each of their *Employees*. They are also responsible for providing a ***Conflicts of Interest Disclosure* summary** (Appendix 3) for their units annually to

their respective Vice President's Office. The deadline for submissions is June 30th of each year.

- All forms shall be collected by the Employees' respective *Deans, Directors*, *Senior Administrators*, Vice Provost or Senior Vice President & Provost, or supervisor and sent to the University's Human Resources Office which shall archive the forms. Updated forms must be submitted throughout the year if changes arise that may create a potential *Conflict of Interest*, alter the details of, or eliminate a previously disclosed conflict.

c) Nature of Disclosures

i. All personal *Significant Financial Interests* of an *Employee,* and their *Immediate Family,* and other *Conflicts of Interest* that are related to the *Employee's Institutional Responsibilities* must be disclosed.

ii. *Significant Financial Interests* required to be disclosed include:

- Those which would reasonably appear to affect *Research* (funded or proposed for funding), scholarly, professional, administrative, or educational activities of the *Employees.*
- In *Entities* where financial interests would reasonably appear to be affected by activities of the *Employee.*

iii. *Investigators* applying for funding, regardless of the funding *Entity*, must disclose any personal *Significant Financial Interests* or other potential *Conflicts of Interest* to the appropriate *Senior Administrator* prior to submission of a grant or contract application to the UOG's Office of Research and Sponsored Programs (ORSP). The *Disclosure* can take the form of Attachment A as required annually, or as required by ORSP for all proposals submitted to the National Science Foundation or Public Health Service (e.g., NIH, NCI, NIMHD, CDC, etc.). The following *Disclosure* requirements shall be met:

- Before an application or proposal is submitted to the sponsor when *Significant Financial Interests* could potentially affect the *Research* for which funding is sought, and when involving *Entities* whose financial interests could appear to affect the *Research.*
- At the time of the application or proposal submission. The University must certify to the sponsor that it has a written and enforced administrative process in place to identify and *Manage*, reduce, or eliminate *Conflicts of Interest* with respect to all *Research* for which funding is sought.
- Prior to spending any funds under an award. The University must report to the *Awarding Component* the existence of any *Conflicts of Interest* and ensure that it has been *Managed*, reduced, or eliminated. Upon request the *Institution* will make available to the *Awarding Component* detailed *Conflicts of Interest* information and how those interests have been *Managed*, reduced, or eliminated to protect the *Research* from bias.

  Include in the initial report to the Awarding component shall be the following:
  - Project, Award or Grant/contract number, PD/PI name or contact PD/PI name
  - Name of *Investigator* with a *COI*
  - Name of the *Entity* with which the *Investigator* has a *COI*
  - Nature of the *COI* (e.g., *Equity*, consulting fees, travel reimbursements, honoraria).

- Value of the financial interest $0-4,999; $5K- 9,999; $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K or a statement that a value cannot be readily determined and why.
- A description as to how the *Conflict of Interest* relates to the sponsor's *Research* interests and the basis for the University's determination that the interest conflicts with such *Research.*
- A statement as to whether the *COI* was *Managed*, reduced, or eliminated.
- If *Managed*, details of the University*'s* management plan

Included in the Annual Report to the *Awarding Component* shall be the following:

- Status of the *COI.*
- Changes in the management plan.
- Other records of the University regarding *COI* will be provided to the *Awarding Component* upon request.

- For any *Conflict of I*nterest that the University identifies subsequent to an initial report under an award, a follow up report will be made, and the conflicting interest *Managed*, reduced, or eliminated – at least on an interim basis – within sixty days of that identification.
- When *COI* are identified actions taken by the University to eliminate, reduce or *Manage* the *COI* will be publicly disclosed by display of information on the web site of the University's Office of Research & Sponsored Programs

iv. *Investigators* who receive Federal funding and who assume the role of marketing consultants as defined in 48 CFR, Part 9, Subpart 9.501 are subject to additional *Conflict of Interest* regulations as set forth in Subpart 9.5.

2. Review of Disclosure Statements

a) *Senior Administrators* shall be responsible for the initial review of all *COI Disclosures* filed by the *Employees* assigned to their respective units, determination of whether a *Conflict of Interest* exists, and identification of any conditions or restrictions that may be necessary to reduce or eliminate such *Conflict of Interest*. **All *Disclosures* containing potential *FCOI*, and other *Conflicts of Interest* should be forwarded to the *Office of Research & Sponsored Programs* for further review and possible referral to the Conflict of Interest Committee (*COIC)* or *Deciding Official*.** Approval of a *Research* proposal for *Investigators* that have a *FCOI* or other *COI* shall not be granted until an appropriate management plan has been developed. In reviewing *Disclosure* statements, the following assessment criteria should be used

i. A potential for a *Conflict of Interest* exists when it is determined that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the *Research* or *Scholarly Activity*

ii. *Conflicts of Interest* should be considered in relation to the impact of the *Scholarly Activity* on:

- Integrity of *Research* data or teaching activity.
- Risks to the rights and welfare of *Human Research Subjects.*

- Risks to the rights and obligations of students and trainees participating in the activity.
- Availability of *Research* results to the scientific community and public interest.
- Public perception of a *Conflict of Interest.*

iii. *Investigators* conducting, or proposing to conduct, *Human Subjects Research* must disclose all *Conflicts of Interest* and *FCOI* in accordance with the applicable Committee on Human Research Subjects (CHRS/IRB) policies and procedures of UOG. The CHRS/IRB may consult with the *COI Committee* and develop a management plan when necessary

iv. All *Conflicts of Interest* related to *Research* shall be reviewed and *Managed* by the same *Conflicts of Interest* standards and procedures described here, regardless of funding status or funding source (Federal, State or other)

b) *Senior Administrators* may request that the *Conflict of Interest Committee (COIC)* review *Disclosure* statements and make recommendations on the determination of and/or management of any *Conflicts of Interest*

3. Subrecipient Responsibilities
   Subrecipients (e.g., subcontractor, sub awardee, consortia) shall agree to terms of compliance and may be required to comply with the policy of the University of Guam as the awardee institution. The Office of Research & Sponsored Programs (ORSP) shall obtain a certification from the subrecipient as to whether the University of Guam's *COI* policy or the subrecipient's institutional *COI* policy will be utilized for compliance.

D. UNIVERSITY CONFILICTS OF INTEREST COMMITTEE
1. Purpose. The UOG *Conflicts of Interest Committee (COIC)* is established to review cases of potential or real *Conflicts of Interest or Commitment.* As appropriate, the COIC will prepare written recommendations for management or elimination of *Conflicts of Interest.*
2. Appointment and Membership. The Deciding Official will consider nominations from the University's Faculty Senate and will appoint 5 members, including a Chair. The *Conflicts of Interest Committee:*
   a) May invite individuals with expertise in special areas to assist in the review process.
   b) May include qualified members not employed at the University, should community membership be considered appropriate or necessary.
   c) May confidentially consult with administrators, faculty, and others involved in the Research or administrative matter, the academic discipline in question, or the nature of administrative decision- making in question in order to make a fully informed recommendation.
   d) When University faculty Conflicts of Interest issues are referred to the COIC, committee members assigned will hail predominantly from the University faculty and staff, with the intention of conducting a peer-review evaluation.
3. Responsibility. The *COIC* transmits a report to the *Deciding Official* to make recommendations regarding the following: the disposition of cases involving potential *Conflicts of Interest*, determination as to whether real or potential conflicts exist; how such conflicts should be eliminated, reduced, or *Managed*, and the progress of cases being *Managed*. In some instances, the Committee may decide that a case would be more appropriately referred to the *Deciding Official*, or the Vice Provost for Research and Sponsored Programs.

The *COIC* shall provide the *Employee* with an opportunity to respond to the issues raised in the course of such review. Any such responses will be appended to the Committee's report for review by the *Deciding Official*

4. Confidentiality. The proceedings of the *COIC* including all documents, drafts, and discussions will be kept confidential to the extent possible.

E. CONFLICT RESOLUTION – INDIVIDUAL CONFLICTS OF INTEREST
1. The *COIC* will review cases referred by *Senior Administrators* and determine the appropriate action for conflict resolution. The *COIC* may require a management plan that includes the following:
   a) Description of the potential conflict.
   b) Delineation of criteria that may lead to risk.
   c) Justification for proceeding with management (vs. eliminating the conflict).
   d) Management strategies addressing each of these criteria and the requirements for plan modifications.
2. Conditions or restrictions that may be imposed to *Manage*, reduce, or eliminate *Conflicts of Interest* include, but are not limited to the following:
   a) Public *Disclosure* of the *COI* on the ORSP web site, and additionally may include *Disclosures.*
      i. In all relevant publications and presentations.
      ii. To the appropriate co-*Investigators*, members of the laboratory or *Research* group, students or trainees.
      iii. On *Human Research Subjects (CHRS/IRB)* consent forms. In addition, the appropriate Institutional Review Board (IRB) for *Human Research Subjects* may consult the *COIC* to review *Investigator* Financial Interest *Disclosures* and determine an appropriate management plan when necessary
   b) Monitoring of *Research* by the *COIC* and the *Office of Research & Sponsored Programs*, which may include measures such as:
      i. Reviewing of notebooks, publications, and presentations for accurate *Disclosure* and/or data integrity.
      ii. Meeting regularly with the PD/PI of the *Research* project and the scientific collaborators as well as the responsible department chair.
      iii. Reporting to the *Deciding Official*, at least annually with respect to the management of conflicts.
      iv. Reporting any significant concerns to the *Deciding Official*, immediately, including recommendations for revisions to the management plan or any mitigation concerns.
   c) Modification of the *Research* plan of a *Research* project as originally conceived.
   d) Prohibition from contributing to any *Research* activity that could be influenced because of *Significant Financial Interests*. For example, the *Investigator* may be prohibited from serving as the *PD/PI*, analyzing data, determining whether potential subjects are eligible for enrollment, or soliciting consent.
   e) Divestiture of *Significant Financial Interests*; i.e., allow work to progress contingent upon the sale or disposal of specified financial interests.
   f) Severance of relationships that create conflicts; e.g., relinquishing a seat on a board of an outside *Entity.*
   g) Exception——*Compelling Circumstances*; i.e., facts that convince the *Conflicts of Interest Committee* that an *Investigator*/individual is uniquely positioned and should be permitted to participate in a specific project, activity, or clinical trial under appropriate management despite a *Significant Financial Interest.*

i. The *COIC* may also advise that the potential for significant scientific progress, important technology transfer, and benefits to society or public health and welfare outweigh concerns over *Significant Financial Interests.* In such a case, the *Deciding Official* will make a final determination.

F. Approval and Execution of Conflict Management Plan. When the *COIC* recommends a *Conflict of Interest* management plan, it is to be reviewed and approved by the *Deciding Official* before implementation.

