Addressing Research Participants’ Concerns

212. 1 Written Materials

Participants or their representative can contact the Human Studies Program office or the Principal Investigator if they want to discuss concerns, obtain information, or offer input regarding a study or human subjects research in general. Contact information for HSP and the PI are found on the IRB-approved informed consent document. They also can contact the IO or the OHRP about such matters. If a complaint about the HSP or the IRB is filed with the IO, the IO will investigate the complaint, with the help of the HSP Director and IRBs as appropriate.

Usually the HSP addresses the participants' rights in the research while the PI addresses the content of the study. The HSP consent templates and UH IRB-approved consent forms include that contact information. The HSP also post its contact information and information on being research participants on its website.

Consent Form Requirements

The IRB requires that all consent form documents include information on how to contact the Investigator(s) conducting the research study. Participants are instructed to call or email the Investigators if they have any questions about the research or if they believe they have suffered a research-related injury, and contact the Human Studies Program/UH IRB if they have questions about their rights as a research participant.

Each consent form must include the telephone number for the IRB. 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. The IRB also serves as a conduit for receiving information from any party who is not satisfied with the manner in which a study is (or was) being conducted, or if any party has any concerns, complaints or general questions about research the rights of research participants.

Consent form templates, found on the Human Studies Program website, include instructional text and verbatim language for the inclusion of the Investigator’s contact information and IRB telephone numbers under the consent form heading “Questions.” The Human Studies Program/UH IRB’s email address is included in the consent form template to also allow for written communication.

Recruitment Material Requirements

All recruitment materials must include the appropriate contact information for the Investigator(s) conducting the research. The IRB reviews all recruitment materials, and the addition of IRB contact information is required when appropriate.
See GUIDE 619: Recruitment Guidelines for appropriate language and content to include in recruitment material.

**Telephone (Screening) Scripts**

Telephone scripts are often used to screen prospective participants. Like the consent forms, telephone scripts must include contact information for the IRB and the Investigator(s). This information provides prospective participants ways to ask the Investigators and the IRB questions, communicate concerns and complaints, provide input and acquire information.

As with recruitment materials, the IRB reviews all telephone or screening scripts and materials and must approve them before use.

### 212.2 Responding to Participant Concerns

Concerns from research participants, prospective and current, are followed up by the HSP Director who contacts the individual to gather more information. As appropriate, concerns may be forwarded to the Compliance Specialist. Minor concerns are generally resolved by any HSP staff member via phone call.

More complicated concerns are followed up by the HSP Director with the relevant IRB Chair and others in the ORC. If necessary, the Principal Investigator may be contacted for concerns regarding a particular Investigator, research staff, or the research itself.

See SOP 118: Addressing Concerns of Research Participants for procedures on how participant concerns and questions are handled.

### 212.3 Website Information for Participants

The HSP website includes participant outreach information addressing the general rights of research participants and provides links to various research resources. Additionally, the website has a local 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.