



# Investigator Checklist: Amendment/Revision

For revisions to approved non-exempt human subjects research

## QUICK LIST OF DOCUMENTS

- Completed Amendment/Revision Request Report
- Revised Document(s)
  - Clean version layered (with tracked changes accepted)
  - Tracked changes version
- New Document(s)
  - Clean version (with version date)
- Package Signatures: PI
  - Department Approval Sign-off when applicable

**See detailed list of required actions and documents below.**



## 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 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: Revision Request form*

- Revision Request Report\* (Document Type, Amendment/Modification)

### 3. DESIGNER – Revise an Existing Document

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

- A Research Application (RA) Part 1 (if applicable)
- Clean copy of revised document(s)
- Tracked copy of revised document(s)

### 4. DESIGNER – Attach New Document

Use the "Attach New Document" option when the document you are adding is not a revised or updated version of an existing project document.

- New document(s)

### 5. SIGN THIS PACKAGE

- Amendment/Modification package must be **signed** by the PI\*

### 6. SUBMIT THIS PACKAGE

- Submission Type: Amendment/Modification

## What happens next?

1. IRB Coordinator conducts a pre-review of the submission
2. Incomplete submissions will be unlocked to allow for revisions.
3. Complete submissions will be assigned for review. Click on "Reviews" to check the status of your submission.



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## Translated Documents

- English version of document(s) must be approved by translation
- Version date on translated document matches the version date on the English version
- Certification of translation is provided

## Key Study Personnel

- User has completed CITI training
- User is Lifespan employee (if access medical records)
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