

Taking Steps to Protect Research Participants

A process with and procedures for protecting participants is an important part of any research study that involves human beings as “subjects.” Examples of abuse of human research participants in both private and government-sponsored research have been well documented in our country’s history.

All studies that receive federal funds must be examined and approved by an independent Institutional Review Board (IRB) to ensure that human participants are safeguarded, before the research can begin. In the NCDDR’s technical assistance newsletter, *The Research Exchange*, Volume 7, Number 1 (NCDDR, 2002), some background information, questions and answers from U.S. Department of Education (ED) staff, and extensive resources on this topic were presented.

This document is intended as a brief guide for responding to Federal requirements for protecting human participants (human subjects) in research activities through the following four steps:

- Step 1.** Determine if the project’s research activities fall within the guidelines of the regulations governing human subjects protection, or if they are exempt.
- Step 2.** Develop a plan to show how human research participants will be protected.
- Step 3.** Prepare materials required for IRB review.
- Step 4.** Complete the Human Subjects Protection items on the Application for Federal Education Assistance.

Step 1.

Determine if the project’s research activities fall within the guidelines of the regulations governing human subjects protection, or if they are exempt.

The Federal regulations for protection of human subjects are known as the *Common Rule*. The ED regulations codifying the *Common Rule* are found in 34 CFR 97 - Protection Of Human Subjects, Subpart A--Basic ED Policy for the Protection of Human Research Subjects, and Subpart D--Additional ED Protections for

Children Who are Subjects in Research (see <http://www.ed.gov/offices/OCFO/humansub/part97.html>).

Examine the project’s research activities and the definitions of research and human subjects to determine if project activities fall within the guidelines of these regulations. Some research activities that meet these definitions may not be covered by the regulations if they are in one of six categories of exempt research activities (example: medical record data). *The Research Exchange*, Volume 7, Number 1, page 12 (see http://www.ncddr.org/du/researchexchange/v07n016_granteexp.html#research) has more information. A project that is exempt must describe the proposed activities in an “Exempt Research Narrative” to be included with the proposal application (see Step 4, Item 12a in this document).

Step 2.

Develop a plan to show how human research participants will be protected.

Projects with research activities that do fall within the guidelines for the regulations for human subjects protection are required to include a narrative that describes nonexempt research activities as part of the Application for Federal Education Assistance (Form ED 424). Seven important elements to include are outlined in the *Instructions for Form ED 424*:

Element 1. Human Subjects Involvement and Characteristics

- Provide a detailed description of the proposed involvement of human subjects.
- Describe the characteristics of the subject population, including:
 - their anticipated number,
 - age range, and
 - health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as:
 - children,
 - children with disabilities,

- adults with disabilities,
- persons with mental disabilities,
- pregnant women,
- prisoners,
- institutionalized individuals, or
- others who are likely to be vulnerable to coercion or undue influence.

Element 2. Sources of Materials

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.
- Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Element 3. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects and the consent procedures to be followed. Include:
 - the circumstances under which consent will be sought and obtained,
 - who will seek consent,
 - the nature of the information to be provided to prospective subjects, and
 - the method of documenting consent.
- State if the Institutional Review Board has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

NOTE: §46.116: An Informed Consent Checklist - Basic and Additional Elements is found here: <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm>

Element 4. Potential Risks

- Describe potential risks, including:
 - physical,
 - psychological,
 - social,
 - legal, and
 - other.
- Assess the likelihood and seriousness of the potential risks.
- Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

Element 5. Protection Against Risk

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality.
- Assess the likely effectiveness of the procedures.
- Where appropriate, discuss provisions for

ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

- Where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

Element 6. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Element 7. Collaborating Site(s)

- If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

Step 3.

Prepare materials required for IRB review.

The information developed in Step 2 will serve as the basis for the documentation required by the IRB. The IRB that reviews the project will have its own guidelines, forms, and procedures that must be followed. Depending on the size of your organization, there may be a specific department dealing with research proposals that can help you identify what information will be needed to present to the IRB, give you the appropriate forms, and tell you when the IRB will meet to review proposals.

