

DATA and SAFETY MONITORING MINUTES

Date: _____

Phase: _____

IRB Number: _____

Title of Protocol: _____

Principal Investigator/Designee: _____

PART I: Adverse Events: Were Serious Adverse Events presented and discussed at conference?

Yes No

If no, provide explanation: _____

PART II: Completion of Therapy: Have all subjects completed therapy?

*Yes No

* If "yes" please provide date of last treatment: _____

PART III: Action

- a) Continue trial without modification
- b) Continue with increased monitoring, not requiring protocol change
indicate reason in comment section
- c) Changes in protocol recommended
indicate reason and proposed change in comment section
- d) Protocol closure (to accrual) recommended
indicate reason in comment section
- e) Protocol closed
indicate reason in comment section
- f) Protocol closed to accrual AND it has been 3 months since last patient completed active treatment

DSM MINUTES NO LONGER NEED TO BE COMPLETED

PART IV: Comments Section (mandatory if there has been a change in status since last DSM submission):

Signature/Principal Investigator or Designee:

Person Completing Form:
