

In This Issue

- Revisions to the Adverse Event Reporting Policy

Quick Links

- [University Hospitals Center For Clinical Research](#)
- [Office of Research Compliance](#)
- [UHCMC IRB](#)
- [UHCMC Grants and Contracts](#)

Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Summer 2007 Research Seminars:

Ensure that your research approval is issued by the IRB; remain compliant by maintaining current requirements for continuing research education credits (CRECs) Register at: <http://ora.ra.cwru.edu/research/orc/education/onlincalendar.cfm>

Contact Us

Office of Research Compliance
Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576
E-mail us!

Revisions to the Adverse Event Reporting Policy

As many of you are aware, the UHCMC Center for Clinical Research has been engaging in continued quality improvement efforts directed at our Human Research Protection Program (HRPP) to ensure compliance with the Federal regulations. Most recently, many of the IRB policies have undergone administrative revisions, aimed to provide additional clarification and guidance of the regulations. However, several IRB policies have more major changes that will impact procedural requirements.

This issue of Collaboration Corner will focus on the newly revised [Event Reporting Policy](#). The primary responsibility for the evaluation of internal and external adverse events lies with the principal investigator of the protocol. For those events that require reporting to the IRB it is the principal investigator's responsibility to submit the reports in a timely manner. *The timelines for reporting an adverse event are determined by the following classifications: study design (observational, non-interventional, and interventional), severity of the event, relationship to the research, and whether the event is internal or external.*

The major change relates to the reporting of fatal adverse events (subject death) that occur on an interventional protocol that has active approval by the UH IRB. Previously, fatal events were required to be reported to the UH IRB within three (3) working days, regardless of whether the death was internal (occurred at the UH study site) or external (occurred at another study site on the same trial). The revised Event Reporting time frame for deaths that occur on an **interventional** study active at UH is as follows:

- Internal death-study related or possibly study related: report to the UH IRB within 7 calendar days
- Internal death- not study related: report to the UH IRB within 14 calendar days.
- External death*—study related or possibly study related: report to the UH IRB within 7 calendar days
- External death*- not study related: report to the UH IRB at the time of continuing review or study closure

**EXTERNAL DEATHS OCCURRING AT ANOTHER SITE IN A RESEARCH PROTOCOL THAT IS ALSO ACTIVE AT UH SITE*

Interventional Studies	Internal		External
	Study Related or Possibly Study Related	Not Study Related	
Death Expected or Unexpected	Within 7 calendar days	Within 14 calendar days	Within 7 calendar days if study related/possibly related; or At Next Continuing Review if not study related
Serious Expected or Unexpected	Within 10 working days	At Next Continuing Review or Study Termination	At Next Continuing Review or Study Termination
Non-serious Expected or Unexpected	At Next Continuing Review or Study Termination	At Next Continuing Review or Study Termination	Retain in Investigator's File

The following tools are available for additional guidance:

- 1) [Adverse Event Reporting Flowchart for Protocols with Greater than Minimal Risk](#) and
- 2) [Adverse Event Reporting Policy Summary](#)

Please note that the Staff at the Center for Clinical Research will be providing education to the research community to discuss the policy revisions and assist investigators/coordinators with practical application of the revised requirements.