When a project involves only minimal risk to participants, it may qualify for an expedited review that does not go to the entire IRB. Minimal risk “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (34 CFR 97, Subpart A., 97.102 (g)).”

If the IRB requires modification to any of the proposed research activities, these must be made and approved by the IRB *before* the research can be initiated. If changes are made to protocols or any of the research activities after they have been approved, these changes must be submitted to the IRB for further approval before they can be implemented. IRB approval is in effect for

one year, a review must be requested each year the project continues.

ED does not require that the proposal application include certification of IRB approval. If an application that involves non-exempt human subjects research is selected for funding, ED will request that the applicant seek IRB approval and send the certification to ED within 30 days (from *Instructions for Form ED 424*).

Step 4.

Complete the Human Subjects Protection items on the Application for Federal Education Assistance.

With the information gathered and developed in the previous three steps, completing the required items in the Application for Federal Education Assistance (Form ED 424) should be straightforward. Form ED 424 serves as the cover page for proposals submitted to the ED.

Following are the items for Human Subjects Protection.

ITEM 12. *Are any research activities involving human subjects planned at any time during the proposed project period?*

- Check **“Yes”** if research activities involving human subjects are planned, even if the research is exempt from the regulations for the protection of human subjects, and go to Item 12a.
- Check **“No”** if research activities involving human subjects are not planned at any time during the proposed project period, and go to Item 13 (Item 12a. is not applicable).

ITEM 12A. *Are all the research activities proposed designated to be exempt from the regulations?*

- Check **“Yes”** if all the research activities proposed are designated to be exempt. Give the number(s) corresponding to one or more of the six exemption categories (see “Research and Exempt Research Activities,” *The Research Exchange*, Volume 7, Number 1, page 12).

If **“Yes”** is checked, a brief “Exempt Research Narrative” must be included with the proposal, immediately following the ED 424 face page. It must contain sufficient information about the involvement of

Special Considerations for Participants with Disabilities

People with disabilities are identified among populations that may be vulnerable to coercion or undue influence and thus need additional safeguards to protect their rights and welfare. Special considerations may be needed at all levels of a study, from recruitment, to explanation and informed consent, and throughout the study to ensure the participant is adequately protected. Respect for the individual’s autonomy must be maintained for all participants as well as potential participants.

The American Psychiatric Association Guidelines for Assessing the Decision-making Capacities of Potential Research Subjects with Cognitive Impairments discusses standards and procedures for assessing decision-making capacities (APA, 1998).

Researchers who recruit participants with cognitive disabilities must be aware of a participant’s decision-making capacities and ability to give informed consent. Some participants may be able to make their own decisions, with some modifications and with assistance. Other participants may have alternative decision-makers whose consent can be substituted (APA, 1998). People who may not be able to give fully informed consent may be asked to give verbal assent

to participate once the project has been explained.

The ability to indicate a choice, to understand information presented, and to recognize possible consequences may vary for some individuals at different times, places, or for other reasons. The APA suggests that researchers establish standards and procedures for assessing potential research participants to ensure that only those persons capable of giving informed consent are invited to make decisions about their research participation, or, that surrogates are asked when it is in the best interest of the individuals (APA, 1998).

A risk/benefit analysis may be more difficult for participants with cognitive disabilities. When minimal risk and some potential benefit are involved, the decision is not as difficult. More safeguards are needed when potential risks are greater than minimal (Berg, 1996).

Cultural differences may affect the understanding of research participants who are deaf, in addition to communication differences. It is important to have trained interpreters to explain the study and not rely on family members, in order to promote truly

informed consent for deaf participants (NIDCD, 1999).

