

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

### **Serious or Continuing Non-Compliance**

#### **Who is Responsible for the Initial Review of Reports of Non-Compliance?**

The HPA serves as the primary individual for screening each incident of non-compliance. Upon consultation with the HAC Chairperson or CRRRI representative, the HPA will initiate an investigation to determine if the incident of non-compliance is serious or continuing non-compliance. The HPA, in consultation with the HAC Chairperson, Vice President for Research, representative from the Office of Legal Affairs, Provost and President determines if each allegation of non-compliance has a basis in fact.

#### **How do I, as an HAC Member, Receive Reports of Serious or Continuing Non-Compliance?**

HAC members are notified via the meeting agenda of any reports of serious or continuing non-compliance. These reports are made available to the members via the common computer drive or submitted in their packets for those who do not have access to the common computer drive. These are discussed at the HAC meetings by the full convened HAC.

#### **What is Included in the Reports of Serious or Continuing Non-Compliance?**

The following documents will be included:

- OHRP Audit Report and other support documentation
- HAC Form 113
- Support documentation from the research team site
- Corrective action plans, if applicable
- Notification to any external sponsors or regulatory authorities

#### **Who Serves as the Primary Reviewer to Receive Reports of Serious or Continuing Non-Compliance?**

The HAC Chairperson or designee serves as the primary reviewer.

#### **What Range of Actions can be Considered by the HAC?**

The HAC has several options that can be considered as a response to the report of serious or continuing non-compliance such as:

- Suspension of the study or degrees of suspension such as:
  - Suspension of study enrollment
  - Suspending any activity on the study as long as subject on active treatment are adequately cared for
- Asking the OHRP to audit the study or all of the studies under this investigator
- Requiring continuing review more often than annually
- Requiring a change in principal investigator (PI)
- Requiring the addition of a mentor for the PI
- Requiring additional education and training for the PI and research team
- Requiring monthly or quarterly reports on the activity of the study
- Terminating the HAC approval for the study thereby requiring all study related activity to cease immediately
- Requesting confirmation from outside experts or consultants related to the activity of the study

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- Requiring additional information from the PI
- Revise the informed consent document
- Inform enrolled subjects
- Increase monitoring of subjects to include observation of the informed consent process

### **Are There other Instances when the HAC can Suspend or Terminate Research?**

The HAC can suspend or terminate research that:

- Was not being conducted in accordance with the IRB's requirements.
- Had been associated with unexpected serious harm to participants.

### **What does the HAC have to Consider When Approval is Suspended or Terminated?**

The HAC has to consider the following when approval is suspended or terminated:

- Consider actions to protect the rights and welfare of currently enrolled participants.
- Consider whether procedures for withdrawal of enrolled participants took into account their rights and welfare.
- Consider informing current participants of the termination or suspension.
- Have any adverse events or outcomes reported to the IRB.

### **What Tool Does the HAC use when HAC Approval is Suspended or Terminated?**

The HAC uses the "HAC Approval Expiration, Suspension or Termination Internal Routing Form" to determine that human subjects are protected.

### **What is the Process for the HAC to Notify the Regulatory Agencies, and Appropriate Organizational Officials?**

The process for this notification is the same as notification of research non-compliance as outlined in the MCG Human Research Protection Program Policies and Procedures.