

## **Office of Research Quality Improvement How to Request a “For Cause” Audit**

Anyone can request an audit. An audit must be authorized before it is initiated. The information in this document provides an overview of the process including the forwarding of information to Office of Research Administration, determination of the need for an audit, and examples of events, which may generate “For Cause” audits.

- If you have an allegation or complaint regarding non-compliant or unsafe conduct of a study involving human research participants contact the Director Assistant Dean of Clinical Research or the Quality Improvement Coordinator III.
  - Assistant Dean of Clinical Research  
David C. Clark, PhD  
Phone 456-8422  
Email [dclark@mcw.edu](mailto:dclark@mcw.edu)
  - Quality Improvement Coordinator III  
Roxanne Pritchard, RN  
Phone 456-8844  
Email: [rpritcha@mcw.edu](mailto:rpritcha@mcw.edu)
- The allegation/complaint may be written or verbal, filed anonymously or associated with the reporter’s name.
- The received allegation/complaint and associated information will be reviewed. Appropriate measures will be taken.
- Only the Assistant Dean of Clinical Research authorizes the proposal to conduct a “For Cause” audit.
- The Quality Improvement staff initiates the conduct of the “For Cause” audit upon receipt of authorization.
- The individual who filed the allegation/complaint will be notified of the plan to proceed with the “For Cause” audit, except in the event of an anonymously filed complaint/grievance.

Reasons for initiating a request for a “For Cause” audit may include but are not limited to the following:

- Study conducted outside of principal investigator’s expertise.
- Conflict of interest poorly managed or not managed.
- Study was previously audited with plan/recommendation for re-audit.
- Study not conducted in accordance with IRB approved protocol, investigational plan institutional policies, and/or federal regulations. Examples include but are not limited to the following:
  - Enrollment of ineligible individuals
  - Randomization errors
  - Serious adverse events not reported
  - Incorrect use of product
  - Protocol deviation