





| Job Aid Title | How to Submit a Modification |
|-----------------------|--------------------------------------------------------------|
| Relevant Users | Principal Investigator (PI), Additional Contact, Study Staff |
| Covered Topics | How to create and submit a Modification |

! Note:

- You can only submit one Modification, Continuing Review, or Continuing Review/Modification submission at a time.
- If you have submitted a plain Modification that has not yet been approved and you need to submit additional Modifications to the study, or you need to submit a Continuing Review, please contact the IRB office for assistance (x6-4261).
- Create a Modification submission
 - Once in the "Parent" study (i.e. the study's initial submission in eIRB), select the **New CR/Modification** button as shown below.

| 100 | | | | | |
|--------------------------------|---------------------------------------|-------------------|-----------------------------------------------------------|------------------------|----------|
| Home IRB | | | | | |
| IRB > IRB Studies > R01 | | | | | |
| Current State | H00006056: R01 | | | | |
| Approved | Principal Investigator | PI Test | | | |
| | IRB Owner | Michelle Ferretti | | | |
| IRB | Submitted Date | 11/14/2014 | | | |
| IRB Studies | Approval Date | 11/14/2014 | | | |
| IRB Meeting | Expiration Date | 11/13/2015 | | | |
| IRB Committee | Letter | Approved Letter_ | H00006056pdf(0.01) | | |
| View Submission | | | | | |
| Print Submission | Documents Project Personnel Follow-On | Submissions | Clarifications Requested RNI Full History Summary History | Respor | nd to IR |
| CR/Modification | Category | | Original File Type | Date | Stamp |
| New CR/Modification | Investigator Study Plan | | studyplan_14nov14.docx - 0.02 History | 11/14/2014 10:54 AM | studyp |
| Reportable New Information | Consent Document(s) | | Consent_14nov14.doc - 0.04 History | | Conse |
| Reportable New Information | Grant Application | | researchportiongrant_2014.docx - 0.02 History | | resear |
| My Current Actions | Grant Application | | humansubjectsportiongrant_2014.docx - 0.02 History | 11/14/2014 10:54 AM | human |
| Edit Consumer - Lay Summary | НІРАА | | hipaawaiver_14nov14.doc - 0.02 History | 11/14/2014 10:54 AM | hipaav |
| C Edit Research Staff | HIPAA | | HIPAA Authorization Template 14nov14.doc - 0.02 History | 11/14/2014 10:54 AM | HIPAA |

• In (1) Select **Modification**. Then review the **Current Protocol Status** in (2) and select any of the four statements that are true or not applicable. Click **Continue**.









- On the **Modification Summary** page, check any of the items in (1) that are true. Then in (2) provide a <u>description and a justification</u> of the modification. Include a list of all documents that have been modified. Click **Continue** to proceed to the next page.
 - **!Note:** Please avoid copying and pasting document text (e.g. text from a 'Summary of Changes' document) into the Modification Summary. Rather, please reference the relevant pages from the document in the Modification Summary.



- Once you have finished with the **Modification Summary**, click the **Continue** button and you will be taken to a copy of the currently approved study information. Edit the information in the various 'SmartForm' sections (Section 1.0 Study Information, Section 2.0 Funding Information, etc.) as needed.
 - If you would like to revise or add new study documents related to the modification, you may **Jump To** or **Continue** to Section **7.0 Attachments.**
 - Please refer to the <u>How to Manage Files in eIRB</u> Job Aid for steps on how to add or update study documents in Section 7.0 Attachments.
- When you have completed the Modification submission, click the **Finish** or **Exit** button to close.







• Submitting the Modification

- For Study Staff:
 - After clicking **Finish** or **Exit** in the submission, select **Ready for PI Review** under **My Current Actions** in the submission workspace. **The PI is the only member of the study team that may submit the Modification to the IRB office.**

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|----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pre-submission | H00006049_1: Test: Mod | | |
| RB | Principal Investigator | PI Test | |
| IRB Studies | IRB Owner Study Expiration Date | 12/15/2015 | |
| IRB Meeting | Submission Type | Modification | |
| IRB Committee | Submission Review Date | | |
| Edit CR/Modification | | | |
| | | | |
| Print CR/Modification | Documents Clarifications Requested | Full History Summary History | |
| Print CR/Modification | Documents Clarifications Requested | Full History Summary History | -> |
| Print CR/Modification ty Current Actions Cancel Ready for PI Review | Documents Clarifications Requested | Full History Summary History | My Current Actions |
| Print CR/Modification 4y Current Actions Cancel Ready for PL Review | Documents Clarifications Requested | Full History Summary History Original Submitted File Investigator Study Plan 11.7.14 - 0.02 | My Current Actions |
| Print CR/Modification Ay Current Actions Cancel Ready for PI Review | Documents Clarifications Requested | Full History Summary History Original Submitted File Investigator Study Plan 11.7.14 - 0.02 Fiyer 11.7.14 - 0.01 History | My Current Actions |
| Print CR/Modification ty Current Actions Cancel Ready for PI Review | Documents Clarifications Requested UpdetedDocument Category Investigator Study Plan Advertisements Consent Document(s) | Full History Summary History Original Submitted File Investigator Study Plan 11.7.14 - 0.02 Filver 11.7.14 - 0.01 History Informed Consent Form Version 1 date | My Current Actions |

• For the PI:

• After clicking **Finish** or **Exit** in the submission, select **Submit** under **My Current Actions** in the submission workspace.

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|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pre-submission | H00006049_1. Test. 1 | NDG | |
| RB | Principal Investigator | PI Test | |
| IRB Studies | Study Expiration Date | 12/15/2015 | |
| IRB Meeting | Submission Type | Modification | |
| IRB Committee | Submission Review Date | | |
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| Edit CR/Modification | | | |
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| Print CR/Modification Print CR/Modification IV Current Actions IV Current Actions Cancel | Documents Clarifications Rec UpdatedDocument Category | uested Full History Summary History Original Submitted File | My Current Actions |
| Edit CK/Modification Print CR/Modification 4y Current Actions Cm Submit Cancel Ready for PI Review | Documents Clarifications Rec UpdatedDocument Category Investigator Study Plan | Uested Full History Summary History Original Submitted File Investigator Study Plan 11.7.14 - 0.02 | My Current Actions |
| Edit LX/Modification Print CR/Modification Aly Current Actions Submit Cancel Cancel Ready for PL Review | Documents Clarifications Rec UpdatedDocument Category Investigator Study Plan Advertisements | Uuested Full History Summary History Original Submitted File Investigator Study Plan 11.7.14 - 0.02 Fiver 11.7.14 - 0.01 History | My Current Actions |

• You will know that you have submitted successfully when the submission's "state" in the upper left-hand of the screen has changed from **Pre-submission** to **Pre-Review**.

