Executive Policy Chapter 12, Research
Executive Policy EP 12.301, Protection of Human Participants (Note: Previously part of A5.503)
Effective Date: December 2015
Prior Revision Dates: N/A (Note: A5.503 split into EP 12.301 and AP 12.301)
Responsible Office: Office of the Vice President for Research and Innovation
Governing Board or Executive Policy: RP 12.201, Ethical Standards of Conduct
Review Date: August 2018

I. Purpose

To describe general policies and principles to protect human participants involved in research overseen or conducted by University of Hawaii (UH).

II. Definitions:

A. Director: the Director of the Human Studies Program, Office of Research Compliance.

B. Human participants a living individual about whom an investigator conducting research—whether professional or student—obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. It is also referred to as "subject," "human subjects," or "participant."

C. Institutional Review Board (IRB): an institutional review board established in accordance with and for the purposes expressed under federal regulations.

D. Interaction: communication or interpersonal contact between an investigator and a participant.

E. Intervention: physical procedures by which data are gathered (e.g., venipuncture), and manipulations of the participant or the participant’s environment that are performed for research purposes.

F. IRB approval: the determination by an IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

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1 45 C.F.R. § 46.102(f) (2013).
2 45 C.F.R. § 46.102(g).
3 45 C.F.R. § 46.102(f).
4 Id.
5 45 C.F.R. § 46.102(h).
G. **Private information**: includes information
   - that is about behavior that occurs in a context where an individual can reasonably expect that no observation or recording is taking place, or
   - that an individual has provided for specific purposes and can reasonably expect will not be made public (e.g., a medical record).

   Private information must be individually identifiable—i.e., the identity of the participant is or may readily be ascertained by the investigator as associated with the information—for obtaining the information to constitute research involving human participants.6

H. **Research**: a systematic investigation—including research development, testing and evaluation—designed to develop or contribute to generalizable knowledge.7

I. **Research Involving Human Participants**: research that involves human participants. It is also referred to as “human participants research” or "human subjects research,” or sometimes “research” for short if the context allows.

III. **Executive Policy**

A. **UH IRB Authority**

   1. UH IRB has the following authority:

      a. To approve, require modifications to secure approval, or disapprove human participants research overseen or conducted by UH;8

      b. To suspend or terminate IRB approval of research that is not being conducted in accordance with IRB’s requirements or that has been associated with unexpected serious harm to participants;9 and

      c. To observe or have a third party observe the consent process and the conduct of research.10

   2. Human participants research may not commence before IRB approval.11

B. **Further Review by UH**

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6 45 C.F.R. § 46.102(f).
7 45 C.F.R. § 46.102(d).
8 45 C.F.R. § 46.109(a).
9 45 C.F.R. § 46.113.
10 45 C.F.R. § 46.109(e).
11 See 45 C.F.R. § 46.103(b).
1. Human participants research may be subject to further review by UH officials.\textsuperscript{12}

2. UH officials may not approve human participants research that has not been approved by an IRB.\textsuperscript{13}

3. Any study from UH that is ceded to another IRB must first be reviewed and approved by a UH IRB and the Director pursuant to HSP standard operating procedures.

C. Independence of the IRB: no person may unduly influence the operation of a UH IRB.

IV. \textbf{Delegation of Authority}

There is no policy-specific delegation of authority.

V. \textbf{Contact Information}

Office of the Vice President for Research and Innovation, telephone number: (808) 956-4740; and email lgouveia@hawaii.edu may be contacted for information relating to this Executive Policy.

Human Studies Program, Office of Research Compliance, telephone: (808) 956-5007; and email uhirb@hawaii.edu may be contacted for information relating to this Executive Policy.

VI. \textbf{References}


B. Website: http://manoa.hawaii.edu/researchcompliance/human-studies

\textbf{Approved:}

Signed \hspace{2cm} December 30, 2015 \hspace{2cm} Date
David Lassner \hspace{2cm} President

\textsuperscript{12} 45 C.F.R. § 46.112.
\textsuperscript{13} Id.