G. Sanctions. Allegations of violations of the UOG Research Policy IX: "Guidelines for Completing Annual Conflicts of Interest" may be forwarded to the Office of Research & Sponsored Programs, which will investigate the circumstances and take appropriate action.
   1. The failure of an *Employee* to disclose a personal *COI*; failure or refusal to respond to requests for additional information; providing incomplete, misleading, or knowingly inaccurate information; failure to comply with directives from the *Deciding Official*; failure to cooperate with appointed project monitoring persons; or failure to eliminate a conflict when so directed may be grounds for disciplinary action up to and including termination for cause.
   2. Agreements may be terminated with sub-grantees, sub- recipients, contractors, or collaborators (e.g., consortia) who either fail to file a complete *Disclosure* or fail to comply with directives of the UOG Research Policy IX: "Guidelines for Completing Annual Conflicts of Interest".
   3. In addition, the University is required to report to Federal sponsors any violation of Federal *Conflicts of Interest* regulations.

H. COI Inquiries. Questions or concerns related to potential COI should be brought to the Office of Research & Sponsored Programs, Compliance section, preferably in writing. Questions or concerns may be raised anonymously. Confidentiality will be maintained to the greatest extent possible.

I. Conflicts for Committee Members. A Committee member shall not participate in the evaluation of a case when the following conditions apply:
   1. The *COIC* member has a personal interest because of personal or professional relationships, such as collaboration with the individual whose case is under consideration.
   2. Then *COIC* member has a financial interest in the case under discussion.

J. The *COIC* may make exceptions to the above by majority vote.

K. CONFLICT RESOLUTION – INSTITUTIONAL CONFLICTS OF INTEREST

With respect to *Senior Administrators* and their roles as representatives of the University in initiation and management of interactions with *Entities* outside of the University community, the University will honor the guiding principles and objectives as stated in the UOG Research Policy IX: "Guidelines for Completing Annual Conflicts of Interest", and herein. The procedures to be followed in addressing possible *Institutional Conflicts of Interest* are the same as when considering the activities of individual faculty, *Investigators*, and staff, but some differences may apply.

Like all other *Employees*, *Senior Administrators* must file yearly *Conflicts of Interest Disclosures* of personal/individual activity. If *Senior Administrators* disclose an activity or interest as a representative, or on behalf, of the University, then these *Disclosures* must be reviewed by the Administrator's supervisor and/or referred to the *Deciding Official*. If determined that the activity or interest could potentially give rise to an *Institutional Conflict* and require management or elimination, the *Conflicts of Interest Committee* may be asked to evaluate the *Disclosure* and make recommendations to the *Deciding Official*. In such cases the procedures described in section V. above will apply. By involving the

Conflicts of Interest Committee, representatives of the faculty and the central administration will evaluate the institutional activity and the appropriate University response.

L. CONFLICT RESOLUTION –SCHOLARLY AND SCIENTIFIC CONFLICTS OF INTEREST
A scholar should not allow the potential for personal, financial, or professional gain to influence his or her judgments in reviewing, evaluating, and commenting on the writings of other individuals. Knowledgeable scholars are routinely called upon to conduct peer review of documents and manuscripts that are under consideration for publication or that may be used in facilitating effective decision-making by governmental agencies or businesses, that may be used in deciding whether there will be an award of a contract or grant, or that may be used in arriving at decisions regarding promotion and/or tenure. If a reviewer is in competition with the author(s) of a document under review or has an undisclosed personal bias, then a *Conflict of Interest* exists and must be disclosed to the person or organization requesting the review, or the reviewer must excuse him or herself. Likewise, *Disclosure* must be made by a scholar to the editors of periodicals or other publications who are asked by the scholar to publish his or her unsolicited editorial comments regarding a publication. After *Disclosure*, the decision as to whether to proceed with a review or commentary would be made by the requestor of the review.

If an individual observes what appear to be violations of these expectations in scholarship on the part of a University *Employee*, allegations should be filed with the Research Integrity Officer, following the procedures stated in the UOG Research Policy IX: “Guidelines for Completing Annual Conflicts of Interest”.

M. CONFLICT RESOLUTION – CONFLICTS OF COMMITMENT
For the benefit of the University, *Employees* are expected to commit their work efforts to the tasks specified in their job descriptions.

Faculty are hired to perform teaching, *creative scholarly activity and research, extension and outreach, library services*, and service; however, in that context administrators have a special agreement with the University in that they are allowed to devote one workday per week at their discretion to the pursuit of outside activities that are relevant to the University’s and their own professional interests and faculty are permitted up to 50% FTE overload with Dean/Director approval (Agreement Article VI, E. Faculty Endeavors Beyond a Full Workload). *Conflicts of Commitment* most often arise when the time commitment of a faculty member to outside interests quantitatively exceeds what is expected as a direct commitment to the University and/or qualitatively differs from the interests and functions of the University.

Commitment issues are to be initially addressed by the immediate *Senior Administrator*, communicating directly with the faculty member. This is to be regarded as an administrative matter not requiring involvement of the *COIC* unless there are substantive issues that cannot be resolved.

N. RETROSPECTIVE REVIEWS
When the University discovers a *Conflict of Interest* not disclosed according to the UOG Research Policy IX: “Guidelines for Completing Annual Conflicts of Interest”, it will be reported to the appropriate *Senior Administrator* for evaluation. If determined that there is a need to *Manage*, reduce, or eliminate the conflict, then the matter shall be addressed by the *Senior Administrator* or referred to the *COIC*. The *Deciding Official* will make final decisions

if the *COI* cannot be resolved. The retrospective review and resulting action may be reportable to *Awarding Components.* Retrospective reviews should be completed within 120 days from discovery of the conflict

O. RECORDS RETENTION

All records relevant to issues of *Conflicts of Interest*, including personal *Disclosure* forms, whether or not a conflict exists, will be retained by the University's Human Resources. Records shall be retained for a minimum of three years. For *Disclosure* records related to a funded award, these shall be retained for a minimum of three years after acceptance of the final grant or contract report by the funding *Entity*. If a *Conflict of Interest* matter was addressed, and all requirements were adequately satisfied upon acceptance of the final report, these records will be retained for three years after all conflicts are resolved.

P. TRAINING

It is important that *Senior Administrators* be adequately trained in identifying *Conflicts of Interest*, how to resolve conflicts that are identified, or when to refer a case for evaluation to his or her supervisor. This training may be provided in the form of the Collaborative Institutional Training Initiative's (CITI) online *Conflicts of Interest* educational training modules, or a tutorial provided by the National Institutes of Health**.** In addition, interactive sessions in a classroom or video-conference setting may be provided by the *Office of Research & Sponsored Programs*. These sessions are to be designed for *Senior Administrators* to help them meet their obligations as described in this document. For the rest of the University's *Employees*, the same training may be provided using an interactive session designed to assist *Employees* in understanding and identifying *Conflicts of Interest* and University policy and procedures.

IX. RESEARCH INTEGRITY & MISCONDUCT POLICY

Policy

It is the policy of the University of Guam to foster a research environment that discourages misconduct in all research, research training or research related activities pursued at the University or under the sponsorship of the University. It is also the policy of the University of Guam to pursue the highest standards of research and academic integrity.

Misconduct in research means: fabrications, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the academic and scientific community for proposing, conducting, exhibiting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

Integrity in research means active adherence to the ethical principles and professional standards essential for the responsible practice of research. These practices include: honesty and fairness in proposing, performing, and reporting research; accuracy and fairness in representing contributions to research proposals and reports; proficiency and fairness in peer review; collegiality in scientific interactions, communications and sharing of resources; disclosure of conflicts of interest; protection of human subjects in the conduct of research; humane care of animals in the conduct of research; and adherence to the mutual responsibilities of mentors and trainees.

In the event of allegations of such misconduct, it is the policy of the University to: (1) initiate a preliminary inquiry into such allegations; (2) conduct an investigation, if warranted; and (3) impose appropriate sanctions, which may include initiation of adverse action procedures, if warranted; and, if appropriate, to report to the federal Office of Scientific Integrity (OSI), a component of the Office of the Director of the National Institutes for Health, or to the Office of the Inspector General (OIG) of the National Science Foundation.

These actions will be undertaken in accordance with 42 CFR Part 93, and 45 CFR Part 689 following procedures and with due consideration to the rights and reputation of the accuser and accused, A finding of research misconduct is not, in and of itself, an adverse action. Any adverse action will follow the BOR-Union Agreement process found in Article X.

It is the responsibility of all persons at the University involved in research, research training or related research activities to familiarize themselves with these policies and procedures. Copies of 42 CFR Part 93, and 45 CFR Part 689 are available online.

Acts of retaliation against those who, in good faith, make allegations of misconduct shall be investigated on their own merit. Allegations that are determined to have been made in bad faith shall be deemed to be misconduct in research. In the interest of protecting the reputation and privacy of those who may be involved, it is important that allegations be treated with confidentiality.

Definitions

1. **Adverse action** – can include written censure, reduction in salary, suspension without pay, demotion, denial or curtailment of emeritus status and/or dismissal. For student discipline, can include probation, delay of graduation, or revocation of degree. A finding of research misconduct under this policy does not constitute adverse action.
2. **Allegation** – a report of possible research misconduct through any means of

communication to the RIO.

3. **Cognizant Federal Sponsor or Federal sponsor** – the federal sponsoring agency of the research project, for example, PHS, NIH, NSF, DOE, NASA, DOD and FDA.
4. **Conflict of interest** – the real or apparent interference of one person's interests with the interests of another, where potential bias may occur due to prior or existing personal, professional, or economic relationships.
5. **Deciding official** – the Senior Vice President & Provost or designee. The Deciding Official will not be the same individual as the RIO and should have no direct prior involvement in the preliminary assessment, inquiry, or investigation.
6. **Employee** – any person paid by, under the control of, or affiliated with the University of Guam. For the purpose of this policy, "employee" also includes independent contractors and guest researchers.
7. **Experts** – may be appointed or carried over from the inquiry to advise the committee on scientific or other issues.
8. **Fabrication** – making up data or results and recording or reporting them.
9. **Falsification** – 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.
10. **Good faith allegation** – an allegation made with the honest belief that research misconduct may have occurred.
11. **Immediate health hazard** – a condition that exists or has the potential to exist which should be abated or corrected immediately to prevent imminent or ongoing danger of serious damage to human or animal health or the environment.
12. **Investigation** – the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.
13. **Legal Counsel** – the UOG legal counsel is responsible for advising the RIO, the investigation committee, and the Deciding Official on relevant legal issues. Legal Counsel does not represent the Respondent, the Reporter or any other person participating during the assessment, inquiry, investigation, or any follow-up action, except the officials responsible for managing or conducting the research misconduct process as part of their official duties.
14. **Office of Research Integrity (ORI)** – the Federal agency responsible for overseeing and investigating research integrity and misconduct issues as they relate to federally funded research.
15. **Official** – RIO or Deciding Official.
16. **Plagiarism** – the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
17. **Remedial action** – actions necessary to protect research funds. These actions are not disciplinary but are intended to ensure the appropriate expenditure of research funds and to protect the integrity of the research.
18. **Reporter** – anyone who makes an allegation of research misconduct.
19. **Research** – a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
20. **Research Integrity Officer (RIO)** – the Vice Provost of Research and Sponsored Programs or the person delegated this responsibility.

