DATA AND SAFETY MONITORING PLAN (required for all protocols)

[This Form and the DSMP Program (i.e., guidelines/instructions) are available at the GCRC and at the GCRC website. This form can also be e-mailed to you at your request].

GCRC #   IRB #

Protocol Title:

Principal Investigator: ___________________ Telephone: ___________________ E-mail: ___________________
Study Coordinator: ___________________ Telephone: ___________________ Email: ___________________
GCRC Nurse assigned to this study: ___________________

Brief Description of study–Protocol abstract or equivalent.
(Place a brief description here; use as much space as needed)

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You may refer to the Data and Safety Monitoring Program, section on Data and Safety Monitoring Plan Guidelines and Instructions.

1. Please list the Risk Category (minimal, moderate, severe) and why the protocol fits in that category (choose only one level). Also state whether or not this study has a Data and Safety Monitoring Committee or Board.

2. Monitoring and Safety Review
   A. Who will monitor (e.g., PI, independent reviewer)?

   B. What will be monitored (e.g., number of subjects screened, enrolled, drop-outs, etc)?

   C. How frequently will monitoring occur (e.g., every 3 months, 6 months, etc)?
D. Plans for interim analysis (if none, please state).

E. For a study with an external sponsor (refer to Guidelines and instructions section). Please provide a summary of the DSMC/DSMB organization, responsibilities and operating procedures, membership, plans for interim analyses to include frequency and documentation of DSMB periodic reviews, mechanism for distributing the DSMB periodic review to all participating investigators, etc.

3. Plan for Adverse Event Reporting (refer to Guidelines and instructions section).
   Please provide information on how you will report on and/or review adverse events to see if the protocol should be stopped or changed. (Serious events to be reported within 72 hours to the RSA, GCRC, and to the IRB; other non-serious events should be reported to the RSA monthly).

4. Confidentially and Privacy for research participants (i.e., relative to HIPAA).

   Will the Howard University form - Authorization to Use and Disclose Health Information for Research Purposes be utilized at the time of consenting?
   Yes ☐ No ☐

   If No, provide explanation_

   Signature of Principal Investigator: ________________________________ Date: