

Documents to be submitted with HIC submissions:

### **New Protocols**

- 1 original and 1 copy of the HIC protocol 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)
- 1 copy of the following from the grant: the face page (which indicates the title of the grant and the overall PI), the Research Plan (which describes what the research is), Specific Aims (related to the HIC protocol), and the Human Subjects section (so we can see the planned recruitment, the population being studied, etc.).

### **Reapprovals**

- 1 original and 2 copies of the Form 5R
- 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**

- 1 original and 2 copies of the Form 5 R
- 1 original and 2 copies of the completed 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**

1 original and 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 one copy is needed. Remember to attach a CV or biosketch.

### **Medical Record Review Request**

1 original and 1 copy of the Medical Record Request

2 copies of the HIPAA waiver request (if applicable)

### **Request for Exemption and Not Human Subjects Research form**

1 original and 1 copy

### **Requests to Close – HIC Form 5C**

1 original and 1 copy

**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.