21. **Research misconduct** – fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. It does not include honest error, differences of opinion, or authorship disputes.
22. **Research record** – the physical and/or electronic record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles and any documents and materials provided to the United States Department of Health and Human Services (DHHS) or a University official by a Respondent in the course of a research misconduct proceeding.
23. **Respondent** – the person(s) against whom an allegation of research misconduct is directed or the subject(s) of a preliminary assessment, inquiry or investigation.

Requirements

Time limits
Federal law imposes specific time limits upon many of the steps described below including:
- Complete inquiry process within 60 days of the first meeting of the inquiry committee unless a delay is clearly warranted.
- Initiate investigation within 30 days of completion of inquiry if investigation is indicated.
- Submit investigation report to the federal sponsor within 120 days of initiation of investigation.

This policy applies only to research misconduct occurring within six years preceding the date an allegation of research misconduct is received. The exceptions to the six-year statute of limitations are as follows:
- If, for the potential benefit of the Respondent, the Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitations period through the citation, republication or other use of the research record that is alleged to have been fabricated, falsified or plagiarized.
- The alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

Evidentiary standards
The University has the burden of proving research misconduct.

Standard of proof
A finding of research misconduct must be established by a preponderance of the evidence, which means that the evidence demonstrates that it is more likely than not that the Respondent committed research misconduct as defined in this policy.

A finding of research misconduct requires:
- A significant departure from accepted practices of the relevant research community; and
- The misconduct is committed intentionally, knowingly or recklessly.

The destruction, absence of, or Respondent's failure to provide research records documenting the questioned research may be considered evidence of research misconduct where the preponderance of the evidence establishes the Respondent intentionally, knowingly or recklessly had research records and destroyed them, had the opportunity to maintain the

records but failed to do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

For purposes of this policy, misconduct is committed recklessly when an individual makes a false, fabricated or plagiarized representation with callous disregard as to whether or not it is true or requires attribution to another. Such callous disregard can be demonstrated by evidence that shows the representation is:

- In fact, false, misleading, or plagiarized; and
- The individual had a high degree of awareness of the probable falsity or misleading nature or source of the representation or in fact entertained serious doubts as to the truth of the representation. This subjective awareness of the falsity or misleading nature of a representation can be inferred from evidence indicating that there were obvious reasons to doubt the accuracy of the representation and the individual did not act reasonably in dispelling those doubts.

General Rights and Responsibilities

Duty to report misconduct

All employees or individuals associated with UOG should report, either in writing or orally, observed, suspected or apparent misconduct in research to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may discuss the suspected misconduct with the RIO informally.

At any time, an employee or individual may have confidential discussions and consultations about concerns of possible research misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

If the RIO receives any allegations of misconduct that do not meet the definition of research misconduct, the RIO will refer the reporting individual or the allegation to the appropriate office or administrator for further handling. When a report of research misconduct also contains allegations of other misconduct that does not meet the definition of research misconduct, the allegations will be severed and handled separately.

Duty to cooperate

Employees shall cooperate with the RIO or other individuals delegated responsibility in the review of research misconduct allegations and the conduct of preliminary assessments, inquiries, and investigations. Employees shall provide relevant evidence to the RIO or other officials responsible for reviewing an allegation of research misconduct.

Protection from retaliation

Employees who receive or learn of an allegation of research misconduct will treat the Reporter who makes a good faith allegation of research misconduct and others involved in the preliminary assessment, inquiry or investigation of research misconduct who act in good faith with fairness and respect. The RIO will take reasonable steps to protect the position and reputation of such individuals and protect them against retaliation. Employees shall immediately report any alleged or apparent retaliation to the RIO, who will review instances of alleged retaliation for appropriate action.

Confidentiality
The RIO will take all reasonable steps to protect the confidentiality of the preliminary assessment, inquiry and investigation process and to protect the identities of those who participate in these processes. If a Reporter requests anonymity, an effort will be made to honor the request during the preliminary assessment or inquiry to the greatest extent possible and in compliance with applicable policies, regulations, and federal, state and local laws. The Reporter will be advised that if the matter is referred to an investigation committee and the Reporter's testimony is required, anonymity may no longer be guaranteed.

Employees who make, receive, or learn of an allegation of research misconduct will protect, to the greatest extent possible, the confidentiality of information regarding the Reporter, the Respondent and other affected individuals. The RIO may establish reasonable conditions to ensure the confidentiality of such information.

Restoration of Reputation
If neither UOG nor the Federal Sponsor finds research misconduct, and if requested by the Respondent, the University will work with the Respondent to develop a plan to undertake reasonable and practical efforts to protect or restore the Respondent's reputation. Similar efforts will be employed when requested and when necessary to protect or restore the reputation of a Reporter, witness and/or committee member.

Duties and Responsibilities of Officials

Research Integrity Officer (RIO)
The RIO, also known as the Vice Provost of Research and Sponsored Programs or the person delegated this responsibility, in addition to the rights and responsibilities set forth above, the RIO is responsible for:

- Implementation of the procedures set forth in this policy and for ensuring that any preliminary assessment or investigation is conducted in a fair, timely, objective, thorough and competent manner.
- With the Vice Provost for Academic Excellence, Graduate Studies & Online Learning, form the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured, if needed, to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation.
- Providing the Respondent with written notification regarding the inquiry within seven days of the decision to conduct an inquiry.
- Taking reasonable precautions to ensure that the individual(s) who conduct(s) the inquiry or investigation is/are unbiased and free of any conflict of interest.
- Assisting the inquiry and investigation committees and other involved personnel in complying with these procedures and with applicable standards imposed by government or external funding sources.
- Serving as the recorder of the record during research misconduct proceedings, maintaining files of all relevant documents and evidence, and maintaining the confidentiality and the security of the files.
- Reviewing the preliminary assessment, inquiry and investigation reports and delivering the reports to the Deciding Official.
- Reporting any allegation not made in good faith to the Deciding Official for appropriate action.

- Communicating with Federal and non-Federal Sponsors as required by federal law and this policy.

The RIO's role may be delegated to one of the remaining vice provosts.

Reporter
In addition to the rights and responsibilities set forth above, the Reporter is responsible for making allegations in good faith.

The Reporter is entitled to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to receive information about the results of the inquiry and investigation, and to be protected from retaliation. Also, if the RIO has determined that the Reporter may be able to provide pertinent information on any portions of the draft report, these portions will be given to the Reporter for comment. The reports may be redacted as deemed necessary to protect confidentiality and to prevent the Reporter from accessing information not pertinent to his/her participation in the review of the allegation.

If the Reporter is a person charged with oversight of some aspect of the research integrity process, he or she should not participate in the inquiry or investigation of the issue other than to provide relevant information to the RIO and inquiry or investigation committees. In the event that the Reporter who is charged with oversight responsibilities has pertinent work products or information predating the allegation, that material may be reviewed by the individuals and/or committees charged with reviewing the allegation.

Respondent
In addition to the rights and responsibilities set forth above, the Respondent is entitled to:
- Receive written notification regarding the opening of an inquiry or investigation and the final determinations and resulting actions.
- The opportunity to challenge the membership of the committee and experts based on bias or conflict of interest.
- The opportunity to be interviewed by and present evidence to the inquiry and investigation committees.
- The opportunity to receive information about the results of an inquiry or investigation, to review the draft inquiry and investigation reports, and to provide written comments regarding the reports.
- Retain and consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and bring the counsel or personal adviser to represent him/her during interviews or meetings regarding the allegation.

Deciding Official
In addition to the rights and responsibilities set forth above, the Deciding Official is responsible for:
- Receiving the inquiry report and any written comments made by the Respondent and/or the Reporter to the draft report, consulting with the RIO or other appropriate individuals, and determining whether to conduct an investigation.
- Receiving the investigation report and any written comments made by the Respondent and/or the Reporter on the draft report, consulting with the RIO or other appropriate individuals, and determining whether research misconduct occurred.

- Notifying the Respondent of the finding(s) of an investigation.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she may take any remedial actions which are deemed necessary to protect research funding and integrity. These remedial actions may include:

- Notifying publishers of the findings so that publishers may withdraw or correct all pending or published abstracts and papers emanating from the research where research misconduct was found.
- Coordinating with Dean/Directors and the project/grant Principal Investigator (if applicable) to redirect University funds by removing the Respondent from the particular project, and to institute mechanisms for special monitoring of future work.

If research misconduct is found, the Deciding Official will inform the President who will then notify the appropriate office responsible for discipline or administrative action pursuant to the appropriate policies and procedures.

Securing Pertinent Records

Pertinent research records should be secured before or at the time the Respondent is notified that an investigation has begun. The need for records may occur for any number of reasons.

Immediate securing of records

If the relevant research records have not been obtained at the assessment stage, the Investigation Committee Chair will immediately locate, collect, inventory and secure them to prevent the loss, alteration or fraudulent creation of records.

Institutional access

Employees cannot interfere with UOG's right of access to research records produced under federal grants and cooperative agreements. Under contracts, certain research records may belong to federal sponsors, but UOG will be provided access to contract records in the custody of UOG for purposes of reviewing research misconduct allegations.

Original records

The documents and materials to be secured will include all the original items (or copies if originals cannot be located) that may be relevant to the allegations. These include, but are not limited to, research records as defined in this policy.

Securing records from the Respondent

The RIO should notify the Respondent that an inquiry is being initiated simultaneously with the securing of records so that the Respondent can assist with location and identification of the research records. The RIO should obtain the assistance of the Respondent's supervisor and Campus Counsel in this process, as necessary. If the Respondent is not available, securing of the records may begin in the Respondent's absence.

The Respondent should not be notified in advance of securing of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the Respondent of tampering with or fabricating data or materials after the notification.

In addition to securing records under the control of the Respondent, the RIO may need to secure records from other individuals, such as co-authors, collaborators or Reporters.

A copy of each secured record will be provided, within 10 working days, to the individual from whom the record was taken.

Inventory of the records

A dated receipt and inventory list of what has been taken will be signed by the securing official and the person from whom an item is collected, and a copy of the receipt will be given to the person from whom the record is taken at the time of the securing and taking of the record.

Security and chain of custody

The RIO will lock records and materials in a secure place. Where feasible, the person from whom original records were collected will have access to his or her own original items under the direct and continuous supervision of a UOG official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to University General Counsel.

Notification of the Respondent

The Respondent will be notified as soon as reasonably possible after the determination is made to open an investigation. The notification should include:

- The specific allegations;
- The sources of federal funding;
- The definition of research misconduct;
- The procedures to be followed in the investigation, including the appointment of the Investigation Committee and experts;
- The opportunity for the Respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest and to comment on the draft report;
- Anticipated timelines.

