

GUIDANCE

File Conversion

IRB File conversion activity is required to move submissions that originated in the eIRB protocol management system to IRBNet. The process of file conversion will begin on January 3, 2022 when the IRBNet system goes live.

Step 1: IRB Staff

- Files for all expedited and full board reviewed studies in eIRB were provided to the IRBNet team for conversion to Shell Files in the IRBNet system.

Note: studies that were reviewed through exempt processes or application for projects that were classified as Not Human Subjects Research were not transitioned into the IRBNet system.

- The data provided in the conversion file included the following information:
 - Study Title
 - PI Name
 - eIRB protocol reference number (Pro#)
 - Date initially approved
 - Expiration Date
 - Current status of the study (i.e., open to enrollment, active with closed enrollment, etc.)
 - Last Board action: new study, renewal, modification, SAE, etc.
 - Date of the last Board submission and effective date.
 - Sponsor Name
- This information creates the Shell File for the study. These files were then shared with the IRB Coordinators.
- The IRB Coordinators will share these files with the identified research coordinator or PI associated with each record so that the Shell File can be completed.

Step 2: Study Staff, Coordinator and/ or Principal Investigator

- A designated Principal Investigator and / or Study Coordinator will be identified to receive the file from the IRB Coordinator for completion.
- The files will be distributed in a manner / volume and frequency as requested by the research managers and study team.
- Study staff receiving the shell files will need to complete their “new user” registration prior to the initiation of file transfer
- On January 3, 2021, the IRB coordinator will initiate file sharing with these identified individuals.

Step 3: Completion of the Shell Files.

- Gather all relevant documents (most current version only*) for each study to include, but is not limited to:
 - Study Protocol
 - Consent(s) Documents
 - Investigator Brochure
 - Package inserts for relevant approved drugs or biologics
 - Any participant facing documents; advertisements or study materials
 - Regulatory documents, i.e., FDA 1572, FDA letters, etc.
 - Data Support Core approval (if applicable)
 - Executed DUA/ DSA (if applicable)
 - Device Information
- Attach these documents using the “add documents” button on the **Designer Page** or via the **drag and drop feature**.
- **Complete the Prisma Health – IRB Application by clicking on the “Start a Wizard” button or in the downloading if from the Document Library. This is a required step for all conversion files as well as all new submissions in IRBNet.**
- Once the Submission Application is complete and all required documents attached, you can determine study file access for study teams members and then share the file with them.
- Please note that you need only upload the most current version of these documents to IRBNet. Prior versions will be archived in the eIRB system.

When this activity is complete, you are finished building out the record for the project!

DO NOT SUBMIT ANY APPLICATIONS TO THE IRB UNTIL THERE IS A REVIEW ACTION REQUIRED, I.E., CONTINUING REVIEW, AMENDMENT, ETC.

The IRB staff will be able to determine when study files are completed. There is no IRB action required for Shell File Completion. Your study files will remain in this state until the next review action is required.