Preparing Your Human Subjects Section

What is Human Subjects Research?

Human subjects research is research involving a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through **intervention** or **interaction** with the individual, or
2. **Identifiable** private information

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Human Subjects Research Exemptions (45 CFR 46.101)

The following research examples are <u>not</u> considered humans subjects research:

1. Research that involves only the use of coded private information or human biological specimens or data if:
    a. All subjects are deceased **OR**
    b. The data/specimens were not obtained specifically for the proposed research AND none of the investigators involved in the research can ascertain the identity of the subjects, either directly or indirectly.
2. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    a. Research on regular and special education instructional strategies, or
    b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
4. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if:
    a. The human subjects are elected or appointed public officials or candidates for public office, or

   b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
6. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
7. Taste and food quality evaluation and consumer acceptance studies, if:
   a. Wholesome foods without additives are consumed, or
   b. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Human Subjects Section Components

The Human Subjects Section of your Fellow or Resident Research Fund application should include the following components:

- Considerations for the Protection of Human Subjects
- Adequacy of Protection Against Risks
- Potential Benefits of the Proposed Research to Human Subjects and Others
- Importance of the Knowledge to be Gained
- Data and Safety Monitoring Plan/Board

Please see below for more information about the content of each section.

Considerations for the Protection of Human Subjects

Describe how human subjects will be involved, characteristics of the subject population, research design and methodology, sources of materials, and potential risks to subjects. Include:

- Description and justification for the proposed involvement of human subjects
- Characteristics and demographics of subject population (e.g., sample size, age range, and health status)
- Inclusion/exclusion criteria
- Rationale for involvement of vulnerable populations (e.g., fetuses, pregnant women, children, prisoners, institutionalized individuals, or others)
- Description and justification of research procedures (e.g., dosage, frequency of intervention, etc.)

- Description of research material, data, and information collected
- Access to personally identifiable information collected and retained
- Methods for the management and protection of materials and information all potential risks to subjects (e.g., physical, psychological, financial, legal, or other) including likelihood and seriousness
- Any alternative treatments or procedures
- Role of collaborating sites where research will be performed

Adequacy of Protection Against Risks

Describe the following:

- How subjects will be recruited
- Description of informed consent process, parental permission and assent
- Waiver for any elements of consent
- How risks described previously, including privacy and confidentiality, will be minimized
- Additional protections for vulnerable populations
- Ensuring necessary medical/professional intervention for adverse events

Potential Benefits of the Proposed Research to Human Subjects and Others

Describe how potential risks to subjects appear reasonable in relation to anticipated benefits.

Importance of the Knowledge to be Gained

Describe how potential risks to subjects appear reasonable in relation to the importance of the knowledge that may result from the study.

Data and Safety Monitoring Plan/Board

If the proposed research includes a clinical trial, include an appropriate Data and Safety Monitoring Plan that includes:

- A description of a monitoring plan, who will be responsible for monitoring and the process by which Adverse Events (AEs) and Unanticipated Problems (UP) will be reported to all relevant regulatory bodies.
- A Data and Safety Monitoring Board (DSMB) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials.

For more information, visit Data and Safety Monitoring Plan.

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Sources and References

1. https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf
2. https://humansubjects.nih.gov/data_safety
3. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html
4. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(b)(2)
5. http://www.hhs.gov/ohrp/policy/cdebiol.html