Procedures for Determining Misconduct in Research

The University employs a two-step review process. The first level of review, a preliminary assessment of allegations, will be undertaken by the RIO. The second level of review, if warranted, will be a full investigation.

Step 1 — Preliminary assessment of allegations

The RIO will initiate a preliminary assessment of allegations. The accused party will have an opportunity to respond to the charges during the inquiry, as specified in procedures. The preliminary inquiry will be performed by Vice Provosts to review if: (1) evidence presented is accurate; (2) parties have attempted to communicate and resolve the situation informally; (3) the appropriate administrators are aware of the actions; and (4) the situation merits a full misconduct in research investigation. The Vice Provosts will issue a finding to the appropriate parties whether a full investigation will be conducted.

The findings of a preliminary assessment are not an adverse action.

Allegation assessment
Upon receiving an allegation of research misconduct, the RIO will assess the allegation to determine whether there is sufficient evidence to warrant an investigation, whether federal support or federal applications for funding are involved, and whether the allegation falls under the definition of research misconduct. The RIO may consult with others whom the RIO determines have the appropriate technical expertise. Before proceeding to an inquiry, the RIO will consult with scientific peers who have the appropriate technical expertise to determine whether or not the allegation falls under the definition of research misconduct.

Sufficient evidence to proceed
There is not always sufficient evidence or information to permit further inquiry into an allegation. For example, an allegation that a scientist's work should be subjected to general examination for possible research misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, an effort should be made to obtain more information before initiating an investigation. This information may be sought from any reasonable source, including the Reporter, if known.

Referral of other issues
Regardless of whether it is determined that a research misconduct investigation is warranted, if the allegation involves federal support and concerns possible failure to protect human or animal subjects, financial malfeasance or criminal activity, the allegation should be referred to the appropriate Federal Sponsor.

Additional allegations received during the inquiry or investigation
When allegations of research misconduct are received during the investigation that were not previously evaluated during the preliminary assessment, the RIO will determine if the allegations should be reviewed as part of the inquiry or investigation, or whether a separate preliminary assessment must be conducted.

Leave
When the Respondent is an academic employee, the President may impose an involuntary or administrative leave with pay on the Respondent, pending the completion of the inquiry and/or investigation pursuant to this policy, and/or applicable disciplinary procedures, if such action is appropriate according to the applicable academic personnel or administrative policies. The President shall immediately give the Respondent written notice of the interim leave, specifying the rule or rules allegedly violated.

Termination of employment or resignation prior to completing inquiry or investigation
The termination of the Respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct procedures. If the Respondent, without admitting to the research misconduct, elects to resign his/her position prior to the initiation of an investigation but after an allegation has been reported, or during an inquiry or investigation, the investigation will proceed. If the Respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

Step 2 — Formal Investigation

Decision not to conduct investigation
If the Deciding Official determines that an investigation is not warranted, ORI and the Federal Sponsor will generally not receive notification. However, the RIO will provide ORI and/or the Federal Sponsor with a copy of the preliminary assessment upon request.

If ORI or a Federal Sponsor that has been informed of a decision not to proceed with an investigation is performing an oversight review of the determination not to proceed to an investigation, the RIO, if so requested, will provide ORI or the Federal Sponsor with the assessment file including, but not limited to, secured evidence, analyses, and transcripts of interviews. The RIO will keep all records secure until ORI or the Federal Sponsor makes its final decision on its oversight of the inquiry.

Decision to conduct investigation
If the Deciding Official decides to initiate an investigation, and the situation merits, the RIO will provide ORI and/or the Director of the Cognizant Federal Sponsor with written notification on or before the date the investigation begins. At a minimum, the notification will include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the definition of research misconduct and the Federal Sponsor applications or grant number(s) involved. The RIO will also provide ORI and/or the Cognizant Federal Sponsor with a copy of the assessment report and the policies and procedures when an investigation is conducted. ORI and/or the Cognizant Federal Sponsor will be notified of the final outcome of the investigation and will be provided with a copy of the investigation report. Any significant variations from the provisions of this policy will be explained in any reports submitted to ORI and/or the Federal Sponsor.

The Vice Provost of Research and Sponsored Programs with the Vice Provost for Academic Excellence, Graduate Studies & Online Learning, (with the Vice Provost for Institutional Effectiveness as an alternate), a representative selected by the Faculty Union President, and a representative selected by the Faculty Senate President will form the core investigation committee. They will identify if additional members of appropriate expertise are needed. They will then carry out a thorough and authoritative evaluation of the relevant evidence in the investigation process. Reasonable steps will be taken to ensure that the members of the committee and the experts have no bias or personal or professional conflicts of interest with the Respondent, Reporter or the case in question.

Objection by Respondent
The Committee Chair will notify the Respondent of the proposed committee membership within 10 days. If the Respondent submits a written objection to any appointed member of the Investigation Committee or expert based on bias or conflict of interest within 10 days, the Chair will determine whether to replace the challenged member or expert with a qualified substitute.

Confidentiality
Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the Respondent, Reporter, witnesses or anyone not authorized by the Chair to have knowledge of

the investigation.

Closeout of Investigation
Before terminating an investigation for any reason without completing all relevant requirements of this policy, the RIO will submit a report of the planned termination to ORI and/or the Federal Sponsor, including a description of the reasons for the proposed termination. ORI and/or the Federal Sponsor will review the information provided and advise whether a further investigation should be undertaken.

When an admission of research misconduct is made, the RIO will contact ORI and/or the Federal Sponsor for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of research misconduct. When the case involves federal funds, an admission of research misconduct is not an acceptable basis for closing a case or failing to undertake an investigation without prior approval from ORI and/or the Federal Sponsor.

If the investigation cannot be completed in 120 days, the RIO will submit to ORI and/or the Federal Sponsor a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by ORI and/or the Federal Sponsor.

The RIO will report to ORI and/or the Federal Sponsor(s) as required by regulation and keep them apprised of any developments during the course of the investigation that may affect current or potential funding for the individual(s) under investigation or that ORI and/or the Federal Sponsor needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

The RIO will notify ORI and/or the Federal Sponsor at any stage of this process if:
- There is an immediate health hazard involved;
- There is an immediate need to protect Federal funds or equipment;
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is (are) the subject of the allegations as well as his/her co-investigators and associates, if any;
- It is probable that the alleged incident is going to be reported publicly;
- The allegation involves a public health sensitive issue, e.g., a clinical trial;
- There is a reasonable indication of a possible Federal criminal and civil violation. In this instance, ORI and/or the Federal Sponsor must be informed within 24 hours of obtaining that information.

Notifying Non-Federal Sponsors
Non-Federal Sponsors will be informed of investigations and outcomes of research misconduct proceedings based on contractual obligations. The Deciding Official, after consulting appropriate University officials and Faculty Senate President, may inform non-federal sponsors even if notification is not contractually required.

Institutional Review and Decision

Acceptance of investigation report
The Deciding Official will make the final determination whether to accept the investigation report and its findings based on a preponderance of the evidence. If the Deciding Official's determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in a letter transmitting the report to the Federal Sponsor. The Deciding Official's explanation will be consistent with the definition of research misconduct, these policies and procedures, and the evidence reviewed and analyzed by the investigation committee.

Request for further fact finding
The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination together with any revised report prepared by the investigation committee constitutes the final investigation report for purposes of the Federal Sponsor's review.

Notification of final determination
In addition to notifying those persons entitled to notification under this policy, the Deciding Official 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, or other relevant parties should be notified of the outcome of the case.

Administration of Adverse Action

Employment Status
The BOR-Union Contract, the University Policy Manual, Student Handbook, and Interim Rules & Procedures Manual set forth expectations for high standards of ethical behavior for faculty and students, respectively, and provide procedures for administration of discipline. Other relevant procedures for administration of adverse action should be adhered to base on the Respondent's employment status. No adverse action may be imposed other than as provided in applicable policies and procedures regarding disciplinary actions. Specifically, if Respondent is:

- An academic employee, the matter will be referred to the employee's supervisor for review under applicable personnel policies;
- A student, the matter will be referred to Dean of Enrollment Management and Student Success for review under applicable student policies;
- A staff member, the matter will be referred to the Chief Human Resources Officer for review under applicable staff policies.

Appeals
The determination of the Deciding Official with respect to research misconduct shall be binding. The appeal of any disciplinary determination shall be handled in accordance with the applicable academic or staff personnel policy or collective bargaining agreement.

Record Retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other

materials furnished to the RIO or investigation committees. The RIO will keep the file for at least seven (7) years after completion of the case.

X. INTELLECTUAL PROPERTY POLICY

A. Purpose

The University of Guam (UOG) fosters the development of Intellectual Property as well as the unrestricted dissemination of research activities. UOG works actively to ensure that its academic community may freely publish the results of scholarly research. In conformance with this principle, all concerned shall cooperate so that essential rights to Intellectual Property shall not be lost.

UOG recognizes that the three primary missions of an educational institution are teaching, research, and public service. UOG further recognizes that, in the course of performing its mission, patentable inventions and copyrightable products will be developed under its auspices. UOG encourages such innovation and will take appropriate steps to aid Creators and to ensure that the public receives the benefit of such innovation in accordance with its public service mission. Appropriate steps include securing research support, identifying and encouraging disclosure of the Intellectual Property, securing appropriate protections, marketing Intellectual Property through licensing and other arrangements, and managing royalties and other related income, such as litigation proceeds. These activities are undertaken in a spirit of cooperation with governmental agencies and private industry as part of UOG's contribution to the economic well-being of the island and surrounding region.

All Net Proceeds realized from the commercialization or other monetization of UOG Intellectual Property, after payment of the Creator's share as defined in *Section (E)* of this Policy and other appropriate costs associated with the evaluation, marketing, development, protection, maintenance, or enforcement of Intellectual Property, shall be used for the support of UOG research programs in a manner consistent with the *Bayh-Dole Act* and its implementing regulations. Net Proceeds shall be applied in a manner consistent with Intellectual Property Procedures. Upon the request of a Creator, UOG shall provide an accounting of the distribution of royalties earned from Intellectual Property of the Creator.

B. Definitions

1. **Affiliate** – For purposes of this Policy, Affiliates include The Research Corporation of the University of Guam, all campus auxiliary units, and all campus foundations.

2. **Created** – Having conceived, researched, authored, reduced to practice, designed, developed, or otherwise having contributed to the making of Intellectual Property.

3. **Creative and Course Content** – Academic course content and materials Created by Personnel including, but not limited to these examples of Intellectual Property: syllabi, course materials and textbooks; other scholarly or creative works of authorship; instructional, dramatic, musical, and artistic works; and manuscripts, articles, poetry, prose, short stories, digital shorts, novels, plays, screenplay.

