

HAC Policies and Procedures

IND Safety Reports For Industry Sponsored Studies

What is an Investigational New Drug (IND) Safety Report?

Serious Adverse Events (SAEs) occurring at sites other than MCG or VAMC that are reported to the investigator by a sponsor are usually referred to as Investigational New Drug (IND) Safety Reports.

What Should the Investigator Do With IND Safety Reports?

IND safety reports should be carefully reviewed to determine if any changes are needed to the HAC approved Informed Consent Document (ICD) and/or Children's Assent Document (CAD). Investigators are responsible for changing the conduct of the trial and/or updating the consent form as soon as any information is received about increased risks to subjects. This action should not wait until the next study continuation review for any information that increases risks to subjects.

Do I Submit These to the HAC?

The individual reports are not required to be submitted to the HAC but must be kept on file by the investigator. If submitted, IND safety reports will be returned to the research team. However, a summary must be submitted to the HAC at the time of initial and continuing review.

How Should Investigators Report IND Safety Reports to the HAC Before the Study Starts?

Have the PI prepare a report at the time of initial submission that includes the following information:

- The number of IND reports received from the sponsor, if any
- A summary synopsis of the types of reports and their effect (example, cancer drug with deaths - deaths only related to disease progression, not the drug)
- The number of reports related to the drug and the system(s) impacted

What if I Receive IND Safety Reports between the Time I Submitted to the HAC and the Time of HAC Approval?

Submit at the time of continuing review if the protocol is approved. The investigator is responsible for changing the conduct of the trial and/or updating the informed consent document as soon as any information is received about increased risks to subjects.

How Should Investigators Report IND Safety Reports to the HAC After the Study Starts?

Have the PI prepare a report at the time of continuing review that includes the following information:

HAC Policies and Procedures

- The number of IND reports received from the sponsor (if “None” or “Not Applicable” so indicate. If the question is not addressed then the report will be returned as incomplete.)
- A summary synopsis of the types of reports and their effect (example, cancer drug with deaths - deaths only related to disease progression, not the drug)
- The number of reports related to the drug and the system(s) impacted

Can These Summaries Be Faxed Or Emailed?

The forms may be emailed to HAC@mcg.edu or faxed to the HAC at (706) 721-1479. The original must follow in campus or US mail or be hand-delivered within three (3) business days.

Who Reviews IND Safety Report Summaries?

Initial IND Safety Report Summaries are reviewed by the HAC primary reviewer system. Refer to the section on Continuing Review for more information. Additional information may be requested.

What If The Sponsor Continues To Send Our Site IND Safety Reports After We Have Completed The Study And Terminated The Approval With The HAC?

If the protocol was terminated and the sponsor continues to provide Investigational New Drug (IND) safety reports to the research team, the research team must submit summaries of those reports to the HAC in compliance with institutional policy. However, if the study was terminated prior to any local subjects enrolling, then the summary reports are not required.

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