Studies Transferred from eIRB to IRBNet

Which data fields from my submission transferred from eIRB to IRBNet?
The following data fields transferred from eIRB to the IRBNet Core Protocol Smart Form:
- PI Name
- Submission Type (All transferred will be listed as a New Study)
- Review Type
- Initial Approval Date, Current Approval Date, Current Expiration Date
- Risk Level
- Project St

Am I required to back-fill any data that’s missing in the IRBNet Core Protocol Smart Form?
Yes, you are required to back-fill any missing data, and submit any applicable supplemental forms when submitting a continuing review or amendment (modification) for the study.

Can I submit a reportable event without back-filling the IRBNet Core Protocol Smart Form?
Yes, you may submit a reportable event only without back-filling the IRBNet Core Protocol Smart Form.

Which documents from my submission transferred from eIRB to IRBNet?
Most currently approval letter and associated approval documents
- Locating Approved Documents from eIRB
  - Select Reviews in the Project Administration menu to view the current approval letter and stamped documents
- Word documents of the most currently approved documents
- Locating the Un-Stamped Word Documents
  - Select Designer in the Project Administration menu to view the current approved documents (Word versions, unstamped)

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Accessing IRBNet and Submitting a Package on a Transferred Study

Step 1- Log into IRBNet (see IRBNet What to Expect for details regarding the log-in process)

Step 2- Select your Study via My Projects
Open the study via the blue hyperlink.
- Study package #1 references the transfer from eIRB to IRBNet.
- The continuing review or amendment will be Package #2. Select Project History in the left menu bar.
  - Select Create New Package- this creates a new package in which you will submit your:
    - Back-fill of the Core Data Form
    - Continuing Review or Amendment
- For Continuing Reviews
  - MANDATORY: You must “back-fill” the IRBNet Core Protocol form at the time of continuing review for a protocol transferred from eIRB
  - To Back-Fill the Core Data Form
    - Select DESIGNER-
      - Select Add new Document
      - In the Online Document section, select the GRU Protocol Form
        - Click Add
        - Complete all empty fields in the Core Protocol Form
          - Select Create a New Wizard from Scratch
          - Upload and complete any required Supplemental Forms, except for:
            - the protocol
            - any approved templates, to include, but not limited to:
To Complete the Continuing Review Smart Form
- Select DESIGNER-
  - Select Add new Document
  - Select the GRU Continuing Review On-Line Document
    - Click Add
    - Complete the Continuing Review Smart Form
      - Upload any required Supplemental Forms
  - Return to DESIGNER and select Link/Un-Link Training Records for all research team members on the study
    - You may view the list of research team members via the Core Protocol Form located on the Designer page

MANDATORY:
- Ensure the package is SHARED with anyone on the study team you wish to have access to the package and receive notifications
  - *A user must have an active IRBNet account in order to share the package with them*

MANDATORY: The PI must Sign This Package and Submit This Package to the IRB Office.
  - Select “Georgia Regents University (GRU) IRB Office” in the “Search for Organization” drop-down menu.
  - Be sure all documents are attached and in final form.
  - Once you “SUBMIT,” you will not be able to edit the application.

For Amendments (Modifications)
- To Back-Fill the Core Data Form
  - Select DESIGNER-
    - Select Add new Document
    - In the Online Document section, select the GRU Protocol Form
      - Click Add
      - Complete all empty fields in the Core Protocol Form
        - Select Create a New Wizard from Scratch
        - Upload and complete any required Supplemental Forms, except for:
          - the protocol
          - any approved templates, to include, but not limited to:
            - consent/assent
            - advertisement
            - data collection form
    - Return to DESIGNER and select Link/Un-Link Training Records for all research team members on the study

- To Complete the Modifications/Amendment Supplemental Form
  - Select DESIGNER
    - Choose the Core Protocol Modifications Supplemental Form
      - Click - SAVE to save the form(s) to your computer. You may complete and edit them at a later time. If you exit the system after this step, you will need to log in again, click My Projects, and return to the DESIGNER screen.
      - Complete the form and upload it via DESIGNER
      - Select Add New Document
        - Document Type- Amendment/Modification
• Description- Amendment for transferred eIRB study, PRO#546
• Attach the completed form
  o Return to DESIGNER and select Link/Un-Link Training Records for all research team members on the study
  • You may view the list of research team members via the Core Protocol Form located on the Designer page

• **MANDATORY:** Ensure the package is **SHARED** with anyone on the study team you wish to have access to the package and receive notifications
  o *A user must have an active IRBNet account in order to share the package with them*

• **MANDATORY:** The PI must **Sign This Package and Submit This Package** to the IRB Office.
  • Select “Georgia Regents University (GRU) IRB Office” in the “Search for Organization” drop-down menu.
  • Be sure all documents are attached and in final form.
  • Once you “SUBMIT,” you will not be able to edit the application.

• **For Reportable Events**
  o Select DESIGNER-
    • Select Add new Document
    • Select the GRU Reportable Event On-Line Document
      o Click Add
      o Complete the Reportable Event Smart Form
        • Upload any required Supplemental Forms and/or documentation

• **MANDATORY:** Ensure the package is **SHARED** with anyone on the study team you wish to have access to the package and receive notifications
  o *A user must have an active IRBNet account in order to share the package with them*

• **MANDATORY:** The PI must **Sign This Package and Submit This Package** to the IRB Office.
  o Select “Georgia Regents University (GRU) IRB Office” in the “Search for Organization” drop-down menu.
  o Be sure all documents are attached and in final form.
  o Once you “SUBMIT,” you will not be able to edit the application.

**Step 3-** To view the status of your submission, return to the “**Program Administration**” menu on the left and CLICK on “**Study Overview**”. Your package status will be “**Pending Review**” until reviewed by the IRB.

*An electronic IRBNet notification will be sent to your email confirming that the IRB has received your package. Once comments (if any) are resolved, you will receive a notification of approval. Please contact the IRB Office at IRB@gru.edu or call 706.721.3110 if you require assistance with a submission.*