4. **Creative Content of Grants and Grant Proposals** – The research agendas, applications, proposals, protocols, and/or results of grant proposals submitted and/or awarded.

5. **Creator** – One who has Created Intellectual Property, in whole or in part.

6. **Incidental Use of UOG Resources** ("Incidental Use") – Any use of publicly or routinely-available UOG resources, such as residence halls, common areas, meeting rooms, Research & Education Centers, laboratories, cafeterias, gymnasiums, libraries, office spaces, furnishings, office supplies, photocopiers, telephones, fax machines and other standard office equipment, personal-type computers, and commercially available software in use on such computers, computer and communications networks, including internet access and data storage, that is nonessential to the creation of Intellectual Property, and any use of UOG resources by a Student in accordance with assigned coursework pursuant to that Student's academic curriculum.

7. **Intellectual Property** – Copyrightable Creative and Course Content and Patentable Inventions such as: tangible research materials, computer software, and any unique or novel innovation in the technical arts or any new and useful improvements thereof, including methods or processes for creating an object or result (a way of doing or making things), machines, devices, products of manufacture, product designs, or composition, layout designs for printed circuit boards or integrated circuits, compositions of matter, materials, any variety of plant, and any know-how essential to the practice or enablement of such innovations and improvements, whether or not patentable or patented.

8. **Intellectual Property Procedures** – A set of guidelines for interpreting and following the Intellectual Property Policy. A supplement to the policy, this document is provided to personnel and students and maintained by the Office of Research and Sponsored Programs. The procedures are periodically reviewed and revised by the Research Council or other duly appointed committee, under the authority of the President.

9. **Inventor** – One who contributes to the conception of a Patentable Invention under the patent laws of the United States or other relevant jurisdiction.

10. **Net Royalty** – Royalty less reasonable expenses incurred by UOG and not reimbursed by licensees for the evaluation, marketing, development, protection, maintenance, and enforcement of the subject Intellectual Property.

11. **Partner** – Any entity or individual who is neither Personnel nor Student, who engages with UOG or a UOG Affiliate through a contract or other business transaction that facilitates the research, teaching, or public service missions of UOG.

12. **Patentable Invention** – Any art or process (way of doing or making things), machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States or other relevant jurisdiction, and the patent applications or patents that embody them.

13. **Personnel** – All full-time and part-time employees of UOG and UOG Affiliates, Student employees (including, but not limited to, research assistants/associates, teaching assistants, extension assistants/associates, fellows, post-doctoral scholars, and Students providing services under sponsor agreements), and other persons holding any paid appointment or position with UOG. Contract Employees are not Personnel in this case.

14. **Royalty** – Cash, equity, or other value received by UOG as consideration for use of rights to UOG Intellectual Property.

15. **Students** – Individuals enrolled in UOG, including, but not limited to, continuing education, undergraduate, graduate, and professional students, non-degree students, and not-for-credit students.

16. **Substantial Use of UOG Resources** ("Substantial Use") – Any use of UOG resources that is more than Incidental Use, including, but not limited to, use of: financial support, funds and grants administered by UOG or a UOG Affiliate; inter-institutional collaborations facilitated by UOG; equipment, facilities, services, laboratories, or space; computers and computer or communications networks not publicly or routinely-available; research, clinical, or other scientific instruments; time spent by Personnel, including secretarial, clerical, administrative staff, and research/extension assistants/associates and teaching assistants; confidential information; Inventions and other proprietary or intellectual property owned by UOG; and any privileged access as a result of a person's affiliation with UOG.

17. **The University of Guam** ("UOG") – References to "UOG" in this Policy may include Affiliates where appropriate under the contexts, whether or not specifically stated. In addition, at the request of UOG, UOG Ownership of Intellectual Property, *Section (E)1* of this Policy, may include ownership, management, promotion, licensing and other transfers, commercialization, and monetization of certain Intellectual Property by the Research Corporation of the University of Guam.

C. **Scope**

1. This Policy applies to Intellectual Property Created, in whole or in part, by UOG Personnel, Students, Affiliates, and Partners using UOG resources.

2. This Policy sets forth the rights and responsibilities of UOG and UOG Personnel, Students, Partners, and Affiliates in the development, creation, ownership, protection, maintenance, dissemination, marketing, licensing, and monetization of Intellectual Property.

3. Copyrightable products are covered in *Section (I)* of this policy.

D. **Ownership of Intellectual Property**

1. UOG Ownership: Subject to the exceptions of *Section (D)2* of this Policy, UOG shall own, and Creator shall promptly disclose and assign to UOG, Intellectual Property Created, in whole or in part:
    a. Within the scope of the Creator's employment by UOG; or
    b. Through the Substantial Use of UOG Resources, unless otherwise agreed upon in writing prior to the undertaking of the project.

2. Creator Ownership: Ownership rights to Creative and Course Content shall be governed by *Section (I)* of this Policy. A 'creator' who is personnel, may retain ownership rights to Intellectual Property that is not Creative and Course Content if:
    a. The Intellectual Property was Created exclusively outside the scope of the Creator's employment by UOG; and
    b. The Intellectual Property was Created through no more than Incidental Use of

UOG Resources; and

c. Creators of Intellectual Property satisfying *Section (D)2. a* and *Section (D)2.b* [above] shall submit a disclosure form as prescribed in UOG's Intellectual Property Procedures.

Student Ownership: A Creator who is a student, and not also Personnel, may retain ownership rights to Intellectual Property Created through no more than Incidental Use of UOG resources, subject to those restrictions that may be required by an external sponsor, if any. A Student shall own the copyright to his or her thesis unless an agreement supporting the underlying work specifies otherwise. Under all circumstances, UOG shall have an unrestricted royalty-free license to reproduce and disseminate Student theses.

For Students who conduct a thesis project that is tied to a faculty member's ongoing research/outreach (through a grant, funded project, or institutional grant or contract) authorship of publications generated as a result of this research/outreach may be subject to institutional and Principal Investigator (PI) prerogative as well as conditions established by funding agency/agencies. Any thesis project that is supported fully, or in part, by institutional and or federal funds is subject to joint authorship and other conditions. Prior to embarking upon a thesis that is fully, or in part, funded by UOG and or federal grant funds, considerations regarding authorship and other conditions must be agreed upon in writing by the Office of Research and Sponsored Programs, the PI/Thesis Chair, Dean, and the student.

Students are strongly encouraged to publish their thesis research. However, there may be occasions when a student who conducts independent research, without any funding from UOG or through federal funds, is not interested in publishing their own research findings. In this case, a student may, in writing, grant permission to their faculty chair and/or other committee member(s) to publish findings from the research project/thesis. The resulting publication(s) must acknowledge the student.

Partner Ownership: Where UOG intends that a Partner engage in Substantial Use of UOG Resources, the ownership of Intellectual Property Created by, or for the Partner, in connection with the use or sponsorship of UOG Resources, shall be formalized in a written agreement between the Partner and UOG or an Affiliate prior to commencement of the project.

Joint Ownership: Intellectual Property may be subject to exercise of ownership rights by two (2) or more parties, including UOG Affiliates, Personnel, Students, and Partners, in which case joint ownership, may be appropriate.

Questions as to Ownership: Where any dispute is raised as to ownership of Intellectual Property, patents, or patent applications under these provisions, the matter shall be referred to the Innovation Policy Board in a manner consistent with UOG's Intellectual Property Procedures.

E. **Royalty Income**

1. Patentable Inventions: With respect to any Patentable Invention obtained by, or through, UOG or assigned to or as directed by UOG in accordance with the foregoing provisions, UOG, in recognition of the meritorious services of the Inventor and in consideration of the Inventor's assignment of the Patentable Invention to UOG, will

make provision entitling the Inventor and the Inventor's heirs or legatees to share in the proceeds from the management and licensing of such Patentable Invention to the extent of forty-five percent (45%) of the first $100,000 of Net Royalty received by UOG and forty percent (40%) of Net Royalty thereafter, unless the Inventor and UOG agree otherwise in a written and duly executed instrument, or if these amounts exceed the limits fixed by applicable regulations of the relevant sponsoring agency; which will control in such cases.

2. Computer Software and Intellectual Property Other Than Patentable Inventions: With respect to any Intellectual Property that is not a Patentable Invention, including Computer Software that is not a Patentable Invention nor subject to copyright, Created in the performance of academic or research/outreach activities and obtained by, or through, UOG or assigned to or as directed by UOG in accordance with the foregoing provisions, UOG, in recognition of the meritorious services of the Creator and in consideration of the Creator's assignment to UOG, will make provision entitling the Creator and the Creator's heirs or legatees to share in the proceeds from UOG's management and licensing to the extent of forty-five percent (45%) of the first $100,000 of Net Royalty received by UOG and forty percent (40%) of Net Royalty thereafter, unless:

    a. The Intellectual Property is a work for hire or subject to a conflicting obligation to a sponsor or a Partner; or
    b. The Creator and UOG agree otherwise in a written and duly executed instrument; or
    c. This distribution amount exceeds limits fixed by applicable regulations of the relevant sponsoring agency; sponsoring agency regulations will take precedent in such cases.

F. **Release and Waiver**

1. UOG shall make decisions regarding evaluation, marketing, development, protection, maintenance, or enforcement of Intellectual Property in consultation with the Creator(s). At the Creator's (or Creators') written request, UOG may release its ownership rights to the Intellectual Property to the Creator(s), subject to those restrictions that may be required by an external sponsor, if any.

2. UOG shall make an initial determination regarding whether to retain title to Intellectual Property within one (1) year of UOG's acceptance of the Creator's fully disclosed, assigned, and properly executed disclosure statement. UOG shall proceed with patenting, developing and marketing of the Intellectual Property by UOG as soon as practicable thereafter. If UOG elects not to retain title or fails to make such an election within one (1) year, all of the UOG's rights to the Intellectual Property shall be released upon written request to the Creator, subject to those restrictions that may be required by an external sponsor, if any.

3. For any Intellectual Property so released to its Creator(s), UOG shall receive ten (10) percent of the Net Proceeds (paid) to the Creator(s), in recognition of the contribution of UOG and the people of Guam to the support of the research that resulted in the Intellectual Property. "Net Proceeds" as referenced in this subpart, *Section (F)3,* means income realized by the Creator from commercialization or other monetization of the Intellectual Property, less reasonable costs incurred directly by the Creator for the evaluation, marketing, development, protection, maintenance, or enforcement of

the subject Intellectual Property.

G. **Innovation Policy Board**

1. The UOG President shall establish and appoint an Innovation Policy Board of the University of Guam and designate the chair thereof in accordance with UOG's Intellectual Property Procedures. The Innovation Policy Board shall have full powers of the organization to undertake periodic review of this Policy and to create, revise and enhance guidelines, procedures, and forms to interpret and implement this Policy.

