The Human Research Protection Program

GPM 201
Revised: December 18, 2015

201.1 Entities Covered Under the University of Hawai`i HRPP

The University of Hawai`i (UH or University) System is comprised of the following ten campuses:

- University of Hawai`i at Mānoa
- University of Hawai`i at Hilo
- University of Hawai`i at West O`ahu
- Hawai`i Community College
- Honolulu Community College
- Kapi`olani Community College
- Kaua`i Community College
- Leeward Community College
- University of Hawai`i Maui College
- Windward Community College

Any components under these 10 campuses are listed in the UH Federalwide Assurance (FWA) are considered part of UH for purposes of the Human Research Protection Program (HRPP) and are therefore covered by the Human Studies Program (HSP) General Policy Manual (GPM).

The UH Cancer Center and the John A. Burns School of Medicine are part of UH at Mānoa, and therefore, are covered under the UH FWA. The two components conduct numerous clinical research with local hospitals such as the Queens Medical Center, Hawaii Pacific Health Systems, and Castle Medical Center.

Non-UH organizations who have filed their FWA appointing the UH Institutional Review Boards (IRBs) to review their human participant research, maintain an IRB Authorization Agreement and/or Memorandum of Agreement with the University of Hawai`i specifying the types of research and other conditions for UH IRB oversight.

201.2 Organizational Components of the UH HRPP

The UH HRPP encompasses the HSP, the Office of Research Compliance (ORC) education unit, the Office of Research Services (ORS), Office of Technology Transfer and Economic Development (OTTED), and the Office of the General Counsel (OGC). The HSP is primarily responsible for the administrative, quality improvement, and education units, including serving as the administrative office for the UH IRBs. These functions may be appointed or delegated to other offices or individuals under the ORC umbrella.
Human Studies Program [HSP]

The HSP Administrative Unit:
- Provides administrative support to the UH IRBs;
- Communicates between the Researchers (Investigators and Research Support Staff) and the IRBs; and
- Facilitates the determination of projects that qualify for exemption from IRB review.

The HSP Quality Improvement Unit:
- Conducts on-site post-approval monitoring of UH research;
- Conducts routine review on the knowledge and operations of the HSP administrative office;
- Assesses knowledge and review outcomes of the UH IRBs and its members;
- Manages non-compliance issues of Researchers and IRBs; and
- Reports on deficiencies found from the various HRPP units and makes suggestions for continuous quality improvement.

Office of Research Compliance [ORC] Education Unit

- Develops and conducts educational sessions based on the reported knowledge deficiencies reported by the Quality Improvement Unit (QIU);
- Develops and conducts lecture series, the content of which may depend on the audience, topic, level of research experience, types of research, and the characteristics of the participant population being studied;
- Update educational materials for website postings and required training related to the protection of human participants in research; and
- Coordinate researcher-led lecture series to the IRB, HSP, and other relevant HRPP units on new and controversial issues related to conducting human participant research.

Office of Research Services [ORS]

- Provides contracts and grants administration
- Establishes and administers project accounts, assuring compliance with applicable laws, regulations, policies and award terms and conditions
- Manages significant financial researchers’ conflict of interests

Office of Technology Transfer and Economic Development [OTTED]

- Executes contracts and agreement for inventions, patents, copyrights, and technology
- Reviews and approves intellectual property (IP) agreements

Office of Export Controls [OEC]

- Provides administrative review of tasks related to export controlled and/or classified research;
- Responsible for ensuring compliance with U.S. laws and regulations which regulate strategic information, technology and/or services;
• Reviews and negotiates Non-Disclosure Agreements (NDAs), Confidentiality Agreements (CAs), Material Transfer Agreements (MTAs), etc., as delegated by the Vice President for Research and Innovation.

**Office of Risk Management [ORM]**

• Identifies, evaluates and manages risks inherent in the operations of the University
• Provides leadership and implements risk management principles and practices and services as a system-wide resource for risk management related issues

**Office of General Counsel [OGC]**

• Reviews and provides counsel on legal issues arising out of activities of the UH system; and
• Serves as consultants to the UH IRB for legal issues arising out of research activities conducted on behalf of UH.

**Information Technology Services [ITS]**

• Information Security, within Information Technology Services, is responsible for protection of institutional data assets both electronic and paper

**Data Governance**

• Focuses on privacy and security of UH Institutional Data (data that is used to meet the University’s administrative and academic requirements and primarily involves student, human resource, and financial data).
• Reviews and approves requests involving the use of UH Institutional Data for research
• Provides training on protecting UH Institutional Data

**201.3 Delegation of Responsibility for Implementing HRPP**

The University President delegates the primary responsibilities for maintaining and overseeing the HRPP to the HSP. The Executive Policy (EP) 12.301, approved by the UH President and the Administrative Procedures (AP) 12.301, approved by the UH Vice President for Research and Innovation, lay the overarching UH policies and procedures in human participant protection.

