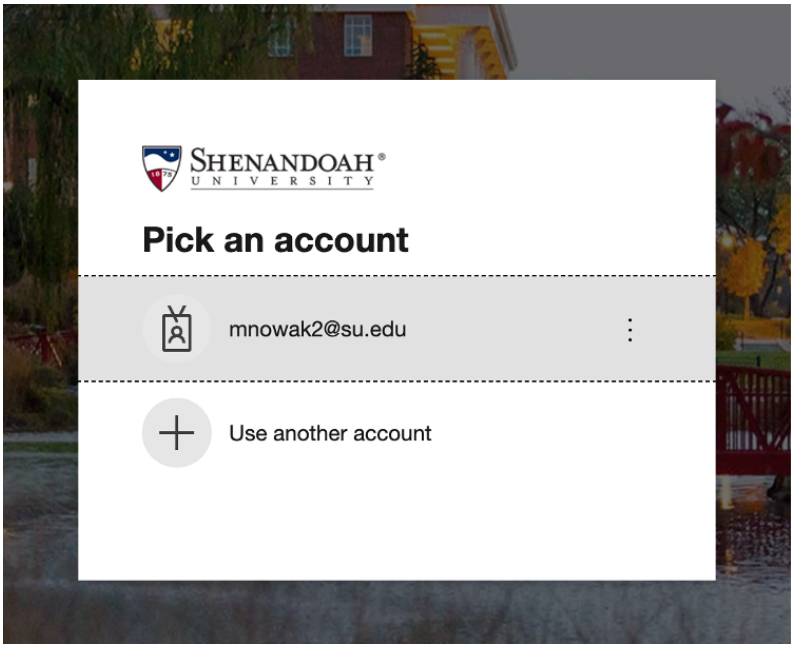
Student Guide: Submitting IRB Protocols

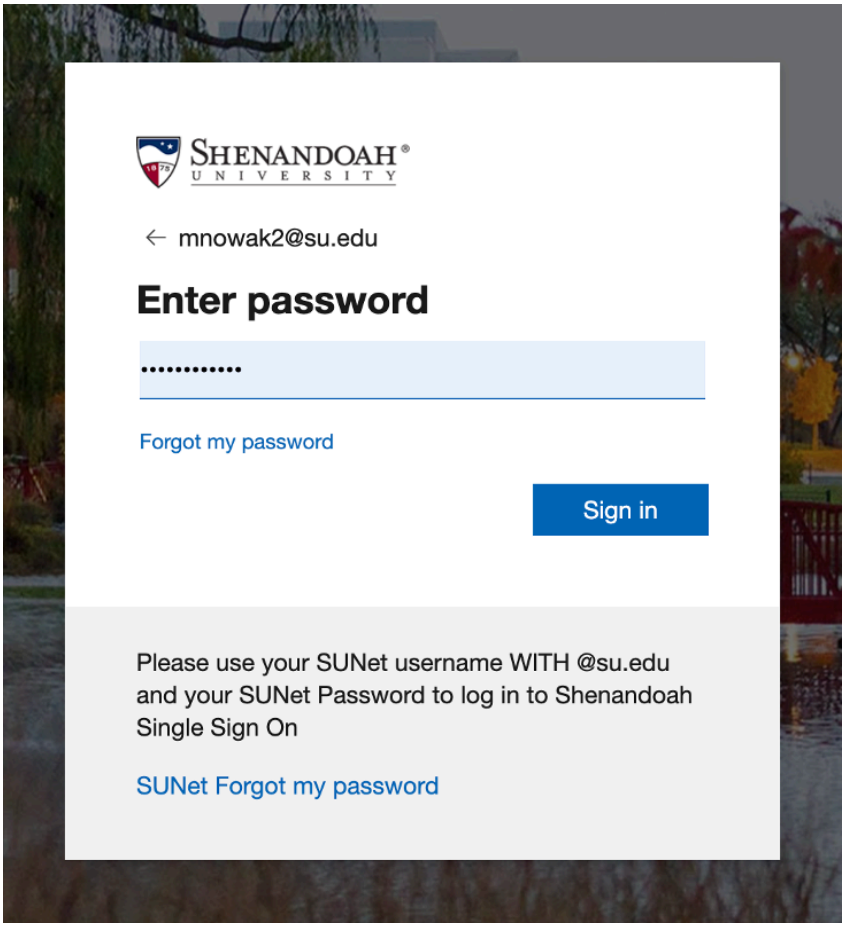
Important considerations before you begin:

