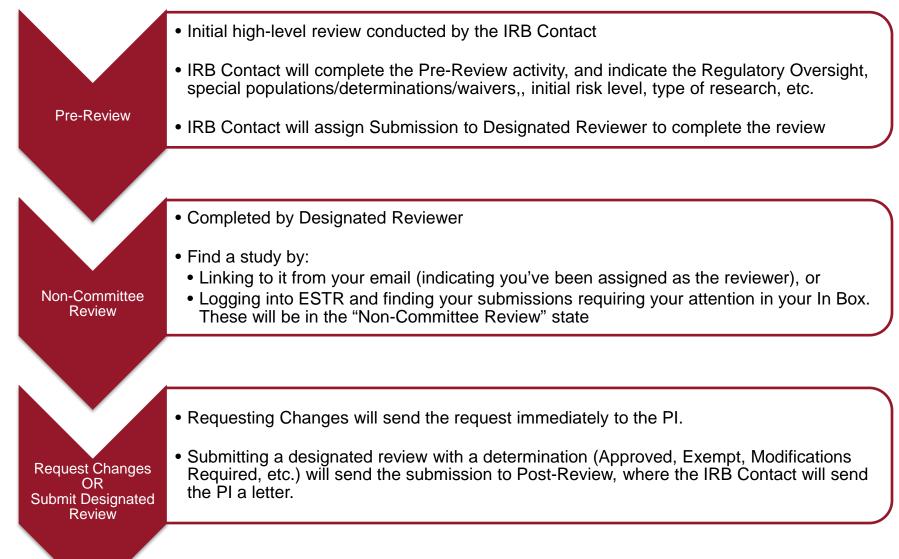# HARVARD
FINANCIAL ADMINISTRATION

Electronic Submission Tracking & Reporting - IRB Committee Member Training Non-Committee Review

Topics

- Non Committee Review Process

- Review Steps

- Requesting Changes

- Changes Received

- Submit Designated Review

- Appendix: Workflow and Activities

Non-Committee Review Process

Pre-Review
- Initial high-level review conducted by the IRB Contact
- IRB Contact will complete the Pre-Review activity, and indicate the Regulatory Oversight, special populations/determinations/waivers,, initial risk level, type of research, etc.
- IRB Contact will assign Submission to Designated Reviewer to complete the review

Non-Committee Review
- Completed by Designated Reviewer
- Find a study by:
  - Linking to it from your email (indicating you've been assigned as the reviewer), or
  - Logging into ESTR and finding your submissions requiring your attention in your In Box. These will be in the "Non-Committee Review" state

Request Changes OR Submit Designated Review
- Requesting Changes will send the request immediately to the PI.
- Submitting a designated review with a determination (Approved, Exempt, Modifications Required, etc.) will send the submission to Post-Review, where the IRB Contact will send the PI a letter.

Review Steps

1. Receive Review Assignments & Navigate to the Workspace

- Review received email and link to the study, or log into ESTR and see studies that are in the "Non-Committee Review" state in your "My Inbox"

2. View the Submission "History" tab

- Review the study History for any preceding events, to see any attachments the IRB Contact has posted (including required or useful checklists), and to see any previous changes the IRB Office has requested.

3. View Related Submissions

- Use the breadcrumb to open the main study; From the Main Study Workspace, use the "Follow-On Submissions" to see any open or previous modifications or continuing review submissions.

4. View the Submission

- Use the "View Study" to view each SmartForm page
- Use the "Printer Version" to view all the SmartForm pages compiled into one document
- Link to any attached documents in either view.

5. Submit Your Review

- Request clarifications to send questions directly to the PI/Study team.
- Make comments on a workspace (these will NOT trigger an email or notice).
- Complete the "Submit Designated Review" Activity and attach any completed required checklists to this form.

Requesting Changes

There are two ways for a reviewer to request changes to a submission:

- By selecting *Request Clarification by Designated Reviewer* activity

  – In the Non-Committee Review state, clarifications may be listed and supporting documents attached to the activity, and

  – The study will immediately be transitioned back to the research team to make changes.

  – The study team will see your comments and will respond to you.

- By selecting the *Submit Designated Review* activity

  – In the Non-Committee Review state, a 'modifications required…" determination may be marked within the Designated Review form.

  – The submission will transition to the Post-Review state, and go back to the IRB Contact to generate a letter for the research team.

  – The Research team will be required to submit changes for review before the study may be approved.

Changes Received

- Once changes are submitted back by the study team, the submission will show up in your inbox.

    - If you selected *Request Clarification by Designated Reviewer* , the changes will immediately appear in your inbox when they are submitted by the research team

    - If you selected *Submit Designated Review*, the changes will be submitted back to the IRB Contact, and they will assign the study back to you for review.

- To view and verify changes, select *View Differences* activity.

Project Review: Submit Designated Review Form

- When in post-review, a submission may be assigned to a designated reviewer to complete non-committee review.

- The Designated Reviewer can request changes by completing the "Request Clarifications" activity. NOTE: if the reviewer requests changes via this method, the submission will go directly back to the PI (no IRB Office intervention).

- To complete the review:

1. Click the "Submit Designated Review" Activity

2. Complete the required items on the form. NOTE: If certain determinations are made, a review level must be selected.

3. Completed checklists should be attached to this form.

4. The Submit Designated Review activity can be executed multiple times.

   - "Yes" to the last question will save the completed items and change the state of the submission to "Post Review."

   - "No" to the last question will save the completed items keep the submission in "Non-Committee Review"

Appendix: Workflow and Activities

Harvard IRB Submission
Workflow Summary