The HRPP General Policy Manual (GPM) and its Standard Operating Procedures (SOPs) comprise of the policies and procedures related to human research protection. The GPM and SOPs are written to comply with applicable federal regulations and guidance, including 45 C.F.R. part 46 and 21 C.R.F.R. parts 50 and 56, and the principles of the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki.

The GPM is a living document that is subject to review and revision, which may be required by amendments in federal regulations, Hawai‘i law, federal guidance, or UH policies. The GPM and other related materials, along with any subsequent changes to these materials, are made available on the HSP
website, and distributed/communicated to the UH research community via presentations, educational
sessions, and electronic communication.

Human Studies Program (HSP)

Responsibilities of the Office

The UH HSP is the administrative office of the UH IRBs. The primary responsibilities of the UH
HSP is to ensure that the rights, safety and welfare of human participants are protected, and that human
participant research is conducted ethically, and in compliance with applicable federal regulations, the
requirements of state law, federal guidance, and UH policies.

Officials Specifically Responsible for Protecting Research Participants

Designated Institutional Official (IO)

As the Designated Institutional Official (IO), the UH Vice President for Research and Innovation is
ultimately responsible for ensuring the protection of human participants involved in UH research. The IO
shall maintain open communication channels between the HSP, research investigators, and institutional
leadership. The IO receives copies of all approved IRB meeting minutes and notices of serious or
continuing noncompliance and unanticipated problems in human participant research.

Director of the HSP (the Director)

The HSP Director is responsible for the day-to-day program operations and oversight, which includes the following:

- Creates, establishes, and maintains the HSP’s policies and procedures and related research
policies and procedures on behalf of UH;
- Oversees the protection of human participants and regulatory compliance for UH;
- Ensures that open communication channels are maintained between the components of the HRPP;
- Oversees research investigators and staff, and research management;
- Ensures the IRBs independence, including the authority to act without undue influence
- Conducts periodic reviews of the HSP and its IRBs;
- Ensures that the HSP is functional, adequately staffed and funded, involving:
  - Annual review of the resources allocated to the HSP, and
  - Participation in the annual budget preparation for the HSP and incorporation of the HSP
    budget into the ORC budget; and
- Serves as the conduit between the IO and the IRBs.

201.4 Laws and Ethics Governing Human Participant Research

Ethical Principles

The main ethical principles that apply to research covered by the HRPP, including protocols and
proposals, “exempt” under the federal regulations pertaining to human participant research are those set
forth by the “Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of
The three main principles are:
1. Respect for Persons (e.g., applied by obtaining informed consent, giving consideration to privacy and confidentiality, and adding protections for vulnerable populations)
2. Beneficence (e.g., applied by weighing risks and benefits)
3. Justice (e.g., applied by the equitable selection of participants)

All parties involved in the conduct of research are expected to also adhere to the principles of expertise (“competent to do the work”) and integrity (“faithfully adhere to professional principles”). Ethical principles from other sources (e.g., International Conference on Harmonization) may also apply to research covered by the HRPP, for example:

- To an individual protocol because its particular circumstances raise a type of ethical issue that most other protocols do not;
- When they are recognized by the federal sponsor or other funding source or the state or country where the research will occur; or
- When they have been developed for specific areas or types of subjects (e.g., embryos and fetal tissue, participants who are illiterate);

These principles are also covered in the Collaborative Institutional Training Initiative (CITI) tutorial for investigators, IRB members, and IRB staff and in the orientation given to new IRB members.

Legal Principles

The following legal principles, covered by the HRPP, govern human participant research and are applicable to individual protocols or proposals are:

- Department of Health and Human Services (HHS) Policy for Protection of Human Subjects in 45 C.F.R. Part 46, which includes:
  - Subpart A (Common Rule), and
  - Subparts B through D (vulnerable populations)
- Food and Drug Administration (FDA) Regulations for the Protection of Human Subjects in 21 C.F.R. Parts 50 and 56
- Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 C.F.R. Parts 160 and 164
- Applicable Hawai`i law

State vs. U.S. Local Law

If a study is conducted in the United States, federal regulations on human participant research must be followed unless the regulations are silent or specifically refer to state or local law on certain issues.

If a study is conducted outside of the U.S.:
1. federal regulations of a U.S. agency control if the study is funded by the U.S. agency;
2. local law controls if the study is not funded by a U.S. agency.
The following issues depend on the state or local law of the location where the research is conducted:

1. The definition of children,\(^1\)
2. Guardian of a child who is authorized to give parental permission for the child to participate in research,\(^2\)
3. Legally authorized representative who is authorized to consent on behalf of a subject to participate in research,\(^3\) and
4. The legality of consent\(^4\).

