User Accounts and User Log-In

**User with active accounts in eIRB:** IRBNet will email you a separate message which contains a temporary password. Please use this password to enter IRBNet. GRU affiliated users (i.e. GRU faculty, students, and staff) will access IRBNet via the IRB Office webpage. Non-affiliated users will need to create a new account (see below).

**New accounts for GRU-Affiliated users:** Go to IRBNet via the link on the IRB Office website. Select **New User Registration**. You must indicate your affiliation with GRU at which time you will need to use your GRU netID and password for all future access to IRBNet.

**New accounts for non-GRU Affiliated users:** Go to www.irbnet.org and select **New User Registration**. You will create a username and password, which you should use for all future access to IRBNet.

**Requirements For all Users:** Upon entering IRBNet for the first time, all users must update their User Profile by:

- Adding a current, dated CV
- Adding your CITI information by selecting **Add an External Account**

*Please note: You must have your CITI User ID available to complete this required step. Visit the CITI website at www.citiprogram.org to retrieve your CITI User ID.*

**Smart Forms Ready for Use**
The following online Smart Forms are ready for use:

- Core Protocol Data Form (i.e. initial application)
- Continuing Review Form

Due to required upgrades, the Reportable Event Smart Form should be available for use within the next week; however, in the interim, researchers may submit a reportable event by using the Reportable Event Supplemental form located in the GRU IRBNet Library.

*Note: All supplemental forms, templates, and other forms are located in the GRU IRBNet Library.*

**Studies Transferred from eIRB**
All studies that were approved and pending approval in eIRB have been transferred to IRBNet. Please see the information sheet: *Studies Transferred from eIRB* located on the GRU IRBNet website. This important information sheet details the list of data and documents that have transferred as well as instructions for completing the required **back-fill** of the project at the time of continuing review or an amendment. The IRB Office has access to the eIRB system and can provide assistance with obtaining documentation, if requested.

Please note the following:

- The Principal Investigator and those indicated as PI proxy in eIRB will have immediate **full** access to studies. The PI or their proxy must **share the project** (study) with other approved research team members, as applicable. The PI is also responsible for removing access to PI proxies who should no longer have access to the project.
- The IRB Office has completed limited data validation and testing for studies transferred from eIRB to IRBNet; however, the **IRB requires your assistance and review of transferred studies to**
ensure the data and documents transferred are accurate and complete. Please notify the IRB Office immediately if there are any data discrepancies noted.

Policy/Process Changes

- CVs- effective May 21st, the IRB will only require a dated CV at the time of an initial application or when a research team member is added to a project. Please note, a revised CV must be submitted if there are changes to licensing and/or credentials.

- Consent Forms
  - IRB-approved, stamped consents will only display the approval stamp on the last page of the consent document
  - The IRB no longer requires the names of Sub-Investigators approved to obtain consent to be listed on the first page of the consent form; however, if the PI chooses to continue to list Sub-Investigators approved to obtain consent on the first page, the IRB will accept the consent form. Please note, the IRB will continue to require the PI to indicate Sub-Investigators who will obtain consent in the IRB application and those individuals must be approved by the IRB before they may obtain consent.

Ancillary Approvals Change- PLEASE READ CAREFULLY

ITSS
1. ITSS (IT Security) review and approval will not be required before submitting an IRB Application.
2. All new IRB Applications (at the time of submission) will prompt the PI to sign and submit an attestation statement which specifies agreement follow Enterprise IT security processes for management, storing, and accessing data.
3. IRB applications can be submitted and approved prior to requesting and receiving secure server space.
4. The PI is responsible to sign and submit the attestation statement with the IRB Submission and must request secure server space (i.e. R:Drive) via IT Service desk.

Medical Center
1. Research involving Medical Center (patients, clinics, assets, medical records, billing information, etc.) CANNOT COMMENCE without receiving Medical Center Approval.
2. IRB applications can be submitted and approved prior to receiving Medical Center Approval.
3. The PI is responsible for initiating the Medical Center approval process.

Note: The most expeditious manner to seek approval is to use eSPRoute.

Biological Safety
1. Biosafety Approval is REQUIRED BEFORE IRB Submission for studies involving Recombinant or Synthetic Nucleic Acids, Gene Transfer/Therapy, DNA Vaccines, Stem Cells, and Select Agents and Toxins.
2. Research involving OTHER BIOLOGIC MATERIALS (e.g. not Recombinant or Synthetic Nucleic Acids, Gene Transfer/Therapy, DNA Vaccines, Stem Cells, and Select Agents and Toxins)will be PROMPTED in their IRB application to complete a “newly simplified” IBC form and submit to the IBC.
   a. A SEPARATE IBC application and approval process will not be required for research involving Other Biological Materials (not specified above) (e.g. not Recombinant or
Synthetic Nucleic Acids, Gene Transfer/Therapy, DNA Vaccines, Stem Cells, and Select Agents and Toxins.

3. The PI is responsible for submitting the IBC form and receiving IBC approval (as applicable). Research cannot commence until these requirements are met.

Radiation Safety
1. Radiation Safety Approval is REQUIRED BEFORE IRB Submission for protocols involving ionizing radiation outside of standard of care procedures.
2. The IRB application should be initiated and “shared” with the Radiation Safety Committee Prior to submitting the application to the IRB Committee.
   a. The IRBNet Core Data SmartForm will prompt/remind investigators to complete the “newly simplified” Radiation Safety form and submit to the Radiation Safety Officer for review and approval.
3. The Radiation Safety Committee will review the IRB Submission (including review of Informed Consent Documents) and provide approval, AFTER WHICH, the project may be submitted to the IRB Committee for review.
4. The PI is responsible for “sharing” the project with the Radiation Safety Committee (as noted in 1a. above), for completing the Radiation Safety Form, and submitting to the Radiation Safety Office.

Chemical Safety
1. Investigators using chemicals in their research require registration with the Chemical Safety Office.
2. Registration is a one-time process and investigators will be prompted/reminded (if the research involves Chemicals) in their IRB application to register with the office and obtain a chemical safety number.
3. The PI is responsible for submitting the Chemical Safety form and receiving Chemical Safety number (as applicable). Research cannot commence until these requirements are met.