



## Guidelines for Protection of Human Subjects

Traditional empirical research is defined in federal regulations as "a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102). When such research involves human subjects, approval must be sought from an Institutional Review Board (IRB) to assure that the study procedures protect the rights and safety of the subjects. Applied Research manuscripts submitted to TNR must contain a statement that the study has been approved by an IRB. While Practice Reflections and Practice Reports usually do not require IRB review, authors should be aware of the standards that ensure protection of participants.

The *Common Rule* spells out the criteria that an Institutional Review Board (IRB) must use in evaluating a study (Breault, J.L., 2006). These same protections should shape the development of any study that involves human participants:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive, even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research, and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”

The *Common Rule* states the basic elements of informed consent as:

1. A statement that the study involves research, an explanation of the purposes of the research, a statement of the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation will be provided, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

The Common Rule standards help assure that subjects will be protected and can freely decide to withdraw from the study at any time. There are additional requirements when subjects are from a group considered to be vulnerable such as children or prisoners. In the case of children, parents must give written permission for their child to participate.

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Breault, J.L., (2006). Protecting human research subjects: The past defines the future, *The Ochsner Journal*, Spring; 6(1): 15–20.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127481/> P

Code of Federal Regulations. (2022, May 6). Title 45 CFR 46.102

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102>