I. Purpose

To describe administrative procedures 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. Engaged: an institution is engaged in a human participants when the institution is involved in the study to such a degree that the institution must have the study reviewed and approved by an IRB before research activities of the study may be initiated.¹

C. 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.² It is also referred to as "subject," "human subject," or "participant."

D. Human Participants Research Overseen or Conducted by UH: human participants research engaged by UH.

E. Institutional Review Board (IRB): an institutional review board established in accord with and for the purposes expressed under federal regulations on human participants protection.³

² 45 C.F.R. § 46.102(f) (2013).
³ 45 C.F.R. § 102(g).
F. **Interaction**: communication or interpersonal contact between an investigator and a participant.\(^4\) Interaction can be indirect, e.g., online survey.

G. **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.\(^5\)

H. **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.\(^6\)

I. **Private information**: it includes information

   - that is about behavior occurring 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 or associated with the information—for obtaining the information to constitute research involving human participants.\(^7\)

J. **Research**: a systematic investigation—including, but not limited to research development, testing, and evaluation—designed to develop or contribute to generalizable knowledge.\(^8\)

K. **Research Involving Human Participants**: It is also referred to as "human subjects research," or sometimes "research" for short if the context allows.

### III. Administrative Procedures

A. UH IRBs and the [Human Studies Program](HSP)

   1. EP 12.301 grants UH IRBs authority

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\(^4\) 45 C.F.R. § 102(f).

\(^5\) Id.

\(^6\) 45 C.F.R. § 102(h).

\(^7\) 45 C.F.R. § 102(f).

\(^8\) 45 C.F.R. § 102(d).
a. to approve, require modifications to secure approval, or disapprove human participants research overseen or conducted by UH;\textsuperscript{9}

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;\textsuperscript{10} and

c. to observe or have a third party observe the consent process and the conduct of research.\textsuperscript{11}

2. The HSP is the administrative office of the UH IRBs.

a. The HSP coordinates the operations of the UH IRBs.

b. The HSP develops standard operating procedures (SOP) to guide its and the UH IRBs' operations, and to comply with federal regulations and Hawaii law, and follow federal guidance.\textsuperscript{12}

c. The HSP is authorized to review and approve applications for exempt status from federal regulations.

3. Human participants research may not commence before IRB approval.\textsuperscript{13}

a. UH Office of Research Services does not release funds supporting the human participants research if the research protocol has not received IRB approval.

b. UH students may not register for the classes Thesis Research (e.g., 700) or Dissertation Research (e.g., 800) if the human participants research has not received IRB approval.

c. UH internal programs do not release funds supporting a student's human participants research before the student's research protocol has received IRB approval.

d. UH encourages reports to the HSP of any incident in which a UH investigator initiates a study before IRB approval. The HSP will promptly investigate such a report following its SOP on noncompliance.

\textsuperscript{9} 45 C.F.R. § 109(a).
\textsuperscript{10} 45 C.F.R. § 113.
\textsuperscript{11} 45 C.F.R. § 109(e).
\textsuperscript{12} See http://manoa.hawaii.edu/researchcompliance/resources for the SOPs.
\textsuperscript{13} See 45 C.F.R. § 46.103(b).
4. 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.

B. Further Review by UH

1. The institutional official on human participants protection will review a study after IRB review and approval.

   a. The HSP will forward all studies that have received IRB approval to the institutional official for review.

2. After IRB approval, some studies are required to be reviewed by other offices in UH before the studies may be initiated.

   a. One of such offices is UH Institutional Data Governance on institutional data, such as student or employee records.

3. In any event, UH officials may not approve human participants research that has not received IRB approval.\textsuperscript{14}

   a. If a UH official approves a study that has not received IRB approval, the HSP will inform the official that such approval violates federal regulations.

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

1. "Undue influence" means exertion of influence over a UH IRB member or a HSP staff member to unduly expedite or delay the review or approval of a study.

2. UH encourages reports to the HSP of undue influence on a UH IRB or the HSP.

   a. If the undue influence was exerted on HSP staff, the director will refer the matter to a UH IRB for review.

   b. If the undue influence was exerted on both a UH IRB and the HSP, the director will refer the matter to relevant UH officials, such as department chairs or college deans.

\textsuperscript{14} 45 C.F.R. § 46.112.
c. The HSP director will promptly review the report on undue influence exerted on a UH IRB.

d. The HSP will report repeated or severe undue influence to UH officials, study sponsors if any, and Office for Human Research Protections in the U.S. Department of Health and Human Services. UH will investigate such a report and take disciplinary actions if sufficient evidence supports the allegation of repeated or severe undue influence.

D. Monitoring: IRB’s authority to monitor studies comes from its authority to observe or have a third party observe the consent process and the conduct of research.

1. The monitor appointed by the HSP or a UH IRB is independent from and does not have conflicts of interest with the study, study investigators, or study sponsors.

2. The monitor will report any noncompliance to the HSP. Upon receipt of the report, the HSP will investigate the noncompliance, following its SOP on noncompliance.

IV. Delegation of Authority

There is no administrative-specific delegation of authority.

V. 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 Administrative Procedure.

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

VI. References


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

Approved:
Signed
Vassilis Syrmos
Vice President for Research and Innovation

December 28, 2015
Date