NDSU NORTH DAKOTA STATE UNIVERSITY

Research Integrity & Compliance

IRB Resource Guide for Protocol Submission

This is a resource document for Graduate Students to use when they are seeking IRB Approval for their research projects that involves Human Subjects. It is the *student's responsibility to receive IRB approval before graduation.* Please plan accordingly.

☐ Discuss with advisor and PI. Get research project approved first.
☐ Set up Novelution profile.
☐ Take required appropriate CITI training.
☐ Make sure all other research team members on the project have also completed required CITI training.
☐ Submit protocol to IRB to obtain approval.
☐ Submit with plenty of time before graduation to account for possible revisions that may be needed.

⬦ **Getting started:**
  o Make sure you have discussed the research proposal with the PI and they read through and approved it. The PI is ultimately responsible for the research and they have to sign off on it. They should be guiding and helping you along the way.

  o Resource: IRB Website located here: [IRB Website](#)

  o Go into Novelution: Link [here](#). If you already have a Novelution profile then you can skip this process.

  o Scroll down to *Using Novelution*. This will help you set up your Novelution Profile. This needs to be done for all NDSU/NDUS internal people who will be on the research team.

⬦ **Complete appropriate [CITI](#) training**. [CITI](#) training is time consuming. Plan ahead to complete all necessary trainings before submitting your protocol.
  o NDSU CITI training requirements found [here.](#)

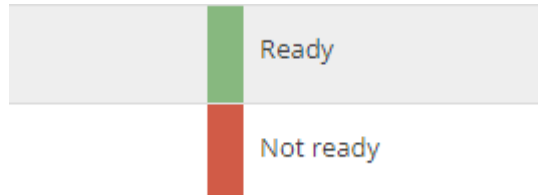⬦ **IRB Tip Sheets for Protocols:**
  o Link [here](#)

⬦ **Once protocol is started:**
  o It will show tasks to complete. Tasks will be in the requirements section; which is found at the bottom of the protocol.

- **Novelution Tasks:**
    - Green= tasks that are <u>ready to be completed</u>; **not** that they have been completed.
    - Red= the task cannot be done until the one that is in green is completed.

    - Tip: If you have a green task and it is related to CITI training, the PI will receive an email and it will state that someone (this means ANYONE; internal or external) is missing CITI training. If it is a:

- **Internal research team members:**
    - Please open the CITI system and your Novelution profile.
    - Make sure the emails match
    - You will see this in the Novelution system. The email in here should match the one that is used in CITI.

- **External Research Team Members:**
    - For members who are external- they will still need the NDSU CITI training. They will not be in Novelution so the verification is a bit different. Once they have completed the training, they can email any other team member a copy of their certificate. The PI or any other research team member can upload it in that member's section in the research team panel.

Adding CITI
training.pdf

- **Next Steps:**
    - Once the protocol has been filled out it can be submitted. The PI and Department Chair have to submit it. Once that happens, it will come to the IRB office. Please give them a few days to review the protocol. If there are any comments from reviewers or required changes that need to be made, they will show up in the reviewed comments section.

    - The student can reply to them in the chat feature if that is appropriate to supply clarification. Most often the changes need to happen in the actual protocol. Once the changes/updates happen it needs to be resubmitted. The protocol *GOES BACK to the PI for them to hit submit. It does not*

automatically get resubmitted to the IRB once the student hits submit. Please look at requirements section before asking IRB office. This tells you where your protocol is at.

- o Once it gets back to the IRB office, and if there are more changes or updates, communication will continue back and forth through Novelution until it's ready for approval.

- o Once approved, the student will receive an emailed notification approval letter. Hold onto that letter for your records, as the Graduate School will need that letter.

🔸 **Tips and things to look :**
- o Student Researchers - NDSU students can log in to Novelution using their NDSU username and password. Student researchers will need to update their Novelution profile with their department before accessing other modules within the system.

Setting Up a
Student Novelution

- o Outside Members/Researchers - NDSU has agreements with several other outside entities to provide compliance reviews (IBC, IRB, or IACUC). If you are a member of one of these institutions (e.g. USDA, Mayville State University) and need access to Novelution to submit a protocol, please contact the committee administrator. Once given a User Name, follow the below instructions for activating your account and establishing a password.

Activating an
External User Account

- o Check the status of your protocol application - The Requirements panel within the Protocol application shows which steps are ready to complete to facilitate the review process. Check to see if training is completed, the department head has approved, or if the protocol is now in the review process.