

Morehead State University
Institutional Review Board (IRB) for the Protection of Human Subjects in Research
Instructions for Completing Your Protocol Application

STEP ONE: Before you begin your application, determine whether the project you are proposing is considered to be “research” under the federal guidelines. For assistance with this decision, consult the IRB Web site, or contact a member of the IRB.

STEP TWO: Before you begin to complete your application, please note you are required to complete CITI online training and provide your Course Completion Record to the committee with your application. In addition, please note that both Research and Sponsored Programs (RSP) and the IRB are available to assist you as you prepare your application and/or to pre-review your application materials. The advantage of contacting RSP or an IRB member first is that details of federal and IRB requirements specifically geared to your research protocol will be provided that should result in a quicker review process.

STEP THREE: Decide whether you believe your research protocol may be considered exempt from the federal regulations. You may get guidance about this from RSP, an IRB member or the IRB Standard Operating Procedures. If you believe your protocol qualifies as exempt, *you still must submit an application to the Board*, and you must complete an Exempt protocol application. Once you have done so, please e-mail the application, any accompanying documents (data collection instruments, consent/assent forms, CITI training completion certification, etc.) to BOTH s.niles@moreheadstate.edu and re.alfrey@moreheadstate.edu. You will not need to complete the other steps listed below. The IRB will determine if your request for exemption is granted and you will be notified of their decision by mail.

STEP FOUR: Consider whether you believe your research protocol may qualify for expedited review or whether it will require convened review. You may get guidance about this from your IRB mentor or from the IRB Standard Operating Procedures. For cases involving either expedited or convened review, you must complete the Expedited or Convened protocol application, then proceed to step five.

STEP FIVE: Complete the sections entitled “Detailed Research Description” (Part A) and “Informed Consent” (Part B). Then proceed to step six.

STEP SIX: Consider whether your research protocol involves data collection from special populations, including MSU students, minors, prisoners, or cognitively impaired persons, or if your protocol involves international research, internet research, or data collection from public elementary and/or secondary schools. If none of these issues applies, then proceed to step seven. If any of these apply to your research, you must complete the appropriate steps listed below:

If your research protocol involves data collection with *college students at Morehead State University*, complete the “MSU Students as Subjects” section (Part C) then proceed to step seven.

- If your research protocol involves data collection with *minors*, you must do the following

before proceeding to step seven:

- Complete the “Research Involving Minors” section (Part D) and the section entitled “Parental Permission and Assent of Minors”
- Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with minors
- Complete the special CITI online training module entitled “Research with Children” and provide your special Course Completion Record in this area to the committee with your application
- If your research protocol involves data collection with *prisoners*, you must do the following before proceeding to step seven:
 - Complete the “Prisoners As Subjects” section (Part E)
 - Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with prisoners
 - Complete the special CITI online training module entitled “Research with Prisoners” and provide your special Course Completion Record in this area to the committee with your application.
- If your research involves data collection with *cognitively impaired persons*, you must do the following before proceeding to step seven:
 - Complete the “Cognitively Impaired Persons” section (Part F).
 - If the impaired persons also are minors you also must complete the “Research Involving Minors” and the “Parental Permission and Assent” sections (Part D)
 - Provide the committee with a 1-2 page description of your qualifications or special expertise for conducting research with cognitively impaired persons (and minors if applicable).
- If your research involves *international research, internet research, or data collection from public elementary and/or secondary schools*, provide your special CITI online Course Completion Record in this area to the committee with your application

STEP SEVEN: Complete the “Assurances and Responsibilities” section (Part G)

STEP EIGHT: E-mail the application, any accompanying documents (data collection instruments, consent/assent forms, CITI training completion certification, etc.) to BOTH s.niles@moreheadstate.edu and re.alfrey@moreheadstate.edu.