About Workflow

The workflow represents the path followed within the system for review and approval of new IRB study applications, amendments, continuing reviews, reportable events, and terminations.

New Study Workflow

New IRB study applications to the Georgetown University Institutional Review Board are subject to pre-review and always require department or equivalent approval (please see below).

Oncology Studies:

*Lombardi Comprehensive Cancer Center:* All new IRB study applications to the Medstar-GU Oncology IRB are subject to pre-review and require approval of the Director of Lombardi CCC. For IRB studies initiated by the Director of Lombardi, approval is required from the Director of the BGRO.

*Washington Cancer Institute at Washington Hospital Center:* All new IRB study applications to the Medstar-GU Oncology IRB are subject to pre-review and require approval of the Medical Director of the Cancer Institute.

*Harry & Jeanette Weinberg Cancer Institute at Franklin Square:* All new IRB study applications to the Medstar-GU Oncology IRB are subject to pre-review and require approval of a Franklin Square director.

Biomedical Studies:

All new IRB study applications to the Biomedical IRB(s) are subject to pre-review and approval. For IRB studies initiated by Division Chiefs, approval is required from the Department Chairs. For IRB studies initiated by the Department Chairs, approval is required from the Director of the BGRO. For IRB studies initiated by the Director of the BGRO, approval is required from his/her Department Chair.

Social Behavioral Studies:

*Students engaged in research for the purpose of writing a thesis or dissertation:* All new IRB study applications to the Social-Behavioral IRB are subject to pre-review and require approval of the student’s designated Faculty Supervisor.

*Faculty:* All new IRB study applications to the Social-Behavioral IRB are subject to pre-review and require approval of the faculty member’s immediate supervisor.
President’s Office: All new IRB study applications to the Social-Behavioral IRB are subject to pre-review and require approval of the Provost of the University.

Upon approval by the designated Department Chair or Equivalent Reviewer (see above), the research application is forwarded to the IRB for review. An IRB Staff member will determine whether the study is eligible to go “expedited” or whether “full board review” is required. At this point in the process, an IRB Staff member may also make the determination that the proposed study is not human subjects research, and therefore review by the IRB is not necessary. Studies which are deemed to be subject to review will be forwarded to the appropriate expedited reviewer or assigned to a meeting for full board review.

Getting Started

eRIC Home Page

eRIC is an internet-based system available at: https://eric.ora.georgetown.edu/eric

There are several links to policy, procedure and general information available from the gateway page.
User Account

The user account is used to manage personal data. The account is accessed by clicking the user name link in the upper right hand corner. The initially populated personal information (NetID, name, email address) was extracted from your registration process. You may need to update this information to reflect preferred e-mails or nicknames. The NetID password is managed by UIS and cannot be changed within eRIC.

To change your NetID password, visit https://sites.google.com/a/georgetown.edu/uis-docs/accounts/password.

Access your user profile by clicking on your name link at the upper right of the screen.

Select “Edit User Profile” from the drop-down menu in the Select View field.
Click Apply to save any changes.

NOTE: If there is information in your user account that you think should be changed, please contact the IRB.

Human Subjects Research Training and Experience can only be updated by the IRB Director. The IRB certification date, renewal deadline, and copies of all approved IRB Researcher Training Records can be accessed here.

The link to the researcher’s profile is available from the researcher’s personal folder under the Profile tab.
Personal Folder

Your eRIC experience is personalized, allowing you access to all of the studies you are working on or reviewing. When you log into eRIC, you are taken to your personal folder, which displays and has links to items applicable to you.

1. **My Roles** allows you to select between user roles if you have more than one. This component will only display if you have multiple user roles. These are listed in the upper left of your screen.

2. The **Top Navigator** is available on almost all screens and has links to your **Name** (to change personal information), **My Home** (always brings you back to this page, your personal folder), and **Logoff** (ends your session and logs you out of the system).

3. The **(Create) New Study** button allows you to start a new IRB application from scratch.

4. The **Inbox** tab displays all studies you are a part of that require some task to be done by the study team.

5. The **IRB** tab allows you to search through all of the respective IRB studies that you are part of, regardless of where the study is in the submission and review process.

6. The **Templates** tab displays a listing of the submissions that you have chosen to save as templates for future studies.

7. The **Profile** tab allows you to edit and view your personal training profile, as well as any research certifications you have received.

