Summary of Process for Human Subject Research Compliance (HSRC) Reviews

In an effort to protect the rights and well-being of clinical trial research subjects, the Duke Office of Audit, Risk and Compliance (OARC) HSRC section will conduct confidential routine and directed (for cause) reviews of research protocols approved by the DUHS Institutional Review Board (IRB). Reviews can be either routine or directed.

Routine reviews are selected based upon the risk metrics generally geared towards high subject enrollment, studies with limited oversight or monitoring, Investigator initiated Investigational Drugs or Devices, federally-funded studies, high degree of risk (based upon adverse events, type of study, or vulnerable populations), Phase I studies, or studies that involve Medicare populations. Directed reviews can be requested by the IRB or the Institutional Official or as a result of any official complaint.

In reviewing DUHS clinical trials, the OARC, HSRC section will examine research studies/clinical trials methodology, processes and systems to assess whether the research is conducted according to the protocol approved by the DUHS IRB. The primary purpose of the review is to verify that the standards for safety of human subjects in clinical trials and the quality of data produced by the clinical trial research are met. The review will serve as a confidential quality assurance measure, internal to the institution. Additional goals of such reviews are to detect both random and systemic errors occurring during the conduct of clinical research and to emphasize “best practices” in the research/clinical trials environment.

A review that “passes” a HSRC review does not imply a guarantee of the absolute integrity of the data that was scrutinized nor the ability of the clinical trial research to stand up to an FDA, or other agency, sponsor or institutional audit or review.

The steps that are involved in a routine review will include: the Opening Meeting, Active Protocol Review, Closing Meeting, and Summary of Review Findings.

All reviews will be performed at a previously determined scheduled location Monday through Friday during regular business hours. The length of the review will vary depending on protocol specific elements (e.g., the number of case report files to be examined, the overall state of the protocol documentation, and the preparedness of the staff).

On the first day of the review, if possible, an Opening Meeting will occur. The attendees will include the HSRC Compliance Auditor, the Principal Investigator, the Lead Study Coordinator and any additional Key Personnel that the Principal Investigator wishes to invite to the meeting.

The active portion of the protocol review will begin with an assessment of the overall conduct of the study, the division of responsibilities for particular portions of the protocol, the documentation of the degree of delegation of authority and the appropriateness of this delegation of authority (certification/training), the “informed consent process,” assess how the data was recorded and how the research article (such as the drug, device, or biologic) was accounted for and maintained, and a review of the quality of systems if the research article was produced and/or manufactured at DUHS.
Consistent to both the routine and directed reviews, the following items will be requested and or reviewed: Protocol specific regulatory binder and IRB documentation, Case Report Forms, signed Informed Consents, research article accountability and storage logs, record retention and storage, and overall data quality.

The Closing Meeting will be held after all review assessments have been performed. At this meeting, all action items assessed during the review will be discussed with the appropriate parties, potentially resolving some of the action items. A confidential Closing Meeting Summary will be presented to the Principal Investigator at the closing meeting. This is a draft of the observations that may appear in the Final Compliance Review Summary. All items will be discussed at the Closing Meeting. A copy of this document will be left with the Principal Investigator. The Principal Investigator will have five business days after the closing meeting to clarify any of the noted observations.

A Final Compliance Review Summary will be generated from the draft closing meeting summary, incorporating any additional information provided by the PI during the five business day clarification window. The confidential Final Compliance Review Summary will be issued from the OARC, HSRC section. This summary will be generated by the reviewers(s) that conducted the protocol specific review. This summary will then be sent (electronically with return receipt) to the Principal Investigator. A copy will also be sent to the IRB office. If protocol deviations are extensive, a copy of the summary may be sent to the Department Chair.

When the reviewer is satisfied that all corrective actions have been implemented and all action items are resolved, the reviewer will send a letter to the Principal Investigator confirming close-out of the review. This letter will be sent to all parties previously notified in the review process including the Chief Compliance Officer. If action items are not addressed in the agreed upon timeframe the review will remain “open”. A Failure to Respond Letter will be issued to all appropriate parties if required.