

**Office of Research Quality Improvement
How to Request Assistance in Preparation for an Audit**

If you are interested in obtaining a review of your regulatory and study subject files in preparation for an upcoming audit by an external party, contact the Quality Improvement staff.

Notification

Whenever possible provide 1-2 weeks advanced notice of pending audit.

Services

Services offered include but may not be limited to the following:

- Identification of beneficial activities in preparation of upcoming audit
- Identification of activities which can be expected during actual audit
- Review of IRB study file
- Review of investigator's regulatory file and comparison of contents to the IRB study file
- Review of signed informed consent forms
- Review of study subject files/source documentation and comparison to recorded research data
- Review of study logs and tracking forms and comparison to correlating documentation

Benefits

Benefits of review:

- Feedback regarding conduct of study, documentation of study activities, or status of regulatory file
- No charge
- Scope of review can be all-inclusive or limited to a specific aspect of the study such as the regulatory file
- Greater sense of preparedness for upcoming audit

Contact information

Roxanne M. Pritchard, RN, BSN, CIP
Program Coordinator III
Phone: 414.456.8844
FAX: 414.456.6565
Email: rpritcha@mcw.edu

Bridget Psichulis, RHIA
Program Coordinator II
Phone: 414.456.8447
FAX: 414.456.6565
Email: bpsicihu@mcw.edu

Tanya J. Rittmann, CCRC
Program Coordinator I
Phone: 414.456.4687

**Office of Research Quality Improvement
How to Request Assistance in Preparation for an Audit**

FAX: 414.456.6565

Email: trittman@mcw.edu