8. The **Ready for Submission** tab lists all submissions which have been filled in by the Regulatory or Study Coordinator for the study and forwarded to the PI for submission to the IRB.
**Pre-eRIC studies**

Basic information for GU IRB studies already in progress when eRIC goes live will be populated into the eRIC system by the eRIC team. This basic information is limited to the following: (1) IRB # of the Study (2) Title of the Study (3) Principal Investigator’s name (4) Co-investigator’s names (5) Approval and Expiration dates. It is the responsibility of the Principal Investigator (or other responsible member of the study team) to fill in the required sections of the IRB study application prior to submission of any new amendment, continuing review, or reportable event report in the eRIC system.

**Overview of the eRIC Submission and Review Process**

The following steps illustrate the basic application review process:

**Step 1: PI and Study Staff**
Prepare and submit application.

**Step 2: Pre-Reviewers**
If applicable, the application is routed for pre-review approval and sign off:
- Department (or Equivalent) Review – This is a blocking review where the IRB will not see the project until it has departmental or equivalent approval.
- Non-Blocking Review – This is for ancillary reviewers (such as Radiation or Biosafety) and will not slow the review process.

**Step 3: IRB Staff Review**
An IRB Staff Member will be assigned to the study. The IRB Staff Member will conduct a staff review and manage the processing and scheduling of the study.

**Step 4: IRB Review**
The IRB committee or Chairperson (for expedited and exempt studies) will review the application and provide the investigator with correspondence. Committee decisions and correspondence are recorded by the IRB Staff Member in eRIC and sent to the PI.

**Step 5: PI and Study Team**
Once the study has received final approval, the study team is responsible for the following:
- Conduct research
- Report adverse events
- Submit requests for continuing reviews
- Submit amendments
The Study Workspace

Every study created in the eRIC system is assigned a folder or workspace. When you click on a study title or IRB number from your personal folder, it will bring you to the main study workspace area for the particular study.

The study workspace displays important information about the study and contains links to help navigate to any information contained in the study. The study workspace shown above is for a study which is in the pre-submission state, and has not yet been submitted to the IRB.

1. The **Current State** displays the progress of this study in the review process.
2. The panel displays summary information about the study. The information will change depending on the study’s progress through the review process.
3. The IRB number for the study
4. The **Edit Study** icon will open the application smartforms.
5. The **Printer Version** icon will open all of the relevant smartform screens in one easy to print window
6. **My Activities** lists of all the available actions you can perform on the study. Click on them and complete the opened screen to perform the action.
7. The **History** tab records all actions performed on the study. Each action is recorded with the date, time, and person performing the action. You may click on the name of the activity to see the system details.
8. The **Attachments** tab contains all uploaded documents for the study.
The study workspace shown below is for a study that has been submitted to and approved by the IRB. Once the study is in an approved state, different options become available under My Activities. Additionally, different tabs appear in the main study workspace area:

1. The Current State displays the status of the study
2. The panel display summary information about the study. This information should be fully filled in once a study has been approved
3. The IRB number for the study
4. The View Study icon will open the application smartform for viewing purposes
5. The View Differences icon will show any changes made between the original submitted copy of the application and the final approved version of the study application.
6. The Printer Version icon will open all of the relevant smartform screens in one easy to print window.
7. My Activities lists all of the available actions you can perform on the study. These differ once a study has been approved.
8. New Amendment directs you to the smartform to create and submit an amendment to the study.
9. New Continuing Review directs you to the smartform to create and submit a continuing review for the study.
10. **New Reportable Event** directs you to the smartform to create and submit a new reportable event report (i.e. adverse events)

11. The **Stamped Documents** tab lists all of the approved and stamped documents for the study (i.e. ICFS, Assents, HIPAA forms, etc.)

12. The **History** tab records all actions performed on the study. Each action is recorded with the date, time, and person performing the action. You may click on the name of the activity to see the system details.

13. The **Amendments** tab records all amendments that have been created and/or submitted for the study. You may click on the name of the individual amendments to see the history of the amendment action in the amendment workspace.

14. The **Continuing Reviews** tab records all continuing reviews that have been created and/or submitted for the study. You may click on the name of the individual continuing reviews to see the history of the continuing review action in the continuing review workspace.

### The Study History Log

Every study has a detailed history log. For auditing purposes, every action performed on the study is recorded in the history log.

The information is viewable under the **History** tab. This is sorted in chronological order and displays only the actions you have permission to see. Each activity, when performed, is recorded in the history log with a data/time stamp and the name of the person performing the activity. You can click on the name of the activity to view the system details.
The history is updated after a new activity is completed by anyone working on the project.