In order to approve research, the UH IRB must be satisfied that, “when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data” regarding research involving human participants.

The IRB reviews each protocol and proposal, based on the information provided in the Application, and assesses the type and volume of private information to be collected, how the information is collected, and plans for its use, storage and disclosure. When necessary, the IRB will request more information during its review.

The terms privacy and confidentiality are often misinterpreted. Privacy refers to persons and their interest in controlling the access of others to themselves. On the other hand, confidentiality refers to maintenance of the researcher’s agreement with the participant about how the participant’s identifiable private information will be handled, managed, and disseminated.

For a detailed definitions of “privacy” and “confidentiality,” see Definitions.

208.1 Protecting Participants’ Privacy

Privacy may be a concern if, based on their privacy interests, people want to control:
   (i) The time and place where they give information;
   (ii) The nature of the information they give;
   (iii) The nature of the experiences that information is given to them; and/or
   (iv) Who receives and can use the information.

To approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the privacy interests of potential or active participants, from the screening and recruitment through all stages of research. If the research plan does not include adequate provisions to protect the privacy interests of participants, the IRB will not approve the research as written.

Provisions to protect privacy interests of participants shall include:
   • Ensuring that the conditions under which a procedure is conducted or information is collected (e.g., physical locations, telephone contact, mail or email solicitations) provides protections against interactions with participants being seen, overheard, or inadvertently intercepted or viewed.
   • Limiting the information being collected to only the minimal amount of data necessary to meet research purposes.

See Definitions section on “Private Information.”

60 45 C.F.R. § 46.111(a)(7); 21 C.F.R. § 56.111(a)(7)
208.2 Protecting the Confidentiality of Participant Information

To approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the confidentiality of information related to potential and active participants, throughout the research life, including data analysis and retention of records. It is the responsibility of the Investigator to design studies that maximizes confidentiality measures to avoid unintentional and unauthorized release or other disclosures.

The Investigator must provide a description of the provisions to protect the confidentiality of data in the Protocol Application. The IRB evaluates the information provided in the application during the review process and at convened meetings. The IRB may request more information during its review, depending on the sensitivity of the information being used, maintained or disclosed. In general, the greater the sensitivity of the information, the more stringent the security measures are needed. For more information on what is considered “sensitive information,” see Definitions.

Evaluation of confidentiality measures takes into account the nature, probability, and the magnitude of harms that would be likely to result from an unauthorized release of the collected information. The IRB evaluates the proposed methodologies for maintaining anonymity (e.g., de-identification, coding), storage plans, access restrictions, data security measures (e.g., encryption, password protection) and other pertinent factors in making its final determination concerning the appropriateness and adequacy of confidentiality measures. See the APP 04: New Research for Initial Approval, Non-Exempt Application for the information requested by the IRB for this review.

Changes to confidentiality protection measures on an active study shall first be requested for review and approval by the IRB before implementation of these changes. Request for these changes shall be submitted to the IRB using the APP 05: Modification Request Application. These changes are reviewed according to the same requirements described above for new research.

Methods to Maintain Confidentiality

Certificates of Confidentiality (CoC)

Where a protocol or proposal involves the collection of sensitive information, the IRB may determine that special procedures are necessary to protect participants from the risks of external investigative or judicial processes (legally mandated release of information for use in federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings). In such situations, the IRB may require that the PI obtain a DHHS Certificate of Confidentiality (CoC) pursuant to Section 241(d) of Title 42 of the U.S.C. Funding through HHS or other federal funding is not a requirement for obtaining a CoC.

When the PI obtains a CoC, the IRB requires that participants be notified about the protections and limitations under the CoC, through the consent document or HIPAA authorization. In order that a participant may weigh the risk of such release of information and not expect more confidentiality protection than is actually provided by the CoC, the IRB requires that the possibility of release for those purposes be stated clearly and explicitly in both the protocol and the consent form. The IRB also requires that any participant enrolled after expiration or termination of a CoC be informed that its protection will not apply to them. Issuance of a CoC is not an endorsement of the research by DHHS.
Data Analysis, Dissemination and Retention

PIs shall consider taking additional safeguards that were not feasible while the research was ongoing, including, but not limited to:

- Removing identifiers (e.g., name, medical record number, student identification number) and coding the information;
- Limiting the number of individuals who have access to participant identifiable information;
- Using secure archival methods or ITS-approved long-term storage services; and/or
- Using ITS-approved encryption software in combination with password protection to database.

PIs are responsible for the secure store of signed consent documents for at least three (3) years after the completion of the research. PIs shall refer to the covered entity(ies)' policies where the research was conducted for retention length on HIPAA authorizations.

Health Information Portability and Accountability Act (HIPAA)

Any research to be conducted by one or more of the medical facilities where UH has a cooperative agreement (i.e., Queens Medical Center, Hawaii Pacific Health, Castle Medical Center) are reviewed under the HIPAA policies of those facilities.

Legal Requirement to Release Private Information

The IRB identifies research that might collect information that could be subject to legally mandated release of information, to the extent that this can be ascertained in advance. When such protocols are identified in advance, the IRB requires that the Investigator notify the participants through language in the consent and HIPAA authorization document(s), as appropriate, of the possibility of legally mandated disclosure. Examples of reportable information may include:

- Child abuse reporting
- Sexual assault and rape reporting
- Reporting to law enforcement when an individual is deemed a danger to others
- Release under a search warrant or a subpoena (e.g., civil or criminal litigation)

Investigators may seek advice from the IRB or the UH General Counsel on additional questions concerning compliance with these laws.

208.3 Confidentiality Breach – Unauthorized Research of Information

The IRB requires that the Principal Investigator immediately reports to the IRB any possible or actual unauthorized release of information. Individuals outside of the research team, including participants themselves, may also file a complaint or allegation with the Human Studies Program staff if they feel that private identifiable information collected and maintained for research has been released without authority.

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61 Chapter 350, Hawaii Revised Statutes
62 Chapters 707-730, Hawaii Revised Statutes
63 Chapter 626-1, Hawaii Revised Statutes
64 Chapter 803, Hawaii Revised Statutes
The HSP and its IRBs consider such release or allegations of release as possible non-compliance, and follows the policies and procedures set forth in Section 203.6, SOP 108: Determining and Reporting Non-Compliance and Protocol Violations, and GUIDE 614: Events and Information That Require Prompt Reporting to the IRB to review and respond to the situation appropriately.