

Human Subjects

What is Human Subject Research?

Investigators conduct human subject research when they carry out experiments on humans, conduct observational studies, or obtain data and individually identifiable private information about human beings. This includes people's responses to surveys and questionnaires. Below are some topics you should be aware of regarding the administration of projects using human subjects.

The National Institutes of Health requires that universities establish the Institutional Review Board (IRB) to oversee the use of human subjects in research. The IRB has the authority to review, approve, disapprove, or require changes in research projects involving human subjects. IRB rules apply to all faculty, staff, and student projects, regardless of whether the project is funded externally, internally, or receives no funding support.

Pre Award Process

The use of human subjects must be noted on the PIF when a proposal request is submitted. The PI is responsible for contacting the IRB and obtaining all required reviews and approvals prior to starting a research project. RA&F will not establish an award in the system or authorize spending until it is notified by the IRB of the approval of an individual project.

The basic IRB procedures are:

- PI completes application and forwards to IRB for review
- IRB reviews protocols and ensures that the science is appropriate and ethical and that all project personnel have received IRB training
- IRB approvals are for a one year period and must be renewed annually
- All modifications to the approved protocol must be submitted using the appropriate form and re-approved by the IRB
- When the project is complete, the PI must submit a closure form to the IRB

Please see the [IRB](#) website for forms and details.

Post Award Management

Payments made directly to Human Subjects should be charged to the 0781 account code. Other incidentals directly related to Human Subjects such as food or refreshments should use account code 009. Please feel free to contact Post-Award if you have any questions regarding the use of account codes for support charges

Please be aware of the distinction between Human Subjects Payments and Participant Support. Even though they are "participating," people who are the subjects of study are

not Participants. The key trait of a Participant is that they receive a benefit in some way from their involvement. In the case of human subjects, the research is receiving a benefit from them. Please see the [Participant Support Tip](#) for more information. If you find that charges have been erroneously placed using the 091 or other participant support account codes, please contact your respective Post Award administrator for assistance.

If you have any questions, please contact your Pre or Post Award RA&F Administrator.

For more on Human Subjects, please see:

The Institute's policy here: [Human Subjects](#).

Department of Health and Human Services: [DHHS 45 CFR 46](#)