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Investigator Checklist: Continuation

For non-exempt human subjects research that requires continuing review

This checklist is a guide to complete the submission process, not a required submission document. Incomplete submissions will be unlocked and increase processing time.

QUICK LIST OF DOCUMENTS

- ☐ Completed Continuing Review Report
- ☐ A Research Application (RA) Part 1 (this form is mandatory for all Continuing Reviews)
- ☐ Full, current protocol (Select Protocol from the drop down menu on IRBNet)
- ☐ Questionnaires/surveys/tools to be used (if applicable)
- ☐ Investigator Brochure (if applicable)
- ☐ Current, stamped IRB approved consent form(s) and IRB approved advertisements.
- ☐ A clean copy of the most updated consent form(s) and advertisements for new approval date stamp. (Select as above)
- ☐ SIGNED HIPAA Waivers, and Requests for Review Preparatory to Research (Select HIPAA Waiver from the drop down menu on IRBNet).
- ☐ Summary of unanticipated problems or safety monitoring reports
- ☐ Copy of publications, interim reports, multi-center trial reports
- ☐ Package Signatures: PI

See detailed list of required actions and documents below.

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REQUIRED DOCUMENTS AND ACTIONS

1. CREATE A NEW PACKAGE

☐ Click to add package description or notes (optional but recommended)

☐ Review Sponsor field in Project Overview
If update is needed, revise Research Application Part 1 and Consent form(s), as applicable.

2. DESIGNER – Download Required Form

Select a Library: Lifespan – Rhode Island Hospital IRB or Lifespan – The Miriam Hospital IRB
Select a Document: Continuing Review Report form

☐ Continuing Review Report
Download, complete, save and upload as Document Type: Continuing review/Progress Report

3. DESIGNER – Revise an Existing Document

Click the pencil tool "  *"to add or create a new version of a project documents that has already been submitted.*

☐ Research Application (RA) Part 1 (this form is mandatory for all Continuing Reviews)

* Review the Research Application to ensure the information is still accurate.
* Review "Study Personnel Information"; Update research activities (review records, obtain consent) and CITI Training completion dates, as applicable.
* Verify Funding Source is still accurate, and matched Project Overview and consent form(s), as applicable.
* If you update the RA at time of continuing review submit a revision to protocol form to indicate the changes. (To update your Research Application Part 1 you MUST use the pencil icon for the UPDATE. Do not upload and save the document to make changes).

4. DESIGNER – View and Download an Approved Document from a previous package

Under "Documents from Previous Packages that you can Revise:", click the document type hyperlink to download the document.

☐ Copy of current approved protocol
(Document Type: Protocol)

☐ Copy of current approved Questionnaires/surveys/tools that are in active use (if applicable)
(Document Type: Questionnaires/Surveys or Data Collection)
If previously submitted documents are no longer in use, include a memo stating that the document(s) are no longer in use.

☐ Investigator Brochure (if applicable)
(Document Type: Investigator's Brochure).

☐ A "clean copy" of the most updated consent form(s) and advertisements for new approval date stamp.
(Document Type: Consent Form or Advertisement, as appropriate).

5. REVIEWS – View and Download Board Documents from a previous package

Board Documents from all previous packages are available at the bottom of the page.

☐ SIGNED HIPAA Waivers, and Requests for Review Preparatory to Research
(Document Type, HIPAA Waiver)

☐ Current, stamped IRB approved consent form(s) and IRB approved advertisements.
(Document Type, Consent Form or Advertisement, as appropriate)

6. DESIGNER – Attach New Document

Browse the computer to attach documents. Select the document type as indicated above.

☐ All applicable documents referenced above

☐ Summary of unanticipated problems or safety monitoring reports

☐ Copy of publications, interim reports, multi-center trial reports

7. SIGN THIS PACKAGE

☐ Continuation package must be **signed** by the PI.

8. SUBMIT THIS PACKAGE

☐ Submission Type: Continuing Review/Progress Report