HOWARD UNIVERSITY
GENERAL CLINICAL RESEARCH CENTER

DSMP Monitoring Progress Report for Continuing Review

[Complete form ONLY if Risk level > minimal. Forward report to the RSA every six months]

IRB #: ______________ IRB Approval Exp. Date: ____________

Reporting Period (Dates): __________

Protocol Title: ______________________________________________________________

Protocol/Study Ending Date: ______________

Study Contact Person (Names, phone and Email) if different from PI:
____________________________________

Current Approved Investigators:

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Degree (e.g. MD, PhD., RN)</th>
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<tbody>
<tr>
<td>(last Name, first Name, MI)</td>
<td>Division/Department</td>
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<td>Phone/Pager</td>
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State Any changes to Person Responsible for monitoring the study:
(e.g., PI, an independent DSMB/DSMC, etc). Attach the latest copy of the DSMB/DSMC summary report (if has study a DSMB/DSMC).

State Any changes to protocol risk level indicated in the DSMP:
(State change and provide a statement as to why modification occurred):

State Any Changes to what is being monitored:

Current Status of Research Activities:
(e.g., currently enrolling, following subjects, analyzing data, etc

Does this study contribute to a specimen repository or data center? Yes or No

If Yes:
Is the repository/data center established and operations approved under this protocol or under a separate IRB protocol? ________________

FDA Regulated Research
Does this study involve the use of drug, device or biologics (or any other article subject to regulation under the FDA? ________________ indicate Yes or No
If Yes, 
State what (i.e., drug, device and/or the biologics) ________________

State if whether it is approved/unproved drug/device, and whether it is Investigational New Drug (IND), Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE), or other

**Number of Subjects**
Indicate total number of subjects authorized by the IRB ___________________

Number of subjects *screened* this reporting period ___________________

Number of subjects *enrolled* this reporting period ___________________

Number of subjects *enrolled since the study started* ___________________

How many subjects withdrew or required **early termination this reporting period** ____________

*Briefly provide summary of major reasons for withdrawal or early termination on the table below (e.g., moved away, disliked common side effects, lost to follow-up, withdrawn by PI for safety reasons, etc.)*

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<th>Reasons</th>
<th>Total Number per reason</th>
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How many subjects withdrew or required **early termination since the study started** ________________?

**Were there any Adverse Events (AEs/SAEs) and unanticipated problems** (if any) that occurred involving risks to subjects or others since last IRB review ____________ Yes or No.

*(Attach all adverse events reports since the last IRB review (only if these were not forwarded to the GCRC/RSA).)*

Does the study recruit any of the following **special populations**? ____________ Indicate all population(s) (e.g., children, sickle cell disease population, cognitively impaired, older population (65+), pregnant

Principal Investigator’s Signature: ___________________________ Date: ____________