

Application for IRB Review
Tips and Guide
082009

General Instructions:

Submit your typed Application for IRB Review with original signatures to the IRB Administrator, AC 616, Northern Kentucky University, Nunn Drive, Highland Heights, KY 41099. Be certain to attach (1) consent forms / statements, (2) CITI IRB training completion certificates, (3) data collection instruments or measures, (4) recruiting materials, and (5) supporting letters or documents. Faxed applications are not accepted.

Project Title:

Provide a descriptive, but brief name for your project.

Application Type:

Three application options are available, new study, revision, and continuation. A "New study" is one that you have not submitted previously for review, or one that you are resubmitting after the initial approval period has expired. The category, "Revise current study", refers to an active, approved research protocol that you are changing or modifying in some way. The category, "Continue current study with no changes", refers only to an active, approved study that you want simply to extend beyond the expiration date with no changes whatsoever. For the Revision and Continuation, enter the IRB protocol number (IRB #) assigned to your initially approved protocol.

Principal Investigator:

Enter all information for the person most responsible for this study. This person may be a faculty member, staff member, graduate student, undergraduate student, or external researcher. Note that principal investigators must complete the required six CITI training modules with an 80% passing score on each module. Modules may be repeated until this score is achieved. Additional modules may be required for special study populations. Print your CITI completion certificate and submit with your IRB Application.

Faculty Advisor:

Enter all information for the faculty member responsible for supervising the student principal investigator's research. Note that faculty advisors must complete the required six CITI training modules with an 80% passing score on each module. Modules may be repeated until this score is achieved. Additional modules may be required for special study populations. Print your CITI completion certificate and submit with your or your student advisee's IRB Application.

Other Researcher(s):

Enter all information for other persons who will be involved in obtaining informed consent, administering the study, working with identifiable data, or interacting with participants in any way. Add additional pages as needed by downloading from the IRB

web site. Note that other researchers on this project must complete the required six CITI training modules with an 80% passing score on each module. Modules may be repeated until this score is achieved. Additional modules may be required for special study populations. Submit a printed copy of other researcher CITI completion certificates with your IRB Application.

Part A – General purpose of study

Briefly explain, in nontechnical lay terms, the reasons for conducting this study. This should be understandable by someone with little training in your field, and not a technical or methodological treatise. We simply need to grasp what you hope to learn by conducting this research.

Part B1 – Participants

Describe your intended or target group of participants in terms of age, gender, or ethnic status, and other characteristics (e.g., demographic, educational, personal, or economic) that are required to participate.

Part B2 – Participants

Check the box(es) for any participant group from whom you intend to collect data.

Part C1 – Recruiting

Check the box(es) for any recruitment method that you will use to obtain participants for your study. Be sure to submit copies of any recruiting document, and the dialogue for any oral (e.g., telephone, personal) recruiting methods.

Part C2 – Recruiting

Describe in greater detail how each type of recruiting method checked in Part C1 will be used.

Part C3 – Recruiting

Identify the persons who will contact potential participants.

Part C4 – Recruiting

Explain how you will document that participation is voluntary (e.g., signed informed consent statement).

Part C5 – Recruiting

Describe any links that researchers have with participants outside of the research study itself.

Part C6 – Recruiting

Describe any agencies, informal groups, or formal organizations from whom you will gather data by contacting members. Be sure to submit a statement on letterhead, signed by an administrator of this group, granting you permission to collect data by contacting group members.

Part C7 – Recruiting

For studies that involve examining existing records – that is, data that has been collected before the study begins – be sure to submit a statement on letterhead, signed by an administrator of this group, granting you permission to collect data by examining its data files.

Part D1 – Informed consent

Check the box(es) for each item that appears in your consent form.

Part D2 – Informed consent

Describe the process that you will follow to obtain informed consent from potential participants. Be sure to submit a copy of your informed consent statement.

Part D3 – Informed consent

Explain how you will minimize the possibility of a participant feeling coerced or unduly pressured to participate.

Part E1 – Risk

Check the box(es) of any potential risks that could occur, both immediately from participating in your study and later after participating in your study if their identifiable data were to be inadvertently released into the public domain.

Part E2 – Risk

In greater detail, describe the risks to participants identified in Part E1 that may occur while participating in your study.

Part E3 – Risk

In greater detail, describe the risks to participants identified in Part E1 that may result from participating in your study if identifiable data are accessed by persons other than the researchers or accidentally released in the public.

Part E4 – Steps to reduce risk

Describe the actions that you will take to minimize the risks identified in E1, E2, and E3. Please address each risk separately.

Part F1 – Procedures

Using nontechnical, lay terms, describe the different activities, tasks, or behaviors in which participants will be asked to engage. For research activities to be conducted in schools, students who choose not to participate or whose parents do not provide informed consent, must be provided with an alternative activity that does not identify them as nonparticipants.

Part F2 – Procedures

Explain the length of time required for a participant to complete all of the tasks in your study, as well as any follow-up tasks or activities.

Part G – Measures

List and briefly describe the measures to be used during your research, regardless of administration format (printed, digital, oral). Provide a copy of each as it will appear to the participant. Be sure to include all instructions. For qualitative research that involves open-ended or unstructured interviews, describe the focus of the interview and give specific examples that demonstrate the range of questions to be asked.

Part H1 – Data collection

Check the box(es) for each type of data collection method that will be used.

Part H2 – Data security

Describe the methods that will be used to ensure that any data collected will remain confidential.

Part H3 – Data anonymity

Explain how anonymous data will be collected, and provide details that explain how researchers will not be able to link responses to individual participants.

Part H4 – Data confidentiality

Explain how data collected digitally (e.g., by email, web interfaces, computer servers or other networked sources) that can be linked to an individual participant will be maintained in a confidential way.

Part I1 – Benefits

Describe how, if in any way, participants will benefit directly from being involved in your study. Note: It is ok if participants do not directly benefit in any way. The IRB simply needs to be aware of any direct benefits to participants.

Part I2 – Benefits

Describe how, if in any way, this study will add to generalized knowledge in science or to society in general.

Part J1 – Dissemination of results

Explain where you will present the results of your research on campus. This could be to a class, department, project group, organizational unit, at the Celebration of Research and Creativity, or some other venue on the campus of Northern Kentucky University.

Part J2 – Dissemination of results

If you have a remote hope to share the results of your research off campus, explain where you hope to present it. This could include an academic paper submitted to a journal, a conference presentation, a report to an organization, a summary for a professional group, or a thesis submitted to Proquest (UMI).