Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Examples of human subjects research include:

- Collecting blood
- Conducting a survey
- Changing participants' environment
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique

Included in the NIH application:

✓ Protection of Human Subjects attachment

If funded, grant recipient will need:

✓ An Institutional Federalwide Assurance (FWA) with OHRP

✓ IRB approval or determination of exemption

✓ Human Subjects education* even for exemptions

If research meets the criteria for one of the eight categories of activities that are **exempt** from the federal regulations, not all of the above may apply. Some of the exemptions require a limited IRB review (7 and 8, and some designs under 2 and 3).

Exemptions:

Exemption 1
Conducted in an educational setting involving normal education practices

Exemption 2
Use of educational tests, surveys, interviews, or observations of public behavior

Exemption 3
Use of benign behavioral interventions in adults

Exemption 4
Collection/study of data or specimens if publicly available or recorded such that subjects cannot be identified*
*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

Exemption 5
Public service program research or demonstration projects

Exemption 6
Taste and food quality evaluations

Exemption 7
Storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.

Exemption 8
Secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required.

Questions/comments? Contact OER-HS@nih.gov