H. **Applicability**

1. Intellectual Property which is fully disclosed and assigned in a properly executed disclosure statement before the effective date of these regulations shall be subject to UOG's prior Intellectual Property Policy.

I. Copyright

1. Title 17 of the U.S. Code on copyrights is the foundation for this section. Where jurisdictional disputes arise, private international law may apply. Copyright may be subject to terms and conditions of external funding agencies and those conditions supersede UOG policy.

2. This section shall apply to all publishable materials, including academic course content and materials, as well as materials created for online delivery using technology adopted by UOG. Creators must not copyright items, in whole or in part, in the public domain or for which there is existing copyright owned by another party.

3. In general, UOG *does not* claim copyright (i.e., the tangible expression) of Intellectual Property defined in *Section (D)2*. This means that Creators of scholarly or creative works may research, craft, publish, reproduce, distribute, perform, and display their works without prior authorization of, or interference by, the University, assuming that any non-UOG use is Incidental and reasonable and does not place an unreasonable burden on UOG resources or the employee's time. Faculty time equivalent to a one-semester load allocation or course release or less would be considered incidental use.

4. UOG *does* claim ownership of said content, as listed above, if a Creator has been paid to produce a specific product, including through "Substantial Use" of UOG resources, unless otherwise stated in writing and approved by the UOG President.

5. Course or other salable materials produced by personnel and commercialized by an outside institution are subject to a 5-percent return to the University on gross sales or as otherwise negotiated with the University. Whenever possible, any commercialization is encouraged via the UOG Press and in-house technologies.

6. The Dean of the respective unit from which the course content or materials arises shall manage intellectual property issues related to this section. The Senior Vice President, or designee, shall serve as the appellate authority.

Intellectual Property Committee

The University of Guam encourages and supports the development of intellectual property. The current *Intellectual Property Policy* was enacted by BOR 18-017. These procedures align with the Policy. The Intellectual Property Committee may conduct revisions to the procedures, subject to the approval of Research Council, Director of Research and Sponsored Programs, Senior Vice President of Academic & Student Affairs, and President.

Purpose
The Intellectual Property Committee (IPC) shall have full powers of the organization to undertake periodic review of Policy and to create, revise and enhance guidelines, procedures, and forms to interpret and implement intellectual property Policy. Where any dispute is raised as to ownership of Intellectual Property, patents, or patent applications under these provisions, the matter shall be referred to the Intellectual Property Committee.

Authority
Intellectual Property Committee is a sub-committee of the Research Council. The Research Council will serve as an advisory body on matters pertaining to University intellectual property, under the management of the Office of Research and Sponsored Programs.

Co-Chairs
- Vice Provost of Research and Sponsored Programs
- Vice Provost for Academic Excellence, Graduate Studies & Online Learning

Membership
- Faculty Senate Vice President
- Chair, Faculty Senate Standing Committee on Faculty Excellence
- Executive Director, RCUOG
- Director, UOG Press
- UOG General Counsel
- Associate Budget and Planning Officer

Procedures
The Intellectual Property Committee will meet at least annually to review IP policy and procedures, and to make recommendations to Research Council before the last meeting of the academic year. The agenda will be set by the co-chairs.

Disclosure
Creators have an obligation to disclose all new intellectual property to the University via their supervisors or directly to the Office of Research and Sponsored Programs. Disclosure is required whenever something unique has been discovered or created that might have commercial value, solve a significant problem, or could be made into a product or service by an industry partner.

This should be done before any presentations of the discovery through publications, poster sessions, conferences, press releases, or other communications – ideally several months before doing so, at the draft manuscript stage – and before talking to any external parties, especially prospective investors.

Disclosure starts a process that could lead to the commercialization of your discovery or creation. This may involve initiating the IP protection process for inventions and working to identify outside development partners. If industry or government funds were used for the research, there may be obligations and reporting requirements to the funding party.

Claims of intellectual property ownership will be disclosed to the Office of Research and Sponsored Programs. The Intellectual Property Disclosure will describe the IP in detail, along with comparisons with alternative or competing solutions. It will list all collaborating sources of support that might be relevant to the ownership of the IP. It will include all necessary information for TLS to determine the intellectual property's ownership and commercialization potential; and with your input to begin pursuing protection, marketing, and commercialization activities, if the decision is made to do so. The Intellectual Property Disclosure will be treated as confidential.

Upon receipt of an IP Disclosure form, ORSP will:

- Check the form to ensure completeness of the submission;
- Email all listed University contributors to the Invention to notify them of the disclosure and to ensure that they are satisfied with the content and accuracy of the submission; and
- Ask the Director to conduct a formal assessment of the disclosure.

Timelines for Response

After the disclosure to the ORSP of the nature of a creation, the Vice Provost shall, within forty-five (45) business days, advise the creator whether the University wishes to take initial steps to register, develop, patent, and market the creation. If the creator agrees, the IPC will be convened.

UOG shall make an initial determination regarding whether to retain title to Intellectual Property within one (1) year of UOG's acceptance of the Creator's fully disclosed, assigned, and properly executed disclosure statement. UOG shall proceed with patenting, developing, and marketing of the Intellectual Property by UOG as soon as practicable thereafter. If UOG elects not to retain title or fails to make such an election within one (1) year, all of UOG's rights to the Intellectual Property shall be released upon written request to the Creator, subject to those restrictions that may be required by an external sponsor, if any.

The University shall be responsible for providing adequate funding, shall provide for the promotional work, and is empowered to enter into negotiations with outside agencies to accomplish this work. If after three years the creator is dissatisfied with or questions the development efforts of the University, he or she may review such dissatisfaction with the IPC. In such cases the IPC shall respond within sixty (60) business days by finding the complaints to be unwarranted, by assuring the creator that corrective steps will be taken or by returning all intellectual property rights to the creator.

Notwithstanding any language to the contrary, the time deadlines set forth above may be expanded by the President for the good of the University.

Campus Net Proceeds

Campus net proceeds shall be applied in a manner consistent with university policies and procedures. Upon the request of a Creator, UOG shall provide an accounting of the distribution of royalties earned from Intellectual Property of the Creator.

Procedures
The Vice Provost of Research and Sponsored Programs will propose the unit and administrator to manage the IP funds, subject to the approval of the Senior Vice President, Vice President of Administration and Finance, and the President.

The managing administrator will establish an account with the university for the intellectual property and ensure that all government laws, university policies and business office procedures are followed correctly.

Net Proceeds will be distributed on an annual (or quarterly) basis from this account.

APPENDIX 1

APPLICATION FOR APPROVAL OF STUDIES INVOLVING VERTEBRATE ANIMALS

UNIVERSITY OF GUAM

Animal Care and Use Committee

Office of the Graduate School and Research

ACUC no.

APPLICATION FOR APPROVAL OF STUDIES INVOLVING VERTEBRATE ANIMALS

PRINCIPAL INVESTIGATOR: _____ DATE: _____

TITLE & DEPARTMENT: _____ PHONE: _____

PROJECT TITLE: _____

PROPOSED SPONSORING AGENCY/COLLEGE: PROJECT START DATE:

_____ _____

Check One:

☐ New Proposal ☐ Old Proposal ☐ Old Proposal without Changes

1.) Summarize your Proposed Research, OUTLINE OBJECTIVES and METHODS. Append proposal abstract and methodology.

_____

_____

_____

List species to be used: _____

Describe the biological characteristics for the species:

_____

List the total number of species to be used each year: _____

List source of animals: _____

Is there a breeding colony for this animal in-house:	☐ Yes	☐ No
Will the animal(s) undergo surgical procedures?	☐ Yes	☐ No
If YES, is anesthesia required?	☐ Yes	☐ No
If YES, who will monitor this procedure?	☐ Yes	☐ No
Will there be a restriction of food or water?	☐ Yes	☐ No
Will there be environmental stress or restraint?	☐ Yes	☐ No

If YES, what, how? _____

_____

_____

Will hazardous or radioactive agents be used in the study ☐ Yes ☐ No

If YES, what precautions have been taken?

Has the study death of the animal(s) as an endpoint? ☐ Yes ☐ No

Will euthanasia of the animal be required by the study? ☐ Yes ☐ No

If YES, which method will be employed?

Are the investigator and other project personnel adequately trained in handling the research animal(s)? ☐ Yes ☐ No

Are there any foreseeable hazards to the animal handler(s): ☐ Yes ☐ No

If YES, what are these hazards?

PLEASE NOTE:

Persons having any nonhuman primates, sheep, dogs or cats, or having 8 hours or more contact with other species should be listed and are required to participate in the University Occupational Health Service Program. Women, pregnant or attempting to conceive, that are exposed to cats should also be listed.

ASSURANCE

The polices and procedures of the University of Guam, AWA and the US PHS apply to all activities involving live vertebrate in this institution. No activities involving the use of these animals animals used for research are to be initiated without prior written approval by the UOG Animal Care and Use Committee (ACUC).

The undersigned is familiar with the AWA and the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the NIH Guide for the Care and Use of Laboratory Animals and the University Guidelines, and agrees to abide by the Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training contained in this document. Any change in the care and use of animals involved in this protocol that would affect their welfare will be promptly forwarded to the ACUC for review. Such changes will not be implemented until the Committee's approval is obtained. Animals will not be transferred between investigators without prior approval.

(Signature of Principal Investigator)
("Per" Signature not acceptable)

Date

APPENDIX 2

UNIVERSITY OF GUAM CONFLICTS OF INTEREST DISCLOSURE FORM

This form must be completed by all employees (defined in Section B.11. of Section IX GUIDELINES FOR COMPLETING ANNUAL CONFLICTS OF INTEREST in the UOG Research Procedures, Regulations, and Policies Manual). Disclosures must be provided:

1. Annually by April 15;
2. Immediately when a new relationship or financial situation arises;
3. When a previous disclosure or conflict status is modified;
4. Within 30 days of new hire or appointment;
5. That exist at the time of filing; and
6. That existed during the previous 12 months;
7. For the employee and members of the employee's immediate family[1].

Part I and Part II (if applicable) must be completed, signed, dated, and given to your supervisor for their review and signature. If assistance is needed Supervisors will forward Part II completions to the Office of Research & Sponsored Programs (ORSP). Please contact ORSP if you have any questions.

PART I - Conflicts of Interest Disclosure Form

Name: _____ Title: _____ Date: _____

Campus: _____ Department: _____

School/College/ Unit: _____

1. Ownership Interests

   Do you or any member(s) of your immediate family own or control any equity interest (e.g., stock, stock options) in an entity[2] that could appear to be related to your institutional responsibilities?

   ☐ YES ☐ NO

2. Offices and Positions

   Are you or any member(s) of your immediate family a director, board member, officer, trustee, partner, employee, agent, or hold any other position for an entity outside the University of Guam that could appear to be related to your institutional responsibilities?

