

# FAQs: Researchers and Research Staff

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Researchers and research staff are an essential element of the Human Research Protection Program. The site visitors have selected a number of people for interviews including primary investigators, co-investigators, coordinators and other research staff. The interviews will take place in a group setting. Discussion will relate to individual characteristics of research projects, regulatory issues, recruitment procedures and feelings about the human research enterprise, in general. The IRB's records of your study may be reviewed but your subject records and regulatory files will not be.

This sheet can help you prepare for the types of questions that may be encountered. Interviewees should also familiarize themselves with some additional resources:

**Pitt Human Research Protection Office (HRPO):** <http://hrpo.pitt.edu/>

**HRPO Policies and Procedures:** <https://www.hrpo.pitt.edu/policies-and-procedures>

**HRPO Guidance:** <http://hrpo.pitt.edu/guidance>

[45 CFR 46: Protection of Human Subjects](#)

[The Belmont Report](#)

Please refer to the AAHRPP Site Visit page at <https://www.hrpo.pitt.edu/aahrpp-site-visit> for information on the following topics:

- Overview of the Human Research Protection Program
- Ethical Conduct of Research and Governing Federal Regulations
- FDA Regulated Studies
- IRB Review
- Conflict of Interest
- Consent and Waivers of Consent
- Reportable Events

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## 1. What is AAHRPP Accreditation and Why is it Important?

The association for the Accreditation of Human Research Protection Programs is an independent organization that reviews and accredits institutions engaged in human subject research to protect the rights and welfare of the research participants.

AAHRPP accreditation bolsters the university's reputation as a leader in human subject research. Research sponsors and other research partners increasingly consider AAHRPP accreditation before pursuing collaborations, or providing funding, for research.

## 2. What training is required to conduct research at the University of Pittsburgh?

At a minimum, all researchers and staff must complete courses from the Collaborative Institutional Training Institute (CITI) through [www.citi.pitt.edu](http://www.citi.pitt.edu). Completion of the following courses satisfies the basic requirements as a researcher. Each provides a track for biomedical researchers and social and behavioral researchers:

- Responsible Conduct of Research
- Research with Human Subjects

Other courses may be required depending on the type of research being conducted. Refer to the Office of Research Protections Training Table (<https://www.orp.pitt.edu/training/training-table-list>) for the summary of courses.

## 3. What other education is provided for researchers?

A variety of educational programs are offered throughout the year through HRP, ORP and CTSI. Program information can be found on the [University Events Calendar](#). An Orientation to Research Fundamentals is provided twice a year for research staff <https://ctsi.pitt.edu/education-training/orientation-to-research-fundamentals/>. Specialized education sessions are available upon request and are customized to the Department's needs. Contact [askirb@pitt.edu](mailto:askirb@pitt.edu) office for specialized options.