Cindy Harrison-Felix, Research Supervisor at Craig Hospital in Englewood, CO re-wrote an Informed Consent to be Understood by Individuals with Brain Injury for the Rocky Mountain Regional Brain Injury Model System project. She used easier words, shorter words and sentences, a question and answer format and bulleted text to help explain major points. The new document is three pages from the original five. The readability level is grade five, compared to grade 12. To see the sample document and a presentation explaining the process, visit the NCDDR Web site: <http://www.ncddr.org/du/products/focus/focus1/consent.html>

References

- American Psychiatric Association (APA), (1998). Guidelines for assessing the decision-making capacities of potential research subjects with cognitive impairment. *American Journal of Psychiatry*, 155(11).
- Berg, J. W. (1996). Legal and ethical complexities of consent with cognitively impaired research subjects: Proposed guidelines. *Journal of Law, Medicine, & Ethics*, 24(1) 18-35.
- National Institute on Deafness and Other Communication Disorders (NIDCD), (1999). Working group on communicating informed consent to individuals who are deaf or hard-of-hearing. NIH Pub. No. 00-4689. <http://www.nidcd.nih.gov/news/inform/printready.htm>

human subjects in the proposed research to allow a determination that the designated exemption(s) are appropriate.

- Check “No” if some or all of the planned research activities do fall within the guidelines for human subjects protection regulations, and provide the institution’s Multiple Project Assurance (MPA) or Federalwide Assurance (FWA) number, if available. Your organization’s grants office will give you this number. Write “None” if there is no Assurance number. If the project is funded, the Assurance must be given before the project can begin.

If “No” is checked, include a brief “Nonexempt Research Narrative” with the proposal, immediately following the ED 424 face page. It should be brief but clear in addressing the elements previously identified in Step 2.

From *Form ED 424 Application for Federal Education Assistance*, including *Instructions and Definitions for Form ED 424*:

PDF format:

<http://www.ed.gov/offices/OCFO/grants/appforms/ed424.pdf>

Word 97 format:

<http://www.ed.gov/offices/OCFO/grants/appforms/ed424.doc>

Word Perfect 6.1 format:

<http://www.ed.gov/offices/OCFO/grants/appforms/ed424.wpd>

SEE: *Pitfalls to Avoid in Responding to Item 12 of the ED 424*:

<http://www.ed.gov/offices/OCFO/humansub/pitfalls.html>

Summary

It is not possible to devise a comprehensive listing of activities that will fulfill the requirements for human subjects protection for every proposed research project. These activities must be unique for every project, reflecting the characteristics of the proposed activities, data collection procedures, and the potential pool of human participants, among other variables. The four steps presented in this document will ensure that researchers are clear about which research activities fall within the guidelines of the *Common Rule* for protection of human subjects. It also provides an outline for

Resources

Copies of the Department of Education’s Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff, Office of the Chief Financial Officer.

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ED’s Protection of Human Subjects in Research Web Site:
<http://www.ed.gov/offices/OCFO/humansub.html>

ED Regulations online:
<http://www.ed.gov/offices/OCFO/humansub/part97.html>

For NIDRR-funded projects, there are additional requirements regarding IRB membership in 34 CFR 350 and 34 CFR 356: <http://www.ed.gov/offices/OCFO/humansub/34cfr350.htm>

The Research Exchange, Volume 7, Number 1 resource list:
<http://www.ncddr.org/du/researchexchange/v07n01/>

- Federal Government Resources on Human Subjects Protection, p. 3
- Resources for Institutional Review Boards, p. 9
- Resources on Human Research Participant Protection, pp. 17-19

developing a plan that will protect the participants in that particular project, and the basic elements to prepare for an IRB review. Finally, it clarifies the expectations of the Federal application form.

This will help to ensure that proposals provide sufficient details about how the researchers will maintain respect for and ensure the protection of the people who serve as research volunteers, including volunteers who may have disabilities, and who help to make research progress possible.



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The NCDDR assists, through information and technical assistance, NIDRR grantees with identifying and crafting dissemination strategies. These strategies are designed to meet the needs of a grantee’s unique target audience. NCDDR also analyzes and reports on dissemination trends relevant to disability research.



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