   ☐ YES ☐ NO

3. Remunerative Activities

Do you or any member(s) of your immediate family receive income or compensation for services (e.g., fees, honoraria, loans, gifts, royalty payments, cash or in-kind compensation) that could appear to be related to your institutional responsibilities from any entity outside the University that when aggregated exceeds $5,000.00 per year?

☐ YES ☐ NO

[1]"Immediate family" signifies the employee's spouse, domestic partner, or reciprocal beneficiary and dependent children.

[2]"Entity" signifies any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business, real estate trust, or any other legal body organized for profit or nonprofit purposes.

PART II - Conflicts of Interest Disclosure Form

Detailed statement of Outside Interests and Activities COMPLETE

PART II IF YOU ANSWERED "YES" TO ANY OF THE PART I QUESTIONS.

1. Equity/Ownership Interests

   Provide details of ownership or equity interest for yourself and any member(s) of your immediate family (including stock, stock options, or other securities) in an entity that appears to be related to your institutional responsibilities.

Entity name	**Description of entity**	**Individual holding the interest**	**Amount of annual income/compensation (if when aggregated exceeds $5,000) or ownership percentage**

Do you use UOG resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

2. Associations, Memberships, Positions

Please provide details for any position(s) you or any member of your immediate family hold as director, board member, officer, trustee, partner, employee, agent, or any other position in an entity outside of the University that appears to be related to your institutional responsibilities.

Entity name	**Amount of annual income/ compensation received (if over $5,000)**	**Position, individual holding the interest & description of activity (in detail)**	**Time dedicated to activity (days/month, days/year)**

Do you use UOG resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

3. Remunerative Activities

Provide details of income or compensation you or any member of your immediate family receives (e.g., consulting fees, honoraria, lecture fees, salary, loans, gifts, royalty payments, cash or in kind) from any entity outside the University that appears to be related to your institutional responsibilities and that when aggregated exceeds $5,000 per year.

Entity name	**Amount of annual income/ compensation received (if over $5,000)**	**Individual holding the interest & description of activity (in detail)**	**Time dedicated to activity (day/month, days/year)**

Do you use UOG resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

4. Outside Employment of Students or Staff

   Do you or any member of your immediate family employ or plan to employ any of your students or staff member(s) in an entity outside of the University? **OR** do any students or staff participate in your non- University activities? If so, please describe below:

Entity name	Name of student(s) or staff	Describe activity performed (in detail)	Time dedicated to activity (hrs/day, days/mo.)

5. Sponsored Travel

   Please provide details about travel (for yourself or members of your immediate family) reimbursed or sponsored by an entity NOT considered to be a federal, state, or local government agency, an institution of higher education or affiliated with an institution of higher education [as defined by 20 U.S.C 1001(a)], which appears to be related to your institutional responsibilities.

Entity/Sponsor/ Organizer name	Purpose of trip	Travel destination and duration of trip	Total travel costs

6. Goods and Services

   Please provide details of your or any member of your immediate family's interest(s) in any contract, sale, or other transaction to which the University of Guam or one of its affiliates is a party.

Entity name	Relationship to entity	Individual holding the interest and role in transaction (in detail)	Amount of transaction

7. Other Situations or Facts

   Are there other situations, not listed above, that you believe may create a conflict of interest or commitment? Please describe such situations, including nature, parties, subject matter, income or compensation received.

PART II: SIGNATURE AND CERTIFICATION

By signing this form, I certify the following: 1) I have read and understand the University of Guam Policy and Procedures on Conflicts of Interest and Commitment; 2) the information in this disclosure form is an accurate and complete statement of my outside interests and activities; and 3) I understand my continuing obligation to disclose any change(s) to my significant financial interests and other conflicts of interests that may arise after submission of this form.

Signature: _____ Date: _____

Supervisor's Certification

I certify that the person named above reports to me and I have reviewed this disclosure form. To the best of my knowledge, full disclosure of significant financial and other interests have been reported. I understand that further review may be conducted by other Senior Administrators, ORS, the Conflicts of Interest Committee or the Deciding Official, and a COI management plan may be implemented.

Based on my review of the completed disclosure(s):

Potential conflict(s) of interest exist? ☐

Potential conflict(s) of commitment exist? ☐

If yes, select one:

- ◯ Conflict(s) have been eliminated.
- ◯ No management plan is necessary/no further action required. An
- ◯ appropriate management plan is/will be in place.
- ◯ A management plan will be developed and submitted for review.
- ◯ Additional assistance is requested.

Print Name: _____ Date: _____

Signature: _____

APPENDIX 3

ANNUAL SUMMARY REPORT OF DISCLOSURES OF CONFLICTS OF INTEREST

Each Dean or Director of an academic unit or department, or other Senior Administrator, shall compile an annual report to submit to their respective Vice Provost or Senior Vice President & Provost by June 30 of each year. The report shall include the following:

1. A list of individuals, if any, who did NOT submit the required disclosure form.

2. The number of department/unit faculty, staff, or administrators who were required to submit disclosure forms, AND the number and percentage of those who actually submitted disclosure forms.

3. The number of department/unit faculty, staff, or administrators who completed Part II disclosures.

4. The number and percentage of department/unit faculty, staff, or administrators whose outside interests and activities were found to conflict with their University and/or professional commitments, but for whom conflicts were resolved by the Dean/Director or the Conflicts of Interest Committee.

5. Pertaining to question #4 (above), list the details regarding corrective actions recommended and taken to resolve conflicts.

6. The number and percentage of department/unit faculty, staff, or administrators whose conflicts of interest were not resolved and summarize the recommendations or plan for each unresolved case.

APPENDIX 4

RECOMMENDED INVESTIGATION PROCEDURES for Research Integrity and Research Misconduct Allegations

Purpose of the Investigation

The investigation is to explore in detail the allegations, to examine the evidence in depth and to determine specifically whether misconduct has been committed, by whom and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations.

Investigation Process

The investigation, whether conducted by a committee or an individual, will follow each procedural step set forth below. The investigation must be completed within 120 days from the first Investigation Committee meeting unless an extension of time is obtained. For research funded by federal sponsors, extensions may be granted by ORI or the sponsor for good cause. For all other sponsored research, an extension may be granted by the RIO for good cause.

Charge to the Committee and the First Meeting

Charge to the committee

The Chair will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, define misconduct and identify the name of the Respondent. The charge will state that the committee is to evaluate the evidence and testimony of the Respondent, Reporter, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the misconduct subject matter of the investigation or would suggest additional Respondents, the Chair will determine whether it is necessary to notify the Respondent of the new subject matter or to provide notice to additional Respondents.

The first meeting

The Chair, with the assistance of Legal Counsel, will convene the first meeting of the Investigation Committee to review the charge, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality. The Investigation Committee will be provided with a copy of these instructions and, where federal funding is involved, the applicable federal regulation.

Reviewing the Evidence

The Investigation Committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

Conducting Interviews

Either the Chair or the entire committee may conduct interviews. The interviews should be in-

depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the Respondent and other witnesses.

Preparing for interviews
All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

Objectivity
The Investigation Committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

Transcribing interviews
Any interview with the Respondent, Reporter, or any witness will be transcribed.

Recording admissions
If the Respondent admits to the research misconduct, he or she should be asked to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the Respondent was advised of his or her right to seek the advice of counsel. The committee should consult with General Counsel on the specific form and procedure for obtaining this statement. An admission may be used as evidence in compiling an Investigation Report.

Committee Deliberations

Burden and standard of proof
In reaching a conclusion on whether there was research misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence.

Official Definitions

The committee will consider BOR-approved definitions for research misconduct or research integrity when making determinations.

Sufficient Evidence
The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden, of proving research misconduct by a preponderance of the evidence. The committee will also consider whether the Respondent has presented substantial evidence of honest error or differences in interpretations or judgments of data such that research misconduct cannot be proven by a preponderance of the evidence.

The Investigation Committee Report

The following annotated outline may be used, unless an external sponsor or exceptional

circumstances suggest a different approach.

Background
Include sufficient background information to ensure a full understanding of the issues including those that would concern ORI and/or the Federal Sponsor under the definition of research misconduct. This section should include a chronology of events, detail the facts leading to the inquiry and include a description of the research at issue, the persons involved in the alleged research misconduct and the role of the Reporter.

Allegations
List all the allegations of research misconduct raised by the Reporter and any additional research misconduct allegations that arose during the inquiry and investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a Reporter requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

External Support
For each allegation of misconduct under the definition, identify any application or external support for the research or report (e.g., publication) at issue containing the alleged fabrication, falsification or plagiarism.

Investigation Process
Summarize the investigation process, including the composition of the committee (names, degrees, departmental affiliation, and expertise) and the charge to the committee. List the persons interviewed, how the interview was conducted and by whom, the evidence was secured and reviewed by; and the measures taken to ensure its security, the policies and procedures used, and any other factors that may have influenced the proceedings.

Presentation of Findings
For each allegation, include:

Background
- Describe the matter (e.g., experiment or component of a clinical protocol) in which the alleged research misconduct occurred and why and how the issue came to be under investigation.

Analysis
- The analysis should include all relevant statements, claims (e.g., a claim of a significant positive result in an experiment), rebuttals, documents and other evidence including circumstantial evidence related to the issue. The source of each statement, claim or other evidence should be cited (e.g., laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).
- Any use of additional expert analysis should be noted (forensic, statistical or special analysis of the physical evidence, such as similarity of features or background in contested figures).
- Summarize accurately or quote relevant statements, including rebuttals, made by the Reporter, Respondent and other pertinent witnesses and reference/cite the appropriate sources.

- Summarize each argument that the Respondent raised in his or her defense against the research misconduct allegation and cite the source of each argument. Any inconsistencies among the Respondent's various arguments should be noted.
- The analysis should be consistent with the terms of the definition of research misconduct. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility and persuasiveness.
- Describe any evidence that shows that the Respondent acted with intent, that is, any evidence that the Respondent knowingly engaged in the alleged fabrication, falsification, or plagiarism.
- Describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

Conclusions

- A finding of research misconduct must be supported by a preponderance of the evidence.
- Concisely state the Investigation Committee's finding for each identified issue.
- If the Investigation Committee finds research misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, or plagiarism) and should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the laboratory or project in which the research misconduct occurred.

Recommended Actions

Identify any remedial actions that should be taken to ensure the appropriate expenditure of research funds and to protect the integrity of the research. If applicable, the final investigation report should include any sanctions or disciplinary action undertaken during the inquiry or investigation.

Attachments

Copies of all significant documentary evidence referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, Respondent and Reporter responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments" and a side-by-side comparison that identifies the allegedly false statement, misrepresentation or area of plagiarism with the actual data or material that is alleged to have been falsified/fabricated/plagiarized.

Documenting the Investigative File

Index of evidence

The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

Purpose of documentation

The purpose of the documentation is to substantiate the investigation's findings.

Record retention
After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for seven years after completion of the case to permit later assessment of the case. ORI and/or the Federal Sponsor will be given access to the records upon request.