## 4. How can study teams contact the IRB with Questions?

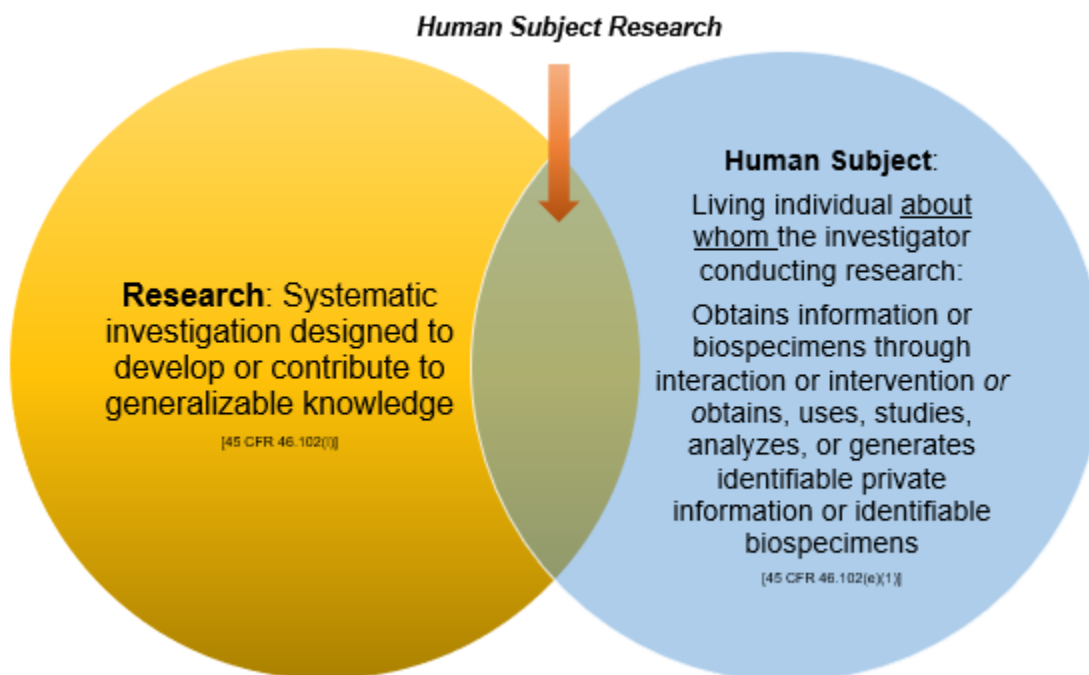
The IRB office has a dedicated account for questions. An answer is usually provided within 24 hours: [askirb@pitt.edu](mailto:askirb@pitt.edu). The IRB staff is always available to answer questions and consult with researchers. Staff can be contacted individually through <https://www.hrpo.pitt.edu/people>. Staff members are assigned to researchers based on the first letter of their last name. Researchers are encouraged to reach out any time in the process. The IRB encourages investigators to consult with IRB staff prior to entering a protocol.

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## 5. When is IRB review necessary?

The IRB is required to review all research that involves human subjects (FDA requirements may differ. See Below, question 11).



## 6. When can a study be started?

Research involving human subjects cannot begin until final IRB approval is secured. Researchers should also ensure that all other required institutional approvals have been secured prior to initiating any research procedures.

## 7. What changes can be made to a protocol without prior IRB approval?

Only those changes that are necessary to eliminate an apparent immediate hazard to the research subject can be initiated without prior IRB approval. All other changes **must** have IRB approval prior to initiation.

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## 8. Is Scientific Review necessary prior to IRB review?

All new protocols and certain modifications must undergo departmental scientific review unless they are federally funded (e.g. NIH, NSF). Note that studies funded by the Department of Defense must undergo departmental scientific review as well.

The mechanisms for Departmental Scientific Review are determined by each individual department. Investigators should check with their department for the requirements and processes. Some departments do require that all research, regardless of funding source, undergo Departmental Scientific Review.

The PittPRO system routes the protocol to the appropriate scientific review body based on the choice made in Study Scope #6.

### 6. \* Determining Scientific Review:

- No scientific review (limited to Exempt projects and Emergency Use requests)
- UPCI PRC - University of Pittsburgh Cancer Institute Protocol Review Committee
- WPIC SRC - Western Psychiatric Institute and Clinic Scientific Review Committee.
- MWH CTRC - Magee Womens Clinical and Translational Research Center
- Department Scientific Review (DOD requires departmental review)
- Received External funding where scientific merit was established as a condition of funding

[Clear](#)

### \* Choose the appropriate organization to conduct the scientific review:

## 9. What type of safety monitoring is required?

Depending on the level of risk of the study, a data and safety monitoring plan or board may be necessary. A DSMP is a specific plan developed by the local principal investigator that outlines how study progress will be monitored throughout the course of the research to ensure the safety of subjects as well as the integrity of the data. The DSMP should indicate who is responsible for monitoring, what will be monitored, how often it will be monitored and how often and what will be submitted to the IRB. The IRB may determine that a group independent of the study performs the monitoring. Some considerations that might play into whether a Plan or a Board is necessary are included:

- a. The study is conducted at multiple sites and the level of risk is greater than minimal
- b. The study involves a large number of subjects (Phase III)
- c. There is a significant likelihood of a serious adverse event to the involved subject or high-risk intervention
- d. The study generates data that is blinded or randomized
- e. The study involves a gene transfer methodology

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## 10. What regulations need to be followed and when?