1. If your project falls into one of the following categories it does not require SU IRB review. If in doubt, email the IRB Chair at irbchair@su.edu.
    - Institutional evaluations of departments, curriculums, or programs.
    - Standard student clinical or teaching situations that do not involve collection of data for publication.
    - Student classroom projects that do not involve the collection of data for publication.
    - Case reports (3 or fewer participants/cases) from standard clinical practice.
2. All researchers must have completed CITI Training prior to collecting data and submitting a research protocol. Please refer to the CITI Certification for Human Subject Research tab on the SU IRB webpage for assistance.
3. Also see Amending, Renewing, Reporting Adverse Events, and Closing a Protocol as needed, or email sucomply@su.edu.

Logging In

Log in to Sitero Mentor using your Shenandoah Single Sign-On via Microsoft. Use your SUNet Login (full email address) and password.


SHENANDOAH UNIVERSITY
Pick an account
mnowak2@su.edu
Use another account


SHENANDOAH UNIVERSITY
mnowak2@su.edu
Enter password
Forgot my password
Sign in
Please use your SUNet username WITH @su.edu and your SUNet Password to log in to Shenandoah Single Sign On
SUNet Forgot my password

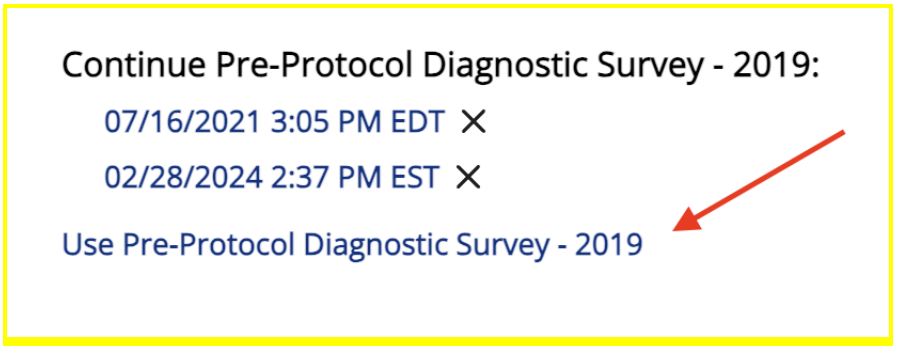
Note: Please read the Shenandoah University IRB policies and procedures on the Sitero Mentor home page before continuing.

Submitting a New Protocol

1. Choose “My Protocols” from the menu on the left.

2. Click “Create New Protocol” once the new screen populates.

3. Complete the Pre-Protocol Diagnostic Survey to determine your review category. (See picture below if it doesn’t auto-populate.)



Note: “Exempt” category research projects **do require** IRB review at SU. “Exempt” category research is different from the bulleted categories listed at the top of this document that do not require submission at all.

Note: Studies involving children under 18 are never exempt.

4. Select your faculty advisor.

    - Begin typing the faculty's last name. The name may populate the field. If they are not in the system, enter the advisor's complete SU email address.

5. Create your protocol by completing the fields on the "Create IRB Protocol" pop-up.

    Note: Please provide as much information as possible. This will aid the IRB in its review process and could save the time needed to revise your protocol.

    Note: If you cancel before saving your protocol, all information will be lost.

