

HAC Policies and Procedures

Serious Adverse Event

Please refer to the section on problems and reports that must be reported promptly to the HAC for additional guidance.

What is a Serious Adverse Event?

Serious Adverse Events (SAE) are defined [21CFR312.32] as:

- Death due to *any cause*
- A permanent or substantial disability
- Hospitalization (inpatient admission or overnight stay) or prolongation of hospitalization
- An immediately life-threatening event
- Report of overdose (intentional or not)
- Report of congenital anomaly

Is There Any Additional Guidance For Hospitalizations?

Hospitalization is not a SAE; it is an action due to an adverse event (AE), serious adverse event (SAE) or unanticipated problem or experience.

What if the SAE is Not Related to the Test Article Under Study in the Protocol?

The HAC requires reporting of all hospitalizations including elective admissions and all deaths even if unrelated to investigational drug or device.

What About SAE Reporting in Long-Term Follow-Up Studies?

Reporting of hospitalizations is not necessary for subjects enrolled in long-term follow-up studies in which the subjects are receiving no investigational therapy. Other hospitalizations that are part of the disease process do not have to be reported to the HAC unless they have increased in severity or frequency or if the sponsor requires notification. Examples of these types of studies are: Gynecologic Oncology Group (GOG), Children's Oncology Group (COG), Eastern Cooperative Oncology Group (ECOG), etc.

What About Deaths?

All deaths must be reported, regardless of relationship to study drug or device or disease progression including those in long-term follow-up studies. The research team should report any death as soon as they become aware of the event.

When Should Deaths Be Reported in Long-Term Follow-up Studies?

The research team should report these deaths to the HAC as soon as they occur or the research team member becomes aware of the death. These deaths must be reported on the HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE).

Do Sponsors Have the Same Reporting Requirements as the HAC?

No. Please note that the sponsor may not have the same reporting requirements as the HAC.

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What About Unanticipated Adverse Device Effects?

An unanticipated adverse device effect is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

Who Reviews Serious Adverse Events?

The HAC Chairperson, or his designee, and the full HAC reviews all serious adverse events.

What Form is Required?

All local subjects (e.g., those followed by our investigators) unexpected adverse events, unanticipated problems, or serious adverse events must be reported to the HAC on HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/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.

When Are The Deadlines?

Click here for information.

Can I Email or Fax These Reports to the HAC?

All events may be sent via email to the hac@mail.mcg.edu or faxed to the HAC at (706)721-1479. The original must be sent via campus mail; US mail or be hand-delivered to CJ-2103 within 10 business days. These events must also be reported to the sponsor as described in the study protocol or agreement.

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 and SAE at the request of a member of the research team. Please contact the HAC Administrative Office to request a copy via email at hac@mail.mcg.edu and provide the PI name and HAC file number. Allow at least two business days for the report, which may be e-mailed, faxed or hard copy mailed.

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Who Do I Contact if I Have Any Questions About How to Complete the Form?
Click here for information.