A. Specific Protocol DSMP

A DSMP is required for each protocol conducted at the GCRC in accordance to the NCRR requirements. (Please, refer to the Data and Safety Monitoring Program (DSMP). This document provides information on DSMP to include: rationale, instructions/guidelines on how to complete a DSMP form, reporting of Adverse Events (AEs), assessing risk levels, etc.). This document and the DSMP form are posted on the GCRC website: www.gcrc.howard.edu


B. DSMP Periodic Progress Report for Continuing Review
(Progress reporting only applies to protocols with more than minimum risk levels)

These Periodic reports are to be completed every 6 months and forwarded to the RSA throughout the duration of the research study. Indicate the reporting period.

(Refer to GCRC website for Progress Report template/standardized form).

Principal Investigators are required to:
Forward periodic/review progress reports every 6 months. These reports should include:

a. Title of study, the person responsible for monitoring the conduct of the study (e.g., PI, an independent reviewer, (indicate DSMB/DSMC; include a copy of DSMB entity report and any other relevant documents).
b. State risk level as indicated in the DSMP (e.g., minimal, moderate, high). If any change/modification to the risk level took place, state change, and give a brief statement relative to this event;
c. Indicate study status (e.g., screening, enrolling, follow-ups/analyzing, etc).
d. Specify what is being monitored as stated in the DSMP.
e. Indicate if study contributes to a specimen repository/data center.
f. Indicate if study is FDA regulated research.
g. Indicate number participants screened, enrolled.
h. State reasons for drop-outs,
i. State (if any) adverse events (AEs) occurred.
j. Attach all AEs reports since the last IRB review (if any) and if these have not been reported to the RSA.
k. State if study recruits special populations (e.g. Children, seniors, etc.

C. Adverse Events

For each protocol that you conduct on the GCRC, it is a requirement to copy the RSA on all adverse events (AEs). Serious events are to be reported within 72 hours to the IRB and to the RSA (and other agencies as required). All other non-serious events should be reported to the RSA monthly. State if these events are expected or unexpected. The AEs reporting is a requirement.

D. GAC Protocol Annual Reviews

Submit a copy of your IRB annual status report, when you submit your IRB Continuing Review Approval letter to the GCRC. Attach a copy of your DSMP for the study, IRB-approved informed consent, and a current DSMP Periodic Report (if applicable).

E. Changes to Study Key Personnel

Changes are to be forwarded to the GCRC Administrator at GCRC@howard.edu
Copy RSA to J_Otado@howard.edu
F. Education in the Protection of Human Research Participants

All PIs, Co-PIs and members of the study team are required to complete the education in the protection of research participants before their involvement with any research study related activities. If you have not completed this requirement, please visit: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

to register for the course. For more detailed information on this course, visit the HU IRB web-site or call HU-IRB at (202-806-7812). Forward me (via e-mail) a copy of the print-out that is generated at the completion of the course or forward GCRC/RSA the IRB certification of completion of course.

G. Observation of the Consenting Process

It is required for the RSA to observe the consenting of GCRC participants. E-mail RSA a listing of the scheduled consenting appointments, include dates, times, and locations. Inform the RSA of any cancellations.

The National Center for Research Resources (NCRR) requires all GCRCs to investigate human subjects’ events surrounding GCRC studies. It is critical that we are in compliance.