Food and Drug Administration (FDA)	Office for Human Research Protections (OHRP)
Establishes regulations that govern study sponsors, investigators and IRBs	Regulates research involving human subjects in order to protect the rights and safety of subjects
-21 CFR 50 -21 CFR 56	-45 CFR 46
Applies to investigations that include FDA regulated test articles (i.e. drugs, devices, food)	Applies to all research conducted, supported or otherwise subject to regulation by a federal agency

Note that both sets of regulations will apply to research studies that fall under the jurisdiction of both agencies.

## 11. What are some differences between the FDA regulations and the Federal Policy regulations?

FDA Regulations	The Common Rule
<p><b>Clinical Investigation:</b></p> <p>Any experiment that involves a test article and one or more human subjects</p>	<p><b>Research:</b></p> <p>A systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge</p>
<p><b>Human Subject:</b></p> <p>An individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient</p>	<p><b>Human Subject:</b></p> <p>A living individual about whom and investigator conducting research obtains:</p> <ul style="list-style-type: none"> <li>information or biospecimens through interaction or intervention</li> <li>or</li> <li>obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens</li> </ul>

## 12. What if a subject complaint cannot be resolved?

Subject complaints that cannot be resolved should be reported to Human Subject Protection Advocate (HSPA) at 1-866-212-2668. The HSPA number connects to the IRB Director's office and

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is triaged for resolution accordingly. The HSPA number is required to be included in all consent forms.

## **13. What are the responsibilities of a Principal Investigator?**

The Principal Investigator (PI) has the ultimate responsibility for the conduct of the research study. This includes following the study protocol, keeping the study up-to-date with modifications and continuing reviews and ensuring that the research team has adequate training and resources to conduct the study safely and properly. The PI also holds the responsibility for the following aspects:

- Promptly reporting any protocol deviations to the IRB;
- obtaining and documenting informed consent according to the process approved in the protocol
- maintaining adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risk/benefit ratio of study participation;
- Promptly reporting any internal or external adverse event that is considered to be 1) unexpected; 2) serious and 3) possibly or definitely related to the study to the IRB (and applicable others like the FDA or sponsor)
- reporting promptly to the IRB any significant changes in the risk/benefit of study participation;
- ensuring that, in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible;
- ensuring that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study;

## **14. What is the Consent Process?**

Informed consent is one of the primary ethical requirements for research involving human subjects and reflects the Belmont Principle of Respect for Persons. Consent reaches beyond the signature on the document to the process behind it. The process includes an ongoing dialog between the research team and the subject and any other people who the subject wishes to involve in the process. The process needs to be designed to provide the potential research subjects with all of the relevant information they need to make a fully informed, autonomous decision as to whether they wish to participate or wish to continue to participate in a research study.

## **15. Who needs to be a part of the consent process?**

The consent process needs to follow the consent procedures in the IRB approved protocol. Study teams should review the [Obtaining Informed Consent](#) guidance while writing the protocol. Usually the consent process is between a member of the research team and the potential subject.

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However, there are many other scenarios that could take place. In the event that the subject is decisionally impaired, a legally authorized representative would need to be a part of the process. In most cases, a parent would need to be a part of the process if the subject is a child. Investigators should consult with the HRPO office to determine the appropriate course of action in unique consent situations.

