

Page 94, #5

Replace the sentence:

The investigator must be satisfied that the explanation has been understood and consent in writing obtained without duress or deception.

With:

The investigator must be satisfied that the explanation has been understood and obtain consent in writing, unless documentation of informed consent has been waived, without duress or deception.

Page 96, Section C

Replace all of Section C with:

C. Research that involves human subjects but does not need approval from the Institutional Review Board

In pursuit with CFR 46.101, federal guidelines state that only the IRB can determine the status of a proposed study. Because of this mandate, all potential research studies involving human participants or identifiable records must be submitted to the IRB for review before being started.

One narrowly defined study type is recognized as an exception to this policy. IRB review and approval is not needed for:

1. Studies in undergraduate classes or graduate seminars that involve human participants and are:
 - a. conducted solely for instructional purposes, and
 - b. not intended to contribute to general knowledge.

When a study is designed to provide a learning experience for students and when the instructor and student investigator(s) have no plan, intention, desire, or hope to publish, present, or report the findings of this study in any off-campus setting (e.g., journal, report, conference, other off-campus outlet, etc.), the activity will not be considered to be research, and will not require IRB review.

In this instance, faculty instructors are wholly responsible for classroom projects conducted by students in their classes, and for ensuring that these student projects treat human participants ethically.

Page 97, paragraph 1

Replace paragraph 1 (The principal investigator should provide the board with...), with:

The Principal Investigator should provide the board with a protocol for each new research project involving human subjects. In addition, all supporting documents should be included, such as: questionnaires, signed letters of participation and agreement by institutions participating with Northern Kentucky University, personal interview statements, and debriefing procedures. In accordance with board guidelines, a single copy should be submitted to the IRB Administrator for review. Please note, grant proposals for external support should not be used as the protocol because they are often too long and frequently do not address the concerns of the board.

Page 97, Section F, 1st sentence

Replace this sentence:

All protocols are screened for completeness by the board chair prior to the conduct of a formal review.

With:

All protocols are screened for completeness during IRB Pre-Review by the IRB Administrator prior to the conduct of a formal review.

Page 99, Section G

Replace Section G with:

G. Actions by the Institutional Review Board

In pursuit with 45 CFR 46, after review and discussion of the protocol, the board will take one of the following actions:

1. Classify the Submission as Not Research: This includes quality improvement projects taking place in the classroom with no intention to present or publish collected data.
2. Approve the Research as Exempt: Exempt studies are those that involve no danger to the subjects. This includes procedures such as standard classroom activities or interviews on non-threatening topics. Projects that do not involve changes in the ordinary risks of daily life or in recognized occupational risks are also considered no-risk. Written informed consent is required in exempt IRB studies. No need for IRB oversight unless changes are made to the protocol.
3. Approve the Research as Expedited: The research may involve some risk to the subjects, but is not unreasonable. The potential benefits of the research outweigh the risks, and risk-management procedures have been taken to minimize the risks. This approval requires oversight

by the IRB and annual continuations must be submitted if the study will continue past the one year approval date.

4. Full Board Review Approval: A Full Board Review approval requires quorum approval of the IRB. The board may request the investigator to be present to discuss the research proposal. This may occur when the IRB finds the research to have more than minimal risks and as defined by federal regulations, the elements, procedures or interventions require additional provisions or safeguards.

5. Disapprove the Research: The board is of the opinion that the potential benefits of the research do not outweigh the risks to the subjects. Some modifications or clarifications might be requested of the PI in all types of research. The modifications required by the board may include such items as revising the consent form to explain the procedures more clearly, restricting use of a certain procedure, or requiring use of specified safeguards necessary for the protection of human subjects.

Page 100, Section K

2nd Sentence, replace this sentence:

Such forms must be retained by the investigator (or faculty advisor) for a minimum of three (3) years after termination of the project.

With:

Such forms must be retained by the investigator (or faculty advisory) for a minimum of six (6) years after termination of the project. If the records are part of a misconduct investigation, all records must be retained for a minimum of seven (7) years after the termination of the project.

Page 101, paragraph 2, sentence 1

Replace this sentence:

These records shall be maintained for at least three (3) years after completion of the research and shall be available to authorized member of the Department of Health and Human Services at reasonable times and in a reasonable manner.

With:

These records must be retained by the investigator (or faculty advisory) for a minimum of six (6) years after termination of the project. If the records are part of a misconduct investigation, all records must be retained for a minimum of seven (7) years after the termination of the project.

The records must be available to authorized members of the Department of Health and Human Services at reasonable times and in a reasonable manner.