IRB Frequently Asked Questions

1. What is the Institutional Review Board?

   Institutional Review Board, or IRB, is a committee created by institutions who review research studies that utilize human research subjects to ensure that the studies comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants. The Common Rule at 45 CFR 46, subpart A requires that an IRB reviews and approves certain human subjects research. More information can be found at the Office of Human Research Protections website.

2. Who are the IRB members?

   Federal guidelines require that an IRB have a minimum of 5 members. The IRB must fulfill the following conditions

   - Have at least one member whose primary expertise is in nonscientific areas (nonscientist) and one whose primary expertise is in scientific areas
   - Have at least one member unaffiliated with the institution (unaffiliated/community member)
   - Have an IRB Chairperson
   - IRB may allow experts and others to assist in reviews – but these people are not members of the IRB and do not vote

     NSU's IRB is composed of members of each College and more information can be found at **NSU's IRB website.**

3. When does the IRB meet?

   The IRB is scheduled to meet once a month during the semester and as needed in the summer months. Applications that could be assigned for full board review must be submitted one week prior to the monthly meeting to be considered. The meeting dates are provided at **NSU's IRB website**.

4. Can I come to IRB meetings?

   IRB meetings are normally closed to the public. Investigators whose applications are being considered can request to be present when their applications are under review to

provide any clarifications or answer questions. Internal discussions and voting on proposals occurs among committee members only and are not open to the public.

5. When do I need IRB approval?

   IRB approval is required when conducting research involving human subjects.

   - Research is defined as a 'systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge'.
   - Human subjects Research is research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable private information is used/studied/analyzed/generated.

   Thus, any research project designed to develop or contribute to generalizable knowledge that collects data from individuals, whether through surveys, interviews, observations, or other methods, requires IRB review and approval before initiating the study.

6. Why do I need IRB approval for my study?

   In the past, researchers have performed research with human subjects that were not ethical. This unethical use of human subjects resulted in the creation of Federal regulations to protect human subjects that included the creation of the IRB. The IRB ensures that Human subjects-based research is performed ethically and follows the federal and institutional guidelines. **NSU requires all human subject-based research to obtain IRB approval <u>before the research study is implemented.</u>**

7. I am a student who would like to perform a human subjects-based research study. Can I submit an IRB application?

   Yes! You may submit an IRB application with the **help of a faculty sponsor.** We cannot accept applications without a faculty sponsor's signature. Faculty sponsors play a pivotal role in providing valuable guidance during the course of the research study.

8. Are faculty sponsors required?

All student researchers who would like to perform human subject-based research must have a faculty sponsor who provides valuable guidance during the course of the research study. Students must prepare their IRB proposals **in consultation** with their faculty sponsors and obtain their signatures before submitting the form to the IRB. This will ensure a more efficient review of the proposal and timely approval can be obtained.

9. What should I keep in mind while completing the IRB application so that it can be approved quickly?

   Please pay attention to the following while preparing your IRB application
   a. Please use the current IRB form that can be found at **NSU's IRB website**. We do not accept old forms.
   b. Please use language that is understandable by all IRB members. It is imperative that the IRB members understand the proposed study and hence please minimize any technical jargon.
   c. Please follow all the instructions specified in the different fields of the application.
   d. If there is a conflict of interest, please specify it and explain how the conflict will be prevented or minimized.
   e. Please be consistent throughout the application.
   f. Read through the descriptions provided for all the fields in the application form and follow the instructions.
   g. Ensure that all the information that is requested is provided in the application.
   h. Please remember to obtain signatures of all investigators including faculty sponsors.
   i. Please complete CITI training. It has good information on the basic principles that guide Human subject-based research that will help with preparing the application.
   j. Ensure that CITI training certificates are still valid and certificate links for all investigators are provided.
   k. Please address the feedback provided by the IRB while revising the application. If you do not agree with what was requested, please let us know. We may have misunderstood certain aspects of the application.

10. I think my research is exempt. Do I still need to submit an IRB form?

    Yes. All investigators who are interested in performing human subjects-based research must submit a completed application to the IRB. The IRB will make the determination if

the study is exempt or not. In order to determine whether a study is exempt, it is imperative to describe all aspects of the study as requested in the application form.

