DREXEL UNIVERSITY
FWA # 0000 5917

DATA SAFETY MONITORING COMMITTEE REPORTING

.

The Institutional Review Board (IRB) is responsible for determining if a study needs formal ongoing monitoring of data to ensure that research subjects will be protected. This responsibility stems from Federal regulations which stipulate criterion for study approval be that "when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects" (45 CFR 46.111[a][6]). Sponsors of studies evaluating new drugs, biologics, and devices are required to monitor these studies (see 21 CFR 312.50 and 312.56 for drugs and biologics, and 21 CFR 812.40 and 21 CFR 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a Data Safety Monitoring Committee (DSMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. In general, all studies posing more than minimal risk should have a data safety monitoring plan (DSMP). The DU IRBs may request that research applications that involve a medical intervention or procedure include a plan to assure the safety and welfare of its participants.

Please complete this DSMC form by replying to all questions in sufficient detail so that the IRB will have sufficient information to perform its continuing review of your proposal. Avoid use of "N/A" unless offered as a reply within the form, and do not leave a reply blank.

Do not use any subject names or identifiers within this report that may breech the HIPAA privacy agreement.

1.0: Project Title and Investigator Information:

1.1: Project Title: (Must exactly match grant/proposal title)

1.2: Sponsor name:

1.3: Principal Investigator: **Degree:**

2.0: Data Safety Monitoring Committee Information:

Please list the names, areas of expertise, and degree of each member. Please note that it is a conflict of interest for a DSMC member to also be affiliated with the research protocol.

Chair Person: **Degree:**

Area of Expertise:

Additional DSMC Members:

Name	Area of Expertise	Degree

3.0 Reporting Information

DSMC Meeting Occurrence Date:	IRB Reporting Date:

3.1: Reporting Status

New Report	☐ Yes ☐ No
Follow up	☐ Yes ☐ No
Final Report	☐ Yes ☐ No
Is this study still open for enrollment	☐ Yes ☐ No
This report is open for data analysis only	☐ Yes ☐ No

4.0 DSMC Meeting Plan and Schedule

Please describe in detail the IRB-approved DSMC meeting plan and schedule in accordance with the investigator's approved protocol. Indicate frequency of meeting (for example: every six months or after every six subjects are enrolled)

Did the DSMC meet in accordance with the investigator's approved protocol plan? If nor explain why and submit a Protocol Deviation Report to the IRB	☐ Yes ☐ No
Were all members of the DSMC present for the review?	☐ Yes ☐ No
If not, indicate which members were present	☐

5.0: Summary of DSMC Findings:

Number of Subjects enrolled and withdrawn from the study

_____

Description of subject population (gender, ethnicity, adult, children)

_____

Has protocol recruitment criteria been followed

_____

Adverse Reactions/Serious Adverse Reactions.
a. Describe frequency and intensity of all events.
b. Indicate whether events have resolved or are on going

_____

Protocol Deviations

_____

Morbidity/Mortality

_____

Benefit/Risk Assessment

_____

If study is blinded in any way, has the blind been broken? If so explain.

_____

Have study endpoints to date been met? Explain in detail

_____

5.1: Quality Assurance for Data Analysis:

Is the DSMC confident that the data presented for their review was accurate and collected in a format consistent with the written proposal?	☐ Yes ☐ No
Would the DSMC recommend any modifications in how the PI collects and records study related data?	☐ Yes ☐ No
If so, describe in detail below	
_____	

5.2: DSMC Recommendations:

In the spaces provided below or as a separate attachment, please provide the written recommendation of the DSMC.

a. Should the study continue as currently approved or are modifications required?
(List all modifications required and submit an amended protocol and consent form for IRB approval.)

_____

b. Have any benefits or risks of a significant nature been demonstrated to suggest early termination of the trial?

_____

6.0: Is this a Single Site or Multicenter clinical trial? ☐ Single Site ☐ Multicenter

6.1: If Single Site, how many subjects were approved for enrollment? ☐

6.2: If Multicenter, how many subjects in total were approved for enrollment? ☐

6.3: If Multicenter, list all other institutions or agencies you have notified regarding this DSMC report.

Name	**Date of Report**

7.0 DATA SAFETY MONITORING COMMITTEE CHAIR'S ATTESTATION:

Name of the DSMC Chair (typed):	
Original Signature of DSMC Chair:	Date:

8.0 Name of Individual Submitting DSMC Report:	**Email**	**Phone Number**

For guidelines, go to: www.research.drexel.edu/compliance OR
For additional help call a representative from Human Research Protection at 215-255-7857