Non-compliance/

epeated failure to obtain prior review and approval by the HSC before
ntinuing human subject research.

epeated failure to obtain or document informed consent from human

epeated omission of a serious risk when obtaining informed consent.

epeated failure to maintain accurate research protocol records, report
es to the HSC, or report unanticipated problems to the HSC.

ification of HSC documents.

Continued Non-compliance

- Some or all of the research protocol must be suspended or terminated.
- The data must be destroyed and may not be used when reporting the research results.
- The PI is suspended or disqualified from conducting human subject research.

Monitoring Research Protocols

All protocols reviewed by the HSC are subject to regulatory monitoring by the HSC personnel. Studies can be selected at random for review to ensure compliance with human subjects regulations or HSC requirements or determinations.

After a protocol has been selected for monitoring and usually two to four days before the planned visit, the HSC Chair or designee contacts the investigator, and study coordinator if applicable, to schedule the monitoring appointment. A written follow-up message from the HSC confirms the

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