## **16. Is a signature always necessary to document consent?**

No. A signature is not always necessary but is the most common form of documenting consent. The regulations state that “No investigator may involve a human being as a subject in research...unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative” (45 CFR 46.116). However, the regulations also allow a waiver to document consent and a waiver to obtain informed consent at all.

## **17. What is a waiver to document informed consent?**

An investigator and subject still engage in a discussion about the research study and go through the consent process but the subject does not sign a consent form. Often times, the subject will be given an information sheet with the details of the study for their reference. The most common reasons to obtain a waiver to document consent are for conduct of phone screening or procedures, online consent, or other situations where written consent doesn't make sense. The PI must demonstrate that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117(c)]

## **18. What is a waiver of informed consent?**

This is when no consent process takes place and subjects do not know that they are a part of the research. The PI must demonstrate that the research activity involves no more than minimal risk to subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research activity could not practicably be carried out without the waiver, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format, and whenever appropriate, the subjects will be provided with additional pertinent information after participation [45 CFR 46.117(f)]. It is most often used for a medical record review for recruitment, a chart review for research, a waiver of parental permission where a child would still provide assent to participate, or other justifiable minimal risk activity.

## **19. Do some funding agencies have additional requirements?**

Yes. Studies funded by the Department of Defense, National Science Foundation, Department of Justice, and EPA, to name a few, have other requirements. Investigators should refer to the Policy and Procedure Manual, [Chapter 26, Additional Requirements for Research Supported by Other Federal Agencies](#).



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## 20. What events must be reported to the IRB?

Unanticipated problems Involving Risk to Subjects or Others, some adverse events, and deviations or non-compliance must be reported to the IRB in a timely manner.

- Unanticipated Problems involving risk to human subjects or others
- Adverse Events
  - Internal Adverse Events that are (i) Unexpected, (ii) Related or Possibly Related to the Research Intervention, and (iii) serious or otherwise suggests that the research places the subject or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.
  - External Adverse Events that are (i) Unexpected; (ii) Related to the Research Intervention and (iii) Serious or otherwise suggests that the research places subjects or others at greater risk than was previously recognized.
- Non-compliance/protocol deviations that: Adversely affect the rights and welfare of human subjects OR compromise the integrity of the research data

Read the [Reportable New Information FAQs](#) and Policies and Procedures, [Chapter 17 – Reportable Events](#) for more information

## 21. What is an unanticipated problem?

Any accident, experience, or outcome that is unexpected in nature, severity or frequency, is related or possibly related to a subject's participation in the research, or places subjects or others at a greater risk of harm (physical, psychological, economic, or social harm) than was previously known or recognized

## 22. What is an adverse event?

Any unfavorable medical occurrence in human subjects, including abnormal signs (e.g., abnormal physical exam or laboratory findings), symptoms, or disease temporally associated with, but not necessarily considered related to, the subject's participation in the research

## 23. What is a protocol deviation or non-compliance?

Failure on the part of the investigator or any member of the study team to follow the terms of University of Pittsburgh IRB approved protocol or to abide by applicable laws or regulations, or University of Pittsburgh IRB policies (includes protocol deviations).

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## 24. What are some questions that could be asked of PIs or study team members during an interview?

A variety of study specific questions may be asked regarding study conduct and procedures.

### **Recruitment:**

- How are subjects identified?
- How is inclusion/exclusion criteria verified and by whom?
- Describe the informed consent process

### **Informed Consent:**

- Who introduces the study to prospective subjects?
- Who performs the consent process and who determines who is present?
- In what setting is the informed consent process performed?
- How is the legally authorized representative determined when subjects cannot consent on their own behalf?
- What methods are used to ensure that the subject truly understands what is being asked of them and the risk that is a part of the study?
- Is the PI typically present?

### **Reportable Events**

- How would you report an unresolvable subject complaint?
- What is an unanticipated problem?
- What are the reporting requirements for unanticipated problems and adverse events?
- How would you handle a protocol deviation or non-compliance?