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Office for Research

Rutgers Human Subjects Protection Program Pre-Review Process

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What is Pre-Review

Pre-Review is a process to facilitate a complete submission for human subject studies by providing an optional Pre-Review Service to investigators prior to submitting new studies or substantial modifications to existing studies in eIRB.

*For studies recommended for pre-review after submission in eIRB please refer to specific *Options for studies recommended for Pre-Review after submission in eIRB.

Who Conducts the Pre-Review

- The Pre-Review Team consists of experienced IRB members and Human Subjects Protection Staff as well as key members of the Rutgers University IRB (e.g., the IRB Chair)

- The Pre-Review Team Members have experience with criteria for IRB approval at 45CFR46, HIPAA Regulations at 45CFR46 Parts 160, 162, and 164, FDA Regulations at 21CFR50 and 56, the Rutgers HSPP Policies and Procedures, the Rutgers HSPP toolkit worksheets and checklists, as well as Rutgers Policies and Procedures and NJ State Laws as they pertain to Human Subjects Research

Pre-Review Process

The pre-review process begins when the IRB receives a request for Pre-Review or a Pre-Review is recommended by HSPP/IRB Staff

- Investigators requesting or being recommended for Pre-Review must follow the Pre-Review Instructions for Researchers

The process ends when the investigator has been notified by the Pre-Review Team the pre-review is complete, provided with instructions to address the comments/suggestions as they deem applicable and submit the revised study/modification documents in eIRB.

The Pre-Review process and suggestions are optional

- It is not required that investigators utilize the Pre-Review process however it is strongly recommended.
- The Pre-Review Team comments are suggestions and are not mandatory prior to submission in eIRB.

Pre-Review Process

Pre-Review Instructions Prior to submitting in eIRB:

1. To begin the process, please upload the relevant documents as WORD documents in Rutgers OneDrive to allow the pre-review team to make tracked changes/comments
2. Share the folder with the pre-review team members listed below:
   - Donna Hoagland, donna.hoagland@rutgers.edu
   - Rebecca Chen, ClinicalTrials.Gov, chennr@research.rutgers.edu
   - Angela Cartmell-McGlyn, Sr IRB Manager, ac2200@research.rutgers.edu
   - Claribel Vega, Sr. Reliance Manager, vegacl@research.rutgers.edu
   - Carlotta Rodriguez, Executive Director HSPP, rodrigcm@research.rutgers.edu
   - Cheryl Kennedy, IRB Chair, kennedy@njms.rutgers.edu

Pre-Review Process

The Pre-Review should be done simultaneously as you work on the following:

- eIRB application **(please do not submit the application or upload the documents until they have been pre-reviewed by the pre-review team and then finalized by you).**

- If your research will be conducted on Robert Wood Johnson University Hospital (RWJUH) New Brunswick property or involve RWJUH New Brunswick patients, their data or biospecimens you must submit an application to the RWJUH Research Utilization Group (RUG).

- To access the RUG form, please visit the website under 'Performance Site Approval Forms': https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit .

Pre-Review Process

- If your research will be conducted on University Hospital (UH) property or involve University Hospital patients, their data or biospecimens you must submit a UH Registration and Research Plan through the Office of Clinical Research Administration.

- Please refer to the website at https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit and view instructions under ‘Performance Site Approval Forms’ then under University Hospital

Pre-Review Process

- eCOI disclosures for the Principal Investigator, co-investigators and all research personnel

  Please click the ‘Create financial disclosure certification in eCOI in the eIRB study workspace and select all study personnel

If you need assistance with completing the disclosure certification, contact the COI Administrator at 732-235-8682.

Pre-Review Process

- CITI training for the Principal Investigator, co-investigators and all research personnel

- CITI requirements can be found at:

https://research.rutgers.edu/researcher-support/research-compliance/research-integrity/collaborative-institutional-training

- CITI can be completed at:

https://about.citiprogram.org/en/homepage/

Pre-Review Process

- Any contracts or agreements applicable to your protocol such as Data Use Agreements, Clinical Trial Agreements, etc.

For assistance with contracts and agreements please contact Melissa Matsil, JD Director, Corporate Contracts Ph: (848) 932-4462 Email: mmatsil@ored.rutgers.edu

- IRB Reliance Agreements, to accept another IRBs approval or for Rutgers to serve as the IRB of record for other sites involved in your research. For information regarding IRB Reliance Agreements please contact the IRB Reliance Administrator: IRBRelianceAdmin@research.rutgers.edu

- Any ancillary reviews applicable to your protocol such as, Biosafety, Radiation Safety, CINJ Scientific Review Board

Pre-Review Process

- The Pre-Review Team reviews the protocol and ancillary study documents such as the consent form, recruitment materials, data collection forms and related documents to provide feedback and suggestions to the investigator for revisions or clarifications prior to or after submission in eIRB.

- The Pre-Review Team adds their comments and suggestions directly onto the WORD version of the documents uploaded in OneDrive

- The process ends when the investigator has been notified by the Pre-Review Team the pre-review is complete, provided with instructions to address the comments/suggestions as they deem applicable and submit the revised study/modification documents in eIRB.

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Instructions for Uploading to One Drive

1. Navigate to connect.rutgers.edu. Log in using your Rutgers NetID and password. If you are already logged into your Rutgers e-mail it will bring you to your email home screen. If you haven't logged in yet it will direct you to log in
2. From your e-mail home screen via connect.rutgers.edu click on the icon in the top left corner (it is a box made up of 9 dots)
3. Click on "OneDrive."
4. Click on the tab "New" (there is a plus sign next to it) and select "folder."
5. Create a name for the folder using the following notation: PI FULL NAME AND SHORT TITLE.
6. Example: "John Doe Perceptions of Masks." (please do not simply label it as "IRB" or a similar generic title.
7. Click on the folder created.
8. Click on the tab "Upload" and select the documents you would like to upload.
9. Return to the previous screen that has the Folder you created.
10. Highlight the folder you created and click on the arrow icon (to the right of the folder name) to "share"
11. Select the Pre-Review Team members for your campus (listed above) to share the file with them by entering their e-mail addresses. You may also enter an optional message to the team. Once you have entered everyone you want to share the file with click on send.
12. The Pre-Review Team will automatically receive an email notification and link to the file.

*Options for studies recommended for Pre-Review after submission in eIRB:

Option 1:

Withdraw the study in eIRB.

Upload the protocol and relevant documents to OneDrive and share with the Pre-Review Team for your Campus listed below.

Once you are notified the Pre-Review is complete, address the comments/suggestions as you deem appropriate.

Create and submit a new application in eIRB and submit for IRB review.

Option 2:

Allow the study/modification to proceed through the regular IRB process as submitted without pre-review

Pre-Review Team Contact Information

For questions regarding the Pre-Review process please contact the Pre-Review Team at

Irbpre-review@research.rutgers.edu

What Pre-Review Is Not

Pre-Review is not a guarantee of IRB approval

- individual IRB members (who are faculty familiar with a variety of research) may have additional comments during the review process, after you submit your protocol through eIRB

Pre-Review is not a replacement for

- Using/following the IRB templates
- Editing and proof-reading the submission documents for inconsistencies and completeness
- Faculty Advisor mentoring and review of the submission documents

Upcoming Changes

- eIRB Revisions
- Consent form
- Research Templates
- Website Updates

HSPP Bulletin

Questions

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