11. I have an old form. Can I use that?

    No. The current form is revised for clarity and includes information to help NSU be in compliance with federal regulations. Hence, the current form should always be used for submitting proposals for IRB review. The form can be found at NSU's IRB website.

12. What is the CITI program?
    The **Collaborative Institutional Training Initiative** is a program that provides many courses to train personnel in research, ethics, compliance, and professional development education. Users can choose the type of training they want and are provided with access to a set of modules on that topic. There are quizzes for each module and once the appropriate modules are completed with a satisfactory score on the quizzes, a certificate of completion is provided. Many institutions use CITI and in many cases the certificate of completion are accepted by a variety of institutions.

13. Do I have to pay for CITI program?

    No! All NSU faculty, students, and staff have access to the CITI program. There is no payment involved but an account has to be created using a valid NSU email address.

14. I have already completed CITI training in the past on the IRB-based topics. Do I need to complete the training again?

    No. As long as investigators can provide an unexpired completion certificate, they do not have to go through the training again. If you have an account from another institution, please reach out to the IRB and we can provide guidance with linking that account with your NSU account.

15. Can I submit a proposal before completing the CITI training?

    All investigators listed in an IRB proposal must complete CITI training before submitting the application to the IRB and provide the weblink for the CITI certificate (not the completion report) in the application form. Applications will not be approved without CITI training. There are some exceptions in place if international collaborators are involved and this will be decided by the IRB on a case by case basis.

16. How do I access the CITI training?

    Here are some steps to access the CITI training:

- Please register for a new account at the CITI website. NSU does not have a Single Sign On system for CITI, so users will need to create an account.
- Click on 'Select your Organization Affiliation'. Select 'agree to terms' and 'affirm your affiliation'.
- Click on 'Create a CITI account'.
- **Please use your NSU email address to create an account.**
- Answer the questions to the best of your ability. Not all questions need to be answered so users can skip questions.
- The last step of creating an account is choosing a list of topics. In this list, users can choose the Biomedical comprehensive or Social-Behavioral-Education comprehensive course. Once the selection is complete you can complete the registration process.
- The account should be created and the courses should be visible and ready to complete at no cost to the user.

17. Do the Co-PI/s need to complete the CITI training as well?
    Yes! All investigators listed in an IRB proposal must complete CITI training before submitting the application to the IRB and provide the weblink for the CITI certificate (not the completion report) in the application form.

18. I have submitted an application to the IRB. Can I begin my study while the IRB reviews my application?

    No! Any human subjects-based research can begin only after IRB approval to be in compliance with institutional and federal regulations and guidelines.

19. I have IRB approval and I want to make changes to it. Can I do that?
    Yes! Investigators who would like to make changes to their study should send a revised application that highlights the changes to the IRB. The IRB can approve those changes or modifications through the amendment process. Once approval is obtained, investigators can implement the changes to the research study.

20. The IRB approval for my study is coming to an end. Can I renew the application?

Yes! Investigators can request for a one time one-year extension as long as the request is made before the application expires. If the application expires, renewal is not possible. Only one year extensions are provided. If the investigators would like to continue the study for a longer time, a new application must be submitted and approved by the IRB before continuing with the study.

21. What parts of the research study does the IRB look at in my application?
    It is the IRB's duty to look at all aspects of research involving human subjects including research design, execution, data analysis, subject safety, informed consent, etc., so that the research study produces robust results that will benefit everyone in a safe and ethical manner. Hence, the IRB looks at many different aspects of the study.

22. I have a concern about a human subject-based study. What should I do?
    If you are a participant, investigator, or any individual with questions or concerns about a human subjects-based research study, please email the IRB at irb@nsuok.edu or call 918-449-6479 immediately. Alternatively, please **complete this form,** which will facilitate anonymous reporting.

23. I have IRB approval and we had an unanticipated critical incident (data breach, harm to participant, possible protocol violation, etc.). What should I do?

    If a participant has been harmed, please ensure that the participant is safe and provide appropriate medical treatment if needed. Then reach out to the IRB immediately for guidance. An **incident form** will be filled out and the IRB can help the investigators.