DECISIONS OF IRB REVIEWS

A simple majority of members present at the IRB meeting is required to approve a study. No votes will be accepted by mail. Members may participate by video-conference or conference call, and be counted as part of the quorum. The PI shall be notified of the IRB's decision by email, phone or voicemail within 48 hours of the review.

"Approved" – Approved as written with no conditions.

"Approved with Contingencies" – Approved with contingencies for minor changes that will be identified to the PI and must be completed and documented prior to beginning the research. A contingency letter is sent to the PI, which must be signed and returned to the IRB office with the requested corrections. For these contingencies, the IRB Chair or designated reviewer can, upon reviewing the PI's response(s) to contingencies, approve the research on behalf of the IRB.

"Deferred" – Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full board meeting in order to clarify the points in question.

"Disapproved" – The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas.

If the protocol disposition is "Approved" or "Approved with Contingencies" and the protocol requests inclusion of a vulnerable population(s), special determinations for the vulnerable population(s) are performed at this time.

Suspended" – All protocols must be ceased immediately upon notification of IRB, and not resume until further notice by IRB. The PI should address the contingencies promptly. Once a PI receives notice that a study is suspended, the PI will have ten (10) days to correct contingencies outlined in the suspension notice and to report in writing to the IRB how contingencies are corrected. If the IRB receives no response within the ten days of issuing the contingencies, the IRB chairperson shall write a memo to the PI inquiring as to whether he or she intends to continue the protocol. Also, the inquiry shall state that lack of a written response within a two-week period will result in discontinuation of the protocol. The IRB will be kept informed of the non-compliance with the contingencies and the administrative actions taken.

Once IRB reviews the written corrections, the PI will be notified in writing of the decision to submit further corrections, resume the study, or to terminate the study.

"Termination" – All protocols must be ceased immediately upon notification of IRB, and not resumed. It is the responsibility of the PI to notify all subjects as to the cessation of the study, and reasons for doing so. Written copies of subject notifications must be submitted to the IRB within one month of notification of study termination.

As per requirements of the Department of Health and Human Services, any suspension or termination of an IRB-approved protocol must be reported to the OHRP: http://www.hhs.gov/ohrp/compliance/reports/index.html