Summary of Process for Human Subject Research Compliance (HSRC) Billing 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) billing reviews of research protocols approved by the DUHS Institutional Review Board (IRB).

Routine billing reviews are selected based upon the risk metrics used for human subject reviews which are 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 billing reviews can be requested by the IRB, DOCR, University Counsel's Office, SOM administrators or as a result of any official complaint.

In reviewing DUHS clinical trials billing, the OARC, HSRC section will examine the study enrollment log, Maestro Care enrollment log, enrollment log consent date versus Maestro Care enrollment date, current protocols and consent forms, as well as any amended protocols and consent forms which make changes to the order set and the research bill template to assess whether the charges billed are according to the protocol approved by the DUHS IRB. The purpose of the billing review is to ensure that the charges are being billed correctly to all payers (grant or insurance). The primary goals of these reviews are to detect both random and systemic errors occurring in the clinical research billing process and to emphasize “best practices” in the clinical trials billing environment.

Once HSRC has completed a billing review a report is issued to the study team and any findings which may lead to possible violations of federal standards or institutional policies related to clinical trials billing are promptly reported to the IRB.

The steps involved in a routine review will include: Contacting the study team and inform them of the billing review; active protocol and consent review; study enrollment log and Maestro Care enrollment log review; data analysis to include order set and research bill templates; a Closing Meeting, and a summary document of review findings. The length of the review will vary depending on protocol specific elements (e.g., the number of research patients, the number of amendments affecting changes in the research bill template for the protocol and consent forms, and the response time of the study team’s staff.).

Generally the billing reviews will parallel the human subject compliance reviews and the active portion of the billing review will begin with the request for a copy of the enrollment log. Reviewers will then compare the study enrollment log and the Maestro Care enrollment log to verify that research subjects were registered within one business day of signing the consent. The reviewer will also compare the enrollment log consent date versus Maestro Care consent date and perform a data analysis to verify that these dates are equal; review each the research bill templates for the protocol, using the Research Billing Review Tool (RBRT); review any amendments in the protocol/consent form which have an impact on the flow of charges in the order set and the research bill template. For non-device studies, the following items will be reviewed, the IRB approved protocols, informed consent, contract and budgets, as well as the
order set and the research bill template. For device studies, an Investigational Medical Device Coverage Review Tool will be completed. Non-Bill protocols will also be reviewed and assessed for accurate designation.

For both routine and directed reviews, the following items will be requested and or reviewed: study enrollment log, Maestro Care enrollment log, protocols, consents, amendments, order sets, research bill templates, and any additional documentation, which may be needed to assist in the review process.

A Closing Meeting will be held with the study team 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 Billing 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. Corrective actions should be completed within 25 business days of the Closing Meeting.

A Final Billing Compliance Review Summary will be generated from the closing meeting summary, incorporating any additional information provided by the PI. The Final Billing 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 billing review. This summary will then be sent (electronically with return receipt) to the Principal Investigator.

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.