



**PROTOCOL REVIEW COMMITTEE DATA & SAFETY MONITORING PLAN
(DSMP) FOR INTERVENTIONAL STUDIES FORM**

PI Name: _____