

## **HAC Policies and Procedures for HAC Members and OHRP Staff**

### **Amendments and Modifications**

#### **What about the Considerations for Review of Amendments for Protocols?**

The HAC must determine if:

- Information has arisen that might affect the willingness of participants to continue to take part in the research?
- Is there indication that a change was made without prior HAC approval to eliminate apparent immediate hazards to participant?
  - If yes, is the change consistent with ensuring the subject's continued welfare?

#### **What Documents do the Primary Reviewers Receive for Expedited Review of Amendments?**

The HAC Chairperson or designee serves as the primary reviewer and receives the following information for review:

- HAC Reviewers' Checklist
- HAC Form 113 with support documentation such as:
  - Revised informed consent documents/childrens assent documents
    - Summary of Changes
    - Clean version for stamping
    - Changes noted copy
  - Revised protocol
    - Summary of Changes
  - Site added or removed information
  - Copies of reports:
    - Unanticipated problem
    - Data safety and monitoring board report
    - Audit report
    - Other
    - Summary of Changes
  - HAC requested information with copy of email/letter/report from the HAC
  - Revised FDA Form 1572
    - Summary of Changes
    - Changes noted copy
  - Revised Investigational Drug Brochure/Revised Package Insert
    - Summary of Changes
  - Research Team Personnel Changes

#### **What Documents do the HAC Members Receive for Full Review of Amendments?**

The following documents are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Reviewers' Checklist
- HAC Form 113 with support documentation such as:
  - Revised informed consent documents/childrens assent documents
    - Summary of Changes
    - Clean version for stamping

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  - Summary of Changes
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