

How to submit an amendment that contains protocol changes AND other changes.

Amendments that include protocol changes as well as other items (i.e., personnel changes, revised IDBs) may be submitted together. All attachments should be made to "IRB Protocol" not "Amendment"

1. Check off "Protocol Change" **ONLY** (do not check any other boxes here)

Verify Save
Close

Select a page below to edit

- Instructions
- Amendment
- *Protocol Change**
- PI Attestations
- Attachments

AMENDMENT (08.0039)

Type of Amendment

Type of Amendment:

- Personnel Change
- Protocol Change
- Enrollment Closure
- P.I. Request for Hold
- Other

Please be sure to make all protocol changes to the appropriate section of the protocol.

2. List all of the documents being submitted and all changes being made.

Verify Save
Close

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Proposed Changes

The following two questions should be answered in lay language or language understood by a person unfamiliar with the research being submitted. Area-specific or technical jargon should be avoided or explicitly explained. Do not say 'see protocol' or 'protocol attached'.

Describe the proposed changes to the protocol. Give a brief non-technical explanation of the proposed changes.

1. List all protocol changes and make changes to IRB protocol below.
2. List all personnel changes and make changes to IRB protocol below.
3. List all items being attached and attach to MISC ATTACHMENTS page of IRB protocol below.

3. Attach documents to MISC ATTACHMENTS page of IRB protocol.

Verify Save
Close

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Do not attach here

AMENDMENT (08.0039)

Attachments

SAVE before adding attachments!

ATTACHMENTS

Please attach all applicable documents: (i.e., sponsors amended protocol, letter of explanation, etc.).

Please enter a description for each item.

File to Attach: Browse...

Description:

Attach

SECTION 10:
*Billing Compliance

SECTION 11:
*Confidentiality

SECTION 12:
*Protected Health Information (PHI)

*HIPAA Form Builders

SECTION 13: *Informed Consent Process

*Consent Form Builders

SECTION 14:
*Scientific or Scholarly Merit Review

SECTION 15:
*P.I. Attestations

MISC ATTACHMENTS

Attach here

Approval Attachments

SAVE before adding attachments!

Please attach any documents that have not been submitted and require IRB approval.

Please enter a description for each item. The item description you enter will print out on the approval letter **exactly** as you have written it.

CURRENTLY ATTACHED FILES

	Filename	Version	Description
<input checked="" type="checkbox"/>	07.0257 ICF [initial submission] 12-3-07.pdf	(3/11/2008 10:32:40 AM)	ICF
<input checked="" type="checkbox"/>	07.0257 attached protocol.pdf	(3/11/2008 10:32:40 AM)	Protocol

File to Attach: Browse...

Description:

Attach