In most situations, it is not difficult to pinpoint the location where the research is conducted, except research conducted on the Internet (Internet research). In Internet research, research can take place at any location with access to the Internet. The UH IRB adopts the policy that the location of Internet research is where the investigator is during the research.

**Laws Governing Transnational Research**

Also known as “international research,” transnational research covers research conducted outside of the United States.

UH Investigators\(^5\) are responsible for:

- complying with local laws and considering the cultural context of the country where the research is conducted;
- complying with U.S. regulations and guidelines if the research is funded by a U.S. agency;\(^6\) and
- following applicable international guidelines on biomedical research, e.g., the Declaration of Helsinki\(^7\), Guideline for Good Clinical Practice (E6)\(^8\), and International Ethical Guidelines for Biomedical Research Involving Human Subjects\(^9\).

UH IRB, as the IRB of record, and UH Investigator share responsibility for ensuring that:

- the same or equivalent protections are provided to human participants in research conducted in countries other than the United States;
- the researchers have sufficient knowledge of local laws and cultural context to determine how the research shall be conducted;
- the consent process is appropriate to the population and culture; and
- the researchers have made adequate provisions for data and safety monitoring.

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1. 45 C.F.R. § 46.402(a).
2. 45 C.F.R. § 46.402(e).
3. 45 C.F.R. § 46.102(c).
5. "UH Investigator" means an investigator who is affiliated with UH, i.e., (1) employees who receive paychecks from the UH; (2) students who are currently taking courses for credit at UH; or (3) members of UH Board of Regents.
The University conducts and oversees biomedical, social and behavioral sciences research. Human participant research conducted at each UH affiliated organization is covered by the UH FWA. Regardless of funding sources, all human participant research engaged\(^{10}\) by UH are governed by subpart A of 45 C.F.R. part 46, and the principles of the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki.

An activity is covered by the UH HRPP when:

1. It is considered “human subject research” – as defined in any of the following regulatory agencies:
   - HHS regulations or other Common Rule regulations
   - FDA regulations
   - Any other applicable state or local regulations, e.g., Hawai`i State regulations, UH policies
   AND
2. UH (or its faculty, staff or students) is engaged in the research
   - UH is engaged in the research if:
     1. UH receives a grant or contract under which the research is conducted, and/or
     2. UH’s faculty, staff or students obtain:
        1. Data about research participants through intervention or interaction;
        2. Identifiable private information about the research participants; or
        3. Informed consent from research participants.

A non-UH investigator who conducts human subjects research and seeks to access UH resources, such as facilities, personnel, data, or information, must consult with the Human Studies Program (HSP). The HSP will determine whether UH is engaged in the research. If the HSP determines that UH is engaged in the research, the non-UH investigator must seek review by the UH IRB.

See SOP 103: When Must a Non-UH Investigator Seek Review by the UH IRB? – The Issue of Engagement for more information.

**Approvals Required Prior to Research Commencement**

Research involving human participants must be reviewed and approved by an IRB before an Investigator initiates activities of the research.

In addition to seeking approval from the IRB, Investigators may need to seek review and approval from ancillary departments before commencing in research activities:

- Funded research (e.g., industry-sponsored clinical trials, federally-funded research) will need to apply to the ORS through myGrant.
- Research involving UH Institutional Data require approval from UH Data Governance Office before the data will be released.
- Research involving primary and secondary schools or offices under Hawai`i Department of Education (HIDOE) need to apply and seek separate approval from the HIDOE Data Governance and Analysis Branch.

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\(^{10}\) "Engaged" means that an institution involves in a human subjects study to such a degree that the institution must have the study reviewed and approved by an IRB before any research activity of the study may be initiated. For details on engagement, see SOP 103, When Must a Non-UH Investigator Seek Review by the UH IRB?—the Issue of Engagement.
- Research involving matters covered by U.S. Export Control Laws (ITAR, EAR, OFAC, etc.) may need to seek review and approval from the OEC (matters involving foreign nationals, select agents, etc.)
- Research involving transfer of biospecimen may require additional approval from the UH Biosafety Office.
- Research involving use of animals for research may require additional approval from the Institutional Animal Care and Use Committee (IACUC).

201.6 Scientific and Scholarly Review

When evaluating the scientific and scholarly validity of a research protocol or proposal, the IRB relies on the review provided by different entities:

- For federally sponsored research, the peer review process by the sponsoring agency (e.g., NIH, NCI, DOD) provides scientific and scholarly review.
- For research subject to FDA review, the FDA conducts a rigorous scientific design review during IND or IDE evaluation. Most industry-sponsored research falls within this category. The exception would be for Non-Significant Risk (NSR) device research, in which the IRB serves as the FDA’s surrogate in reviewing and approving NSR studies.
- For student-led research, the faculty advisor and the academic committee (e.g., Undergraduate Honors, Graduate Thesis, Dissertation, Plan B project), as appropriate, are responsible for scientific and scholarly review of their student’s research project

For research that has departmental funding, gift funding or no funding, or that has not otherwise gone through a scientific review as described above, the UH IRB will review those studies.

