Addressing Concerns of Research Participants

SOP 118
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Purpose and Scope

The purpose of this SOP is to describe the way in which the University of Hawai'i (UH) Human Studies Program (HSP) provides research participants with contact information for any concerns, complaints, or questions about the research study.

UH has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information.

This SOP applies to all HSP staff, Institutional Review Board (IRB) members, and Investigators (PI) at UH.

Procedures

1. Consent Form Requirements
   a. The IRB requires that all consent forms include information on:
      i. how to contact the investigator(s) conducting the research study,
      ii. participants are instructed to call the investigators if they have any questions:
         (1) about the research,
         (2) about their rights as a research participant, or
         (3) if they believe they have suffered a research-related injury.

   b. Each consent form must also include a telephone number for the IRB (a local number and a toll free number).

2. The IRB contact information affords current or past research participants or their designated representatives a means to contact an informed individual who is independent of the research team.
3. The IRB also serves as a conduit for receiving information from any party:
   a. who is not satisfied with the manner in which a study is (or was) being conducted, or
   b. if any party has any concerns, complaints or general questions about research or the rights of research participants.

(AAHRPP Element I.4.A; Element III.1.G.)

4. Consent form information and requirements are available on the HSP website and includes instructions for consent form creation to include the investigator's contact information and IRB telephone numbers under the consent form heading "Contact Information."

   See Guidance: GUIDE 606 Consent Form Guidance
   GUIDE 607 Short Form Guidance
   GUIDE 608 Informed Consent Checklist – Basic and Additional
   GUIDE 627 Lay Language

Recruitment Material Requirements

1. The IRB requires specific contact information to be included in participant recruitment materials – flyers, newspaper ads, newsletters, and web postings. See TMP 475 Recruitment Flyer.
2. All recruitment materials must include the appropriate contact information for the investigator(s) conducting the study.
3. The IRB reviews all recruitment materials, and the addition of IRB contact information is required when appropriate.

Responding to Contacts from Participants or Others

1. HSP Procedures for Responding to Communication from Participants or Others
   a. The HSP will determine the purpose of the communication upon initial contact from the participant or others.
   b. If the contact is regarding the content of a particular study, such as the rationale and methods of the study, the HSP will refer the contacting person to the PI of the study.
   c. If the contact is regarding the participant's rights in research, the HSP will address the matter.
      i. The HSP will forward the contacting person a pamphlet entitled, "*Becoming a Research Volunteer*," and refer the person to its website for more information on being research participants.[1]
      ii. If the contact is a complaint about a particular research, the HSP will investigate the complaint following its SOP on noncompliance.
   d. If the contact is a complaint about the HSP or the IRB,
      i. the HSP may refer the matter to the IO and OHRP;
      ii. the Director may investigate the complaint if appropriate.

2. Participant Concerns
   a. Concerns of research participants are followed up by the HSP Director or designee who calls the individual to gather more information.
   b. Minor concerns are generally resolved by a phone call.
   c. More complex concerns are followed up by the HSP Director designee or with the relevant IRB Chair and others in the Office of Research Compliance.
      i. Formal investigation with possible consultation from other UH departments may be warranted.

[1] See Becoming a Research Volunteer, OHRP, http://www.hhs.gov/ohrp/education/brochures/3panelfinal.pdf (last visited Sept. 30, 2014).

ii. If these concerns lead to issues of serious non-compliance on the part of the researcher or serious safety issues to participants, the HSP Director may report this to UH administrators and other local, state, and federal agencies, as appropriate.

Website

The HSP website includes:

1. participant outreach information addressing the general right of research participants and,
2. provides links to various research resources. See HSP website under the Quicklink, Information for Research Participants.
3. Additionally, the HSP website has a toll free number listed for participants to ask questions, offer input, raise concerns or complaints about research, a research related injury, or any question about the rights of research participants.

Materials

- TMP 441-69 Consent Form Templates
- TMP 475 Recruitment Flyer Template
- GUIDE 606 Consent Form Guidance
- GUIDE 607 Short Form Guidance
- GUIDE 608 Informed Consent Checklist – Basic and Additional
- GUIDE 627 Lay Language

References

- Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information (**AAHRPP Element II.1.G.**).