

Documents to be submitted with HIC submissions:

New Protocols

- 1 HIC protocol application and 1 copy of the application
- 2 copies of the consent documents
- 3 copies of sponsor protocol (if applicable)
- 3 copies of the Investigator's Brochure (if applicable)
- 2 copies of the HIPAA form(s) (if applicable)
- 1 original of each protocol-specific Conflict of Interest forms (if applicable)
- 2 copies of any ads that have been developed
- 2 copies of approval letters from other reviewing bodies (PRC, VA HSS, PPRC, MRRC-PRC, external IRBs, RSC)

For new protocols that take place exclusively at the West Haven VA, the following is required:

- VA Letter of Approval,
- VA Validated Consent Form,
- VA IRB approved Protocol,
- VA Request to Review Research Project (this contains needed funding and IND/IDE information), and
- VA Conflict of Interest Disclosure.

* Be sure to note on the materials submitted to us if the funding does not come through Yale.*

FOR NEW PROTOCOLS THAT TAKE PLACE EXCLUSIVELY AT THE WEST HAVEN VA, NO HIC FORMS ARE REQUIRED.

Reapprovals

Please do not submit copies of any documents with previous HIC approval stamps!

- The Form 5R and 1 copy of the form
- 2 copies of the HIC application
- 2 copies of any consent documents
- 2 copies of the sponsor protocol (if applicable)
- 2 copies of the Investigator Brochure if it has been revised, and not previously submitted to the HIC
- 1 copy of each protocol-specific Conflict of Interest forms (if applicable)
- 1 copy of DSMB reports

If the protocol is greater than 5 years old, two copies of a re-written HIC application using the most recent version of the HIC application inclusive of all amendments.

*Note that the HIPAA RAF is not required to be submitted at this time unless the content is being amended.

Amendments at the time of Reapproval

Please do not submit copies of any documents with previous HIC approval stamps!

The Form 5 R and 1 copy of the form
The Amendment Request Form and 1 copy of the Amendment Request form
2 copies of the protocol application with the changes highlighted using track changes to indicate the amendment
2 copies of the HIC protocol application with the changes accepted
2 copies of the sponsor letter requesting the amendment (or other supporting documentation, sponsor's summary of changes, FDA, MRRC, RSC, etc if applicable)
2 copies of the sponsor protocol tracked (if applicable)
2 copies of the sponsor protocol with the tracked changes accepted (if applicable)
2 copies of the consent form using tracked changes to indicate the amendment (if applicable)
2 copies of the consent form with the tracked changes accepted (if applicable)

Amendments

Please, do not submit copies of any documents with previous HIC approval stamps!

2 copies of the completed HIC amendment request form (or PRC amendment request form if applicable);
2 copies of the HIC protocol application using track changes to indicate the amendment
2 copies of the HIC protocol application with the changes accepted
2 copies of the sponsor letter requesting the amendment (or other supporting documentation—sponsor's summary of changes, FDA, MRRC, RSC, etc if applicable)
2 copies of the sponsor protocol tracked (if applicable)
2 copies of the sponsor protocol with the tracked changes accepted (if applicable)
2 copies of the consent form using tracked changes to indicate the amendment (if applicable)
2 copies of the consent form with the tracked changes accepted (if applicable)

****NOTE** the exception is Amendments to add/remove investigators or change the PI (which are now 2 separate request forms)—in that case the HIC only requires that two copies of the request form be submitted; however, at the time of reapproval, the protocol application should be resubmitted to include all investigators*******

Permission to serve as PI

Only the Request is needed, with no copies. Remember to attach a CV or biosketch.

Medical Record Review Request

The Medical Record Request and 1 copy of the Request
The HIPAA waiver request and 1 copy of the (if applicable)

Request for Exemption and Not Human Subjects Research form

Only the Request is needed, with no copies.

Requests to Close – HIC Form 5C

The Request to Close, and 1 copy of the Request.

And a Disclaimer: In some cases, the HIC may request additional copies for review of specific protocols. If added materials are needed, the coordinator will contact you.