OCR QUALITY REVIEW PROGRAM

It's a wellness visit for your research!

What is a Quality Review Visit?

The Office of Research Compliance is responsible for setting forth and maintaining the regulatory requirements, policies, and procedures to establish and maintain a consistent quality approach to the conduct of research. The Quality Review Program has been developed to support and improve the effectiveness, quality and compliance with organizational policies and procedures and applicable federal, state, and local laws. A major part of this program is the implementation of the Quality Review Visit.

This is a collegial and educational program designed to advocate for our TGH study teams. The program includes periodic Quality Reviews on research involving human subjects. These Quality Reviews are intended to increase the level of protection for research participants by assessing adherence to IRB-approved protocols and can serve as an educational tool for researchers and research staff.

What can you expect?

The Quality Review visit will be coordinated with the Principal Investigator (PI), or designee. Once scheduled, the Quality Reviewer will complete an overview of the protocol in preparation for the review of protocol/subject records at the investigative site. The Quality Reviewer will also meet with the key study personnel and will complete the Quality Review Checklist for each protocol reviewed.

A copy of the draft report and any recommendations for improvement will be provided to the PI and the study coordinator. The PI will have an opportunity to respond to the draft report with any additional information or corrective action plans. If additional reporting to other internal or external departments or agencies is necessary, the Quality Reviewerwill work with the PI to complete that reporting along with a suitable corrective action plan.

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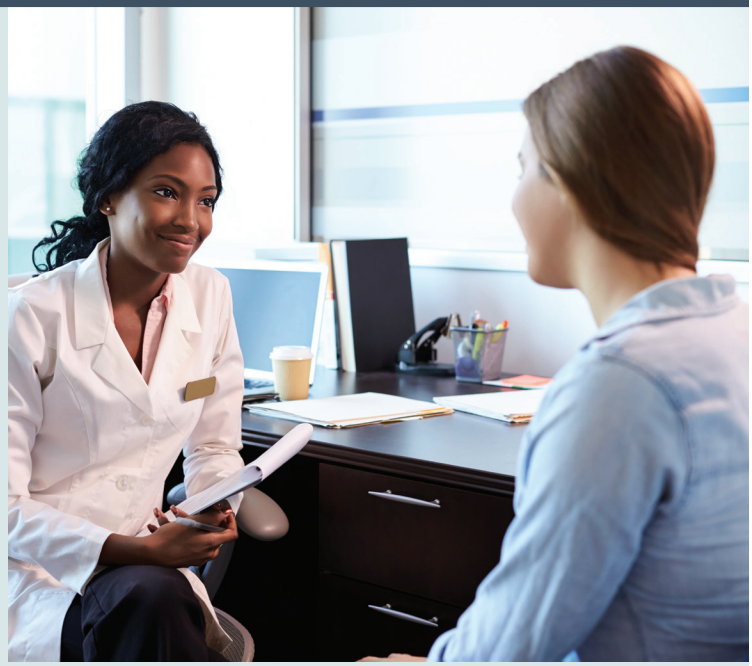
How to prepare?

Please review the selected protocol(s) and associated documents in preparation for your Quality Review Visit. Some of the focus areas that the Quality Reviewer will need access to include:

- ✓ Regulatory Documentation
- ✓ Study/Subject Records
- ✓ Document Retention
- ✓ Sponsor-Investigator Requirements

Note: The Quality Review activities do not replace or minimize the primary roles of the IRB and the PI for protecting human subjects.



How can we help?

This program strives to equip and support TGH study teams in the quality conduct of research.

The Quality Review Program will help to ensure studies are conducted in accordance with regulatory requirements and IRB determinations.

Quality Review results will also provide the framework for development of educational support and guidance for the implementation of best practices related to clinical research conduct.

Do you have concerns about a research study?

We can help! Upon request, we will provide a quick review consultation. Consultations can be requested at any time. If you have any questions about the program or concerns about a study, feel free to contact us.

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