Comments on the draft report

Respondent
The Chair will provide the Respondent with a copy of the draft Investigation Report for comment and rebuttal. The report may be redacted to protect the privacy of the Reporter or others interviewed during the investigation. The Respondent will be allowed 28 calendar days to review and comment on the draft report. The Respondent's comments will be attached to the final report. The findings of the final report should consider the Respondent's comments in addition to all other evidence.

Reporter
The Chair may provide the Reporter, if he or she is identifiable, with those portions of the draft investigation report that address the Reporter's role and opinions in the investigation.

General Counsel
The draft investigation report will be transmitted to the General Counsel for a review of its sufficiency. Counsel’s comments should be incorporated into the report as appropriate.

Confidentiality
In distributing the draft report, or portions thereof, to the Respondent, the Chair will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

The report initially submitted to the Deciding Official will not include sanctions or disciplinary action unless some administrative action occurred to prevent harm to subjects. The investigation report will be amended to include sanctions or disciplinary action once the appropriate body has made final decisions on those actions. If the report must be submitted to ORI or an external sponsor, a description of any sanctions imposed, and administrative actions taken by the University will be included in an amended report once the action has been recommended.

Disciplinary actions, including adverse actions, will follow the policy in the University Policy Manual in accordance with the BOR-Union Agreement.

APPENDIX 5

INTELLECTUAL PROPERTY DECLARATION FORM

Intellectual Property Details

Title	
Primary Creator	
Primary Creator's Position	

Contributors

Please list all contributors to the IP regardless of whether they are considered to have been creators.

Creator	Name	Position	Department / School	External Affiliations (please list all)	Email/ Contact No.	Student	External
☐						☐	☐
☐						☐	☐
☐						☐	☐
☐						☐	☐
☐						☐	☐

Intellectual Property Description

What is the problem solved by this IP?

Do not describe the IP but instead focus on the problem found with existing technology, processes or services, or a recognized problem not adequately solved by existing technologies, processes or services.

What is the stage of development of the IP? Please tick all that are appropriate from the following options:

☐ idea / concept (target identification)
☐ early stage (target assay development and screening)
☐ proof of concept (target validation)
☐ bench prototype
☐ industry interest / use

Summary of the IP

Describe the IP in detail. Consider the commercial applications of the technology and how they might be applied to a product, process or service. Importantly, please describe what aspects of the IP have been proven experimentally and what is shown by the data. Also describe what materials or prototypes have been created in relation to the IP. Attach any technical documents of IP including (submitted or draft) manuscripts, posters, theses and grant applications.

What date(s) did you make the IP?

The date is when the inventor(s) devised the essential concepts of the IP - but without necessarily having proved that it would work or having built a prototype.

How has the IP been documented?

Identify whose laboratory notebook(s) the experimental data for this IP has been recorded in and note any reference numbers.

Competitive Advantage

Describe the competitor technologies, processes or services which attempt to address the problem. What is the closest existing or known technology – please provide links to the related companies' products or service websites. What are the advantages and benefits of your IP over these competitor approaches – have you experimentally compared your IP to the "gold standard" competitor technology or process?

Future Research

What further research will be conducted over the next 12 months to demonstrate proof of concept or further validate the IP? For example, for platform technologies the demonstration of an advantageous application and comparisons to "gold standard" commercial technologies or products.

Public Disclosures

Public Disclosures

Provide details of any public disclosures of this IP by contributors including publications, theses, posters, presentations, abstracts, submitted manuscripts and patents. Please also attach copies or transcripts of these disclosures. In most countries a patent application must be filed before an oral or printed publication is made available to the public. Publication means the first time any person, without restriction of confidentiality, would have been able legally to gain access to your description. This can include where external people attend a UOG internal presentation. 'Oral disclosure' means lectures, seminars, conference presentations, any talk to external research groups, or in general conversation with people outside the University - except where these activities were covered by a documented obligation of confidentiality.

Consider whether any details of any of your research have been disclosed publicly and provide brief details of the disclosure subject matter:

- In a journal (online or in print)
- At a conference or seminar, as an abstract, poster, etc. (including online before the conference)
- In any other publicly disclosed communication, including conversation
- In a PhD, Master's thesis or project write up

For any noted disclosures:

- Attach any relevant disclosure documents
- If students were involved, please include details of any material or presentations made for examination

Provide details of **previous** disclosures of this IP

Date	Type of disclosure	Aspects of the IP disclosed	Details or reference of the Journal/Conference/Seminar/Thesis	Copy attached
				☐
				☐
Provide details of any **upcoming** disclosures of this IP				
				☐
				☐
Provide details of any public disclosures **that are closely related to this IP**				
				☐
				☐

Sources of Funding

Was the IP developed using any research grants/contract funds?

Please answer ☐ Yes or ☐ No

If Yes, provide details:

Give the applicable contract/grant, project title(s) and the project start/end dates on the project(s) in the table below if the IP was made in connection with research funding. Also consider funding used by all **contributors** including **students.** Please note any non-University of Melbourne collaborators who are grant co-applicants, sub-contractors or are otherwise supported under the grant. We need to ensure that we fulfil our obligations under research grants and contracts.

Please attach any relevant contract.

Grant Ref	Title	Sponsor	Collaborators	Start and End Dates

Obligations to sponsors

Are you aware of any obligations to any sponsors e.g. disclosure of IP, final project reports, or commercial grant of rights (option/licenses)?

Details of external collaborators who have contributed to the IP

Please provide details of non-funded collaborations with non-UoM collaborators which have been conducted through a research project relating to the IP.

Start Date / End Date	Collaborator	Affiliation	Contribution of collaborator

Use of Information [Complete if applicable]

Was any aspect of the IP made possible, in whole or in part, using Information obtained from individuals other than contributors listed above or from organizations other than the University of Melbourne?

Date	Information provider	Affiliation of provider	Details of information provided

Materials [Complete if applicable]

Was any aspect of the IP made possible, in whole or in part, using tangible Materials obtained from individuals other than contributors listed above or from organizations other than the University of Melbourne?

Date	Materials provider	Affiliation of provider	Details of Material provided	Was a Material Transfer Agreement (MTA) signed in respect of receipt of the materials? If yes, please provide a copy.
				☐ Yes or ☐ No

				☐ **Yes or** ☐ **No**

In the course of creating the IP have you developed any Materials that may be of commercial value? Please provide details. Such materials are often of a biological nature e.g. cell lines, antibodies, plasmids, disease models and assay but can include any non-biological material or prototypes.

Were any of Materials received from external organizations used in the development of or incorporated into the Material(s) described above? Please provide details.

Software [Complete if applicable]

Was any aspect of the IP made possible, in whole or in part, using Software obtained from individuals other than contributors listed above or from organizations other than the University of Melbourne?

Date	**Information provider**	**Affiliation of provider**	**Details of Software provided**

Has any software been developed?

Please answer ☐ Yes or ☐ No

If yes, please list the authors of the software's source and executable code.

Name	**Author's contributions to the code**	**Department/ School/ Affiliations**	**Student**	**Email/Contact No.**
			☐	
			☐	

Please provide further information in respect of the involvement of any external authors:

Third party code in software

Please complete the list of all third-party code embedded in or accessed by the disclosed software when such software is run. This list must include, without limitation, all open source code, free executable code, public domain code, library code, and all other executable or source code not written by any of the Authors listed in this form, whether such code is directly embedded in the software or accessed by the software when it is executed. ALL AUTHORS MUST DISCLOSE ALL OF THE THIRD-PARTY CODE AND MATERIALS THAT HAVE BEEN EMBEDDED IN THE SOFTWARE. Software code and related materials easily available for download and available without cost are NOT free. These codes and related materials are restricted by licensing terms that must be reviewed and complied with. Also list any code or related materials with which the software automatically links, executes, or integrates that may not be embedded in the software.

Name of third party code	Web page to download code	Web page location of third party license
Further relevant information:		

Prior Art

Please provide details of literature and patent searches

Please list publications that are closely related to your IP. Please also list closely related patents (conduct a patent search using keywords at https://patentscope.wipo.int/search/en/search.jsf and/or https://www.lens.org/lens/) and attach a list of the keywords used and results obtained.

Publication details	Relevance to the IP

Commercialization

Market Information

Please list companies you have contacted, those you think are active in the area, or who want to develop a new product line. When possible please give contact information (we'll consult you before we get in touch with them).

Company	Contact details	Scope of interest and/or relevance to IP

Declaration

- I have discussed this intellectual property with the Office or Research and Sponsored Programs ☐

- I have discussed the content of this intellectual property disclosure and obtained consent for its submission with my co-inventor/s and co-contributor/s ☐

APPENDIX 6

CENTRAL INSTITUTIONAL REVIEW BOARD AND UNIVERSITY OF GUAM PRIVACY BOARD

(Privacy Board provisions adapted from the University of Hawai'i Privacy Board)

Central Institutional Review Board (CIRB)
The NCI Central Institutional Review Board is dedicated to protecting the rights and welfare of participants in cancer clinical trials. Institutions across the country rely on our national experts to ensure that clinical trials are reviewed efficiently and with the highest ethical and quality standards. We play a critical role in helping the National Cancer Institute accelerate scientific discovery and improve cancer prevention, treatment and care

Approval of Cancer Clinical Trials on Guam-Ceding to the CIRB
On matters pertaining to cancer clinical trials review, the Guam CHRS-IRB acknowledges and approves the ceding of its review to the CIRB for the National Cancer Institute for approval of cancer clinical trials in Guam.

Guam Privacy Review Board Purpose
The UOG Privacy Board (UOG-PRB) is charged with reviewing all clinical trials submitted to the CIRB in order to assess the need for and provide authorization to conduct limited screening of protected health information preparatory to research. Members are qualified and demonstrate the qualities required to protect human subjects.

Privacy Review Board Appointments/The Vice Provost of the ORSP roles:
- Solicits nominations and referrals
- Nominates and appoints all members
- Appointment letters
- Designates the Chair of the Privacy Review Board or may assign the IRB Chair to serve concurrently as the Privacy Board Chair.
- Provides administrative support to the Privacy Review Board related to maintaining all files for the Privacy Board

Board Composition
The UOG Privacy Review Board consists of a minimum of three members at all times.

Protected Health Information (PHI)
Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or heath care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual."

The UOG PRB may use an expedited review procedure if the research involves no more than minimal risks to the privacy of individuals.

If an expedited review is chosen as the review procedure, the review and approval may be carried out by the chair or by a member designated by the chair.
Issues requiring a vote will be passed by a simple majority at a convened meeting of the membership.

Other Provisions and Guidelines. As part of the UOG-PRB collaboration, if any of the above provisions do not address a particular issue or concern, the UOG-PRB may consider the established provisions of the UH-Privacy Review Board policies and guidelines to resolve and guide the business of the UOG-PRB and intended only as interim guideline.

***** END OF MANUAL *****