

***** UW-GCRC *****
PROJ. NO.:
P.I.:

**UNIVERSITY OF WISCONSIN MEDICAL SCHOOL
UW-GCRC DATA AND SAFETY MONITORING PLAN
WORKSHEET**

Project Title:

Principal Investigator:

All studies conducted on the UW-GCRC require a Data and Safety Monitoring Plan (DSMP). Please review the Data and Safety Monitoring Guidelines for the UW-GCRC. You may contact the Research Subject Advocate (RSA), Dr. Yoram Shenker (yshenker@facstaff.wisc.edu) with any questions related to Data and Safety Monitoring.

(to use checkboxes, double-click on the box – may not work in older versions of MS Word)

1. Who will conduct protocol compliance checks and data accuracy reviews?

If there is no one who will be performing these functions, please check here:

Name:

Title:

Phone:

2. Who will be the primary contact person to follow-up with the RSA on adverse event reporting and data and safety monitoring reports?

Name:

Title:

Affiliation/Department:

E-mail:

Phone:

Beeper:

Fax:

3. Has the Data and Safety Monitoring Plan been approved by an NIH entity? Yes No

4. Is there an external Data and Safety Monitoring Board (DSMB) that will be monitoring this study?

(Please submit the charter of the board if it exists.)

Yes (Please attach a listing of members and the DSMP OR the applicable Board contact information.)

No

5. Is there an internal DSMB? Yes No

If Yes, please list members below or on a separate page. Include Name, Title, Affiliation/Department, E-mail, Phone, Beeper and Fax. Note: Members should not have conflicts of interest with the conduct of this study or with study personnel. If the investigator is the sole Data and Safety Monitor for a minimal-risk study, please so state.) (Add rows as needed.)

Name	Title	Affiliation/ Department	E-mail	Phone	Beeper	Fax

6. Do any of the above individuals have a conflict-of-interest related to the protocol that needs to be disclosed?

Yes (Please describe below) No

UW-GCRC DSMP WORKSHEET (continued):

11. Please list all the expected risks associated with your study:

12. Please list the steps you will take to minimize these risks:

13. What is the risk level of the study as perceived by the PI?

Minimal

Moderate

Minor increase over minimal

High

14. Please describe the process of reporting adverse events and who you will report them to:

15. Describe the DSM review process itself. *Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?*

16. What are the DSM criteria to be used for decision-making regarding continuation, modification, or termination of study?

PI Signature
(must be GCRC PI):

PI Name (printed):

Date: February 25, 2005