P&P: RR 405 Version No: 1.1 Effective Date: 1/21/2019	MONITORING ONGOING RESEARCH	Supercedes: CPHS Policies and Procedures 9/1/2007

1. POLICY

Federal regulations require the IRB to establish procedures for the concurrent monitoring of research activities involving human subjects. Periodic review of research activities is necessary to determine whether the research should be continued, modified/adjusted, or terminated.

IRB approval for the conduct of a study may be withdrawn if the risks to the subjects are determined to be unreasonably high (e.g., there is evidence that more than an expected number of adverse events have occurred, unexpected serious adverse events have occurred, or the investigator is not conducting the investigation in compliance with IRB or institutional guidelines). Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the study terminated. Methods of monitoring ongoing research include, but are not be limited to, the following activities:

- Verification of Protocol Procedures
- Review of Reports of Unanticipated Problems and Serious Adverse Events
- Review of requested Revisions of Research Protocols
- Review of Significant New Findings
- Review of Reports from Outside Sources
- Review of Reports of Noncompliance and/or Protocol Deviations

Specific Policies

1.1 Site Visits and Third Party Verification

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and/ or verify that the study is being conducted as required by the IRB and within the institutional policies and procedures and site-specific procedures, as appropriate. See QA 903 – Review for Purposes of Verification for details.

1.2 Review of Unanticipated Problems Affecting Risk to Subjects and Others and Serious Adverse Events

Subject safety is of the greatest importance for both the individual subject and the goals of the study. The investigator must promptly report unanticipated problems involving risks to subjects or others and adverse events to the IRB per RR 408 – Unanticipated Problems and Adverse Event Reporting.

1.3 Review of Modifications/Amendment (Revision)

Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review and approval (full committee or expedited review, as appropriate) or a determination of exemption, except where necessary to eliminate apparent immediate hazards to human subjects per RR 404 – Amendment (Revision) Review.

1.4 Review of Significant New Findings

During the course of a study, the IRB may review reports generated from a Data and Safety Monitoring Board (DSMB), adverse event reports, current literature, and other sources to ascertain the status of the study and assess whether or not the risk/benefit ratio is still acceptable. The IRB will also determine whether or not new information needs to be conveyed to subjects, if a segment of the population may be bearing an undue burden of research risk, or a segment of the population is being denied access to promising therapy.

1.5 Review of Reports From Outside Sources

It is the responsibility of the OPHS staff and IRB members to act on information or reports received from any internal (within the University) or external source that indicates a study being conducted under the jurisdiction of the IRB could adversely affect the rights, safety, or welfare of research subjects and/or be in noncompliance with IRB and/or institutional policies.

1.6 Review of Reports of Noncompliance

All reports of inappropriate involvement of human subjects in research must be investigated by the IRB Chair and OPHS Director and may be referred to the IRB for investigation. The results of the investigation will be reported as appropriate for the level of severity to the IRB, the IO, and the appropriate University official(s). Regulatory authorities and Sponsors may also be notified. Such reports of noncompliance may come from any source including IRB members, investigators, subjects, institutional personnel, the media, anonymous sources, or the public. See RR 410 – Noncompliance for additional detail.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB or under the jurisdiction of the institution.

3. RESPONSIBILITY

The OPHS Director and IRB Chair are responsible for ensuring that the review processes for conducting ongoing reviews of research are completed as appropriate under the procedures outlined in the Policies and Procedures of CPHS. IRB Chair/Designee is responsible for preliminary assessments of unanticipated problems and/or adverse events, significant new findings, reports of alleged noncompliance or other concerns and the need for third party verification as described in specific Policies and Procedures.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.64

21 CFR 56.108, 56.109, 56.113

45 CFR 46.103, 46.109, 46.115

FDA Information Sheets, 1998