

## **HAC Policies and Procedures**

### **Adverse Events, Related and Unexpected**

Federal Regulations [45CFR46.103 (a), 45CFR46.103 (b) and 21CFR56.108R] require prompt reporting to the Human Assurance Committee (HAC) of unanticipated problems (as defined below) involving risks to subjects participating in research projects.

#### **What Is An Adverse Event?**

According to DHHS OHRP, an adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

There are two types of adverse events:

1. Internal events that involve our local subjects enrolled by our investigators.
2. External events using subjects enrolled in a clinical trial under an investigator not affiliated with our research site for this study.

#### **When Does Participation In The Research Protocol Begin?**

Participation begins when the research subject or legally authorized representative signs the informed consent document.

#### **What is an Expected Adverse Event?**

Any adverse event that is identified in nature, severity or frequency in the protocol, ICD/CAD Investigator Brochure, or package insert. These do not require reporting to the HAC unless they increase in frequency or severity.

#### **What If An Event Is Expected (Listed In The ICD And Protocol) But It Gets Worse Or Happens More Often?**

The event does not require reporting to the HAC if the event is listed in the protocol or ICD/CAD, unless the event increases in frequency or duration or if any additional measures are needed.

#### **What If I Have An Industry Sponsored Drug Study And The Sponsor Requires An Adverse Event To Be Reported Via The Case Report Form?**

If conducting an industry sponsored drug study and the sponsor requires an adverse event to be listed in the case report form, it must also be reported to the HAC per the guidelines. Such events must be reported in writing to the HAC within 72 hours of any member of the investigative team becoming aware of the event.

#### **What Form is Required?**

All local subjects (e.g., those followed by our investigators) expected adverse events must be reported to the HAC on HAC Form 110 Unexpected and Related Adverse Event/Serious Adverse Event (SAE) if the sponsor requires reporting to them.

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### **What is An Unexpected Adverse Event?**

Any adverse events occurring in one or more subjects, in a research protocol, the nature, severity, or frequency of which is not consistent with either of the following:

- (1) The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) protocol and related documents, such as the HAC approved Description of Research Proposal (DRP), the protocol and the informed consent documents (ICD); and (b) other relevant sources of information, such as product labeling and package inserts; or
- (2) The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

### **How Can You Determine When an Adverse Event is an Unanticipated Problem and Must Be Reported to HAC?**

If the answer to all three of the following questions is yes, then the adverse event is an unanticipated problem and must be reported to the HAC for reporting to DHHS OHRP:

- (1) Is the adverse event unexpected (Was its' specificity and severity not accurately reflected in the informed consent document)?
- (2) Is the adverse event related or possibly related to participation in the research? (If, in the documented opinion of the principal investigator the event was more likely than not caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current subjects?)
- (3) Does the adverse event suggest that the research places subjects or others (such as parents, other students, siblings, etc.) at a greater risk of harm (physical, psychological, economic or social) than was previously known or recognized?

### **Who Reviews These Events?**

The HAC Chairperson or his designee reviews these events. These reports will be submitted to the full Committee for review. The HAC may request additional guidance from other departments or those with certain expertise to assist in the review process of these events.

### **What Form is Required?**

All local subjects (e.g., those followed by our investigators) unexpected and related adverse events or serious adverse events must be reported to the HAC on HAC Form 110 Unexpected and Related Adverse Event/Serious Adverse Event (SAE)

The HAC File #, the protocol title, the Principal Investigator's name and the name of the person submitting the report must be included. The report must also provide the subject identification number , a statement that the PI has reviewed the information and the PI's signature. A copy of the sponsor's adverse event or serious adverse event form(s) may be provided as supplemental information.

### **My Study is Not a Drug or Device Study. Do I Still Have Adverse Events or Unexpected Events?**

Yes. Unexpected, Related adverse events that occur in non-drug or device protocols must be reported as described above.

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### **Can I Email or Fax These Reports to the HAC?**

The reports may be emailed to the email address of [hac@mcg.edu](mailto:hac@mcg.edu) or faxed to the HAC at (706) 721-1479 and the original report must be mailed to the HAC Administrative Office (CJ-2103).

### **What is the Deadline for Reporting?**

Click here for information.

### **What If I Can't Meet the Deadline?**

If the deadline cannot be met, note the cause of the reporting delay on the HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE), as applicable.

### **I Can't Locate My Documentation On What I Reported – Can the HAC Help Me?**

The HAC Administrative Office can provide a database report of all reported AE/SAE at the request of a member of the research team. Please contact the HAC Administrative Office via email at [hac@mail.mcg.edu](mailto:hac@mail.mcg.edu) and provide the PI name and HAC file number to request a copy which can be emailed, faxed, or hard copy can be sent. Please allow at least two business days for the report.

### **Who Do I Contact if I Have Any Questions About How to Complete the Form?**

Click here for information.