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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

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Common Non-Compliance Findings, Part I: Failure to Report Adverse Events and Other Reportable Events

The Office of Research Compliance has identified trends in non-compliance findings while conducting monitoring visits at UHCMC. It appears that while researchers and their staff are often following adverse event (AE) reporting requirements established by sponsors and/or Federal agencies, there is a need to reinforce the reporting requirements as defined by the University Hospital Case Medical Center Institutional Review Board (UHCMC IRB).

The primary responsibility for the evaluation of internal and external adverse events lies with the principal investigator of the protocol. This includes the documentation, investigation, and follow-up of these events. 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.** ([IRB Policy](#), [Event Reporting](#))

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](#)

Interventional Studies (greater than minimal risk): Adverse Event reporting requirements are listed in the table below:

| | Internal | | External ² |
|--|---|---|---|
| | Study Related or Possibly Study Related | Not Study Related | |
| Death Expected or Unexpected | Within 3 working days | Within 3 working days | Within 3 working days |
| Serious Expected or Unexpected | Within 10 working days | At Next Continuing Review or Study Termination ³ | At Next Continuing Review or Study Termination ³ |
| Non-serious Expected or Unexpected | At Next Continuing Review or Study Termination ³ | At Next Continuing Review or Study Termination ³ | Retain in Investigator's File |

****For all study designs (observational, non-interventional, and interventional), any event that changes the risk/benefit ratio or causes a change in the protocol or consent form must be reported to the UHC IRB within 10 working days of learning of the event or of being notified of a required change.**

Failure to report an adverse event in a timely manner may be considered a compliance matter that warrants investigation and/or referral to the IRB for review and a compliance determination ([IRB Policy](#), [Non-Compliance with Human Subjects' Regulations](#)).

NEW: Genetic Research Ethics Consultation Service / Rapid Ethics Action Consult Team

REACT (Rapid Ethics Action Consult Team), a genetics research ethics consultation service, provides practical guidance for investigators. REACT serves Case Western Reserve University and its affiliate institutions including: University Hospitals, Metro Health Medical Center and the Cleveland Clinic Foundation. It is designed for individuals or groups engaged in genetics research and others whose questions are pertinent genetics and/or behavioral biology. To request a REACT consult, please contact Dawn Alpaugh Smith, MA, the REACT coordinator, 216-778-8497, or via email dawn.a.smith@case.edu. This service is free of charge. Refer to accompanying flyer for more details.