The Post-Approval Review (PAR) program for human research protocols

Overview
The PAR program, an extension of continuing ethics review, has been created to provide the necessary tools to ensure that all human research conducted under the auspices of the University of Toronto is done ethically and in compliance with all regulatory requirements. The cornerstone of the program is the PAR site visit however; other components will include education sessions, workshops, study management tools, and online resources. As a collegial and value-added program, researchers will be encouraged to share their experiences and expectations of the process to help foster a culture of continuous evaluation and improvement as it evolves.

PAR site visits
Site visits will be conducted to provide individualized support to investigators conducting human research while assuring adherence to the REB-approved protocol and overall good practices in research-related activities.

Feedback and observations obtained during site visits will provide the ORE with on-the-ground information, which may enable us to identify opportunities for improving human participant protection activities at the University. The site visit may be **routine**, **investigator-initiated** or **for-cause**.

Routine site visits
All currently active REB-approved protocols are eligible to be selected for a site visit as part of the Post-Approval Review (PAR) program. However, priority will be given to projects that involve greater than minimal risk

Research sites may be selected for routine visits based on risk level, associated REB and complexity of the protocol.

Investigator-initiated site visit
Researchers may request a site visit for educational purposes or in preparation for an external audit. This can be done by contacting the Quality Assurance Analyst (QAA) shantel.walcott@utoronto.ca.

For-cause site visit
Site visits may be conducted in response to an allegation of research misconduct, protocol non-compliance, or a serious complaint related to participant safety.

In all cases, any observations that potentially indicate non-compliance with University policy may be referred for further investigation.

Benefits of the PAR Program

- Ensure compliance with ethical standards, policies and regulatory requirements.
- Promote human participant protection by supporting researchers in their efforts to adhere to REB-approved protocols and good practices in human research.
- Encourage constructive communications between the ORE, REB and researchers.
- Help researchers prepare for external audits.
- Serve as an opportunity to review and share best practices while updating our policies and guidelines.

The PAR site visit process

The site visit will involve an introduction meeting, the review of relevant study procedures/materials and a summary meeting. The QAA will ask questions and discuss study procedures with the study team to assess overall compliance with the REB-approved protocol. The duration and activities performed during each site visit will vary depending on the complexity of the protocol, risk level and reason for the visit. Generally, the entire process will take 1-3 hours.

Principal investigators and/or faculty supervisors are encouraged to participate actively in the site visit process and will be required to attend both the introduction and summary meeting.

If the project principal investigator and/or faculty supervisor cannot attend the entire review she/he will be asked to designate a member of the research team knowledgeable in the procedures of the protocol.

After the site visit, the research team will be provided with a formal written report outlining observations, requests for clarification, recommendations and/or required corrective actions as necessary.

When a response from the study team is received, the QAA will review the response and confirm that all issues have either been resolved or require additional clarification. Consultation with senior members of the ORE and REB will be sought as necessary and the QAA may schedule a follow-up site visit under special circumstances.

When the site visit process is complete, the research team will be provided with a close out letter and a copy of the final report will be added to the protocol file. The final report will remain confidential within the ORE and the Research and Oversight Compliance Office. For more information on the site visit process please refer to the PAR site visit overview, PAR pre-visit form or contact the QAA directly at shantel.walcott@utoronto.ca.