

Human Subjects Research

Research involving a living individual about whom an investigator obtains *either* data through interaction *or* identifiable, private information

Examples of human subjects research include:

- Collection of blood
- Administer medicine
- Change their environment
- Conduct a survey
- Interviews
- Administer a psychological test
- Have their name
- Collect data
- Test a new educational technique

In your NIH application:

- ✓ **HS** Protection of Human Subjects Section

If funded, you will need:

- ✓ **FWA** An Institutional Federal-Wide Assurance with OHRP
- ✓ **IRB** Annual IRB approval
- ✓ **EDU** Human Subjects education* even for exemptions

Unless...

you are conducting research with one of the six categories of activities that are considered so low risk for human subjects and are **exempt** from the federal regulations. You will need to justify your exemption in the Protection of Human Subjects section and you will not need an FWA or IRB approval.

The NIH uses 3 of the exemptions:



Exemption 1

Conducted in an educational setting involving normal education practices



Exemption 2

Using tests, interviews, or observations unless identifiable and pose risks



Exemption 4

Collection or study of existing data or specimens if publicly available or de-identified