

## **Committees on Human Research Standard Operating Procedures Audits and Monitoring**

To ensure compliance with the federal regulations and CHR approved study procedures for the protection of human subjects; the CHR may conduct routine, targeted or random audits of all active research activities involving human subjects.

### **Routine Audits**

All research, except research that the CHR has determined is exempt from the federal regulations is re-reviewed at least annually. The investigator submits a detailed progress report for the approval period specified by the CHR and currently used consent document(s). Upon receipt of the progress report, the CHR staff conducts an administrative review. This includes a comparison of information contained in the progress report with the research previously approved by the Committees. The current consent documents are verified with the CHR approved consent document(s). In addition to verifying progress report materials submitted by the investigator, the staff audits the file for outstanding documents, if any.

The primary reviewer has the responsibility for verifying the administrative review, reviewing the progress report summary and the number of adverse events, if any, since initial approval, and in providing his/her knowledge of any recent literature that might change the risks and benefits of the study. A Continuing Review Checklist (*see Appendix*) is completed the CHR staff and the primary reviewer for all continuing review requests.

The CHR staff for all pending and active applications conducts a monthly audit. Investigators will be reminded twice (three months and six months after receipt of a Committee letter requesting additional information) about the status of his/her pending application. If the investigator fails to respond to the Committee's request after 6 months, the staff in consultation with the Co-Chairs, will send a notice to the investigator indicating that the CHR has withdrawn the application from consideration. In addition to auditing pending applications, a specified number of all active research projects (approximately 1/12 of total active projects) are randomly selected for a routine administrative audit.

The CHR Administrator routinely verifies CHR policies and procedures with written guidance, other institutional policies and procedures, new regulations governing human subjects research and a review of the compliance activities of the federal oversight agencies. A Self-Evaluation Checklist (*see Appendix*) is used for this purpose.

The CHR, may at its discretion, convene an internal review committee or consult with outside agencies to review its human protections program. This review may include auditing files, attending CHR meetings, interviewing staff or CHR members and contacting investigators or members of the research team.

### **Random Audits**

Random audits of research activities under the aegis of the CHR may be conducted and involve some or all of the following:

1. Examining investigator research records.
2. Contacting research subjects.
3. Observation of the informed consent process.
4. Verification from sources other than the investigators that no material changes in the project have occurred (i.e., research personnel, study coordinators, etc).
5. Other monitoring or auditing activities deemed appropriate by the CHR.
6. Requiring a third person to observe the informed consent process or research procedures

### **Targeted Audits**

The CHR may conduct targeted audits if the CHR has reason to believe that a research activity is not being carried out as approved. Targeted audits may, for example, be initiated by receipt of a complaint by a subject or when procedures approved by the Committee are not being followed based on evidence provided in progress reports. Auditing activities may include some or all of the actions outlined above.

### **Safety Monitoring**

The CHR may request additional safety monitoring for certain high risk studies beyond what is proposed by the investigator or the funding agency. Upon initial review of the research, the CHR will notify the investigator of any additional safety monitoring requirements.

### **Reporting of Audits**

The findings of audits that adversely affect the risks or benefits of the research or continuing non-compliance with the federal regulations or institutional policies and procedures will be reported immediately to the appropriate Co-Chairs of the Committees and the institutional official. Actions taken as a result of this review may include restrictions placed on the audited study, submission of progress reports more frequently than initially specified, suspension or termination of the project, or other action deemed appropriate by the Co-Chairs and the institutional official, if appropriate. The Co-Chairs will decide if the findings of the audit should be presented to the full committee.