See SOP 104: Ensure Sound Design and Minimize Risk for details and procedures regarding scientific and scholarly review of research.

201.7 HRPP Resources

Human and Fiscal Resources

UH maintains human and fiscal resources for administrative support to the operation of its HRPP.

The HSP receives its annual budget through the Vice Chancellor for Research from the University of Hawaii at Mānoa. The annual budget is established by a three-step process:

1. IRB Chairs and the HSP Director discuss priorities and resources necessary for the new academic year. This includes budget to secure educational materials and training opportunities for IRB members and its collective IRBs for the upcoming year.

2. The HSP Director and ORC budget officers, with input from the ORC Director, prepare income and expense plans for the following year. The yearly expenditure plan takes into consideration:
   - Adequate number of IRBs
   - Adequate staffing
• Adequate technology support
• Adequate funds for educational opportunities for IRB members and HSP staff, including off-site conferences
• Adequate funds to provide ongoing office and logistic support
• Adequate funds to carry out agreed-upon special projects.

3. The HSP Director formulates these plans into a budget, which is then integrated into the ORC budget. The ORC budget is ultimately reviewed and approved by the Vice Chancellor for Research. This budget is then further integrated by the University Fiscal Office into the University’s consolidated budget plan presented to the Board of Regents for approval. Fiscal budget begins July 1st of each year.

**Assessment of IRB Workload**

The HSP assesses its level of activity at least once a year in order to attempt to maximize the efficiency of workflow to IRB load. It takes into consideration the ratio of applications to staff, the number of transactions generated by each submission, the type of review (full-board, expedited or exempt), and any other appropriate variables. Input from the IRB Chairs regarding the volume of work (i.e., hours to review) and other IRB-related matters are discussed in the HSP annual report that is presented to the Vice President for Research and Innovation and the Vice Chancellor for Research. When adjustments are necessary, their financial implications are considered during the budget assessment outlined above. New IRBs, IRB reviewers, or staff positions are appointed or created to meet workload demands.

**201.8 Investigator Resources to Ensure Care and Safety of Participants in Human Research**

To approve a research protocol or proposal, the IRB must determine that, where appropriate, there are adequate resources to ensure the care and safety of participants throughout the entire conduct of the project. Review of the submitted protocol or proposal is assessed from the information provide in the eProtocol Application (see GPM 204.2 for information about eProtocol) and as necessary, requested by the IRB or HSP staff for additional information (see GPM 204 for information about Review Process). If the protocol or proposal does not provide adequate protection, it will not be approved.

Principal Investigators (PIs) are required to indicate in the eProtocol Application whether investigators:

- will have access to a population that will allow recruitment of the required number of participants;
- will have sufficient time to conduct and complete the research; will have adequate numbers of qualified staff; will have adequate facilities;
- will have a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions; and
- will have medical or psychological resources available that participants might require as a consequence of the research when applicable.

PIs shall continually monitor the resources allocated for their research and notify the IRB if any change in the availability of resources may adversely impact the rights and welfare of participants.
201.9 Communication Between HRPP Components

Communication

The IRB ensures that the communications required by the eProtocol Application takes place. Shared access to eProtocol between various components of the HRPP ensures that situations which require communication and interaction between these components are handled appropriately:

- **Protocols involving biosafety materials** and requiring review by the Institutional Biosafety Committee must be reviewed by this Committee and receive an approval letter in addition to review by the IRB.
- **Protocols involving UH institutional data** and requiring review by the IRB must be reviewed by this Committee and receive an approval letter from the IRB. UH Data Governance Office will not process or approve the request for institutional data until IRB has approved the project to which the data will be needed.
- **Investigator Conflict of Interest disclosures:** All Investigators’ conflicting interest is managed via the Conflict of Interest Committee (COIC) under the ORS. The IRB will not approve a protocol or proposal application until any disclosed COI has been reviewed and resolved by the COIC, and as appropriate, a plan or strategy to adequately eliminate, mitigate, or manage the conflict that has been identified by the COIC (See GPM 203.5).
- **Blood, tissue, or data (slides, X-rays, etc.)** that are being transferred in or out of the institution: The PI must coordinate with the Office of Export Control (OEC) about a Material Transfer Agreement (MTA).
- **Funding Status:** Inquiries are made to the ORS to verify whether there is active funding on a particular project. Funding received by ORS for a designated research protocol or proposal will not be released to the PI until IRB approval is secured.

Policies Available to all Parties to Research

This HRPP General Policy Manual and other relevant policies and procedures are available to the sponsors and to the entire UH research community, including researchers, research staff, HRPP staff, IRB members, employees, UH staff, and students through the HSP website.