    - Be prepared to upload a copy of your Informed Consent form:

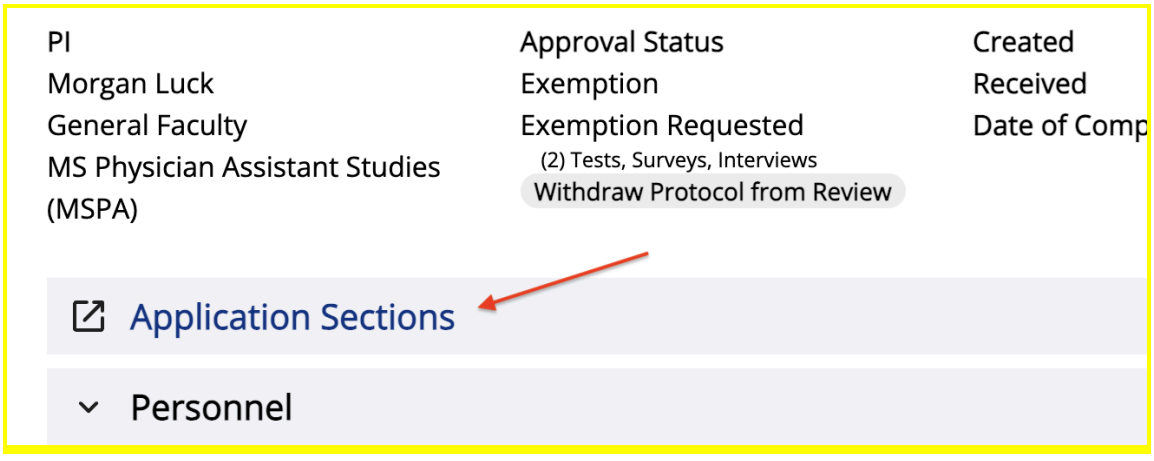
        Only SU IRB informed consent templates are accepted; please do not create your own informed consent form.

        a. **Download** the SU Informed Consent template, or for online surveys use the Survey Consent template (which can then be used as the first survey question on your online survey). Both of these forms can also be found on the SU IRB website under IRB Forms.
        b. **Edit the form(s) as indicated** and **remove instructional headers.** All informed consent language should be appropriate for a layperson with an 8th-grade reading level. Informed consent forms and other outward-facing documents must contain correct spelling and grammar or they will be returned for correction.
        c. **Upload** your completed form.

- Be prepared to answer the following questions in text/essay form:

    a. Clearly state the purpose of the study.
    b. Describe the research procedures and who will be included in the study as participants.
    c. Please explain the procedures you will follow to protect the privacy of the research subjects and the confidentiality of their data.

6. **Save your protocol.** If you cancel before saving your protocol, all information will be lost.
7. On the next page complete the fields and **answer all questions under the "Application Sections" tab** (see picture below)**.** For an editable preview of required application section questions click here.



8. Upload the following required documents, if applicable. Outward-facing documents must contain correct spelling and grammar or they will be returned for correction.

☐ **Minor Assent form**. Only the SU IRB Minor Assent template is accepted; please do not create your own informed consent form.

A. **Download** the SU Minor Assent template (also found on the SU IRB website under IRB Forms).
B. **Edit the form(s) as indicated** and **remove instructional headers.** All minor assent language should be appropriate for the minor's age and/or developmental level.
C. **Upload** your completed form.

☐ **Site Permission Letter**. Upload a site permission letter if your project includes data collection at an institution or facility other than SU. The letter should be on the letterhead of that institution and should be signed by the appropriate administrator at that institution.

☐ **Survey/Questionnaire** and/or **Qualitative Interview Guide.** Upload a Word doc or pdf of your survey, questionnaire, and/or interview guide if you plan to use one.

☐ **Recruitment Materials.** Upload a copy of each recruitment material item that will be used in your project. Each recruitment material item should have a placeholder statement of "This research study has been approved by Shenandoah University's Institutional Review Board, protocol # XXXX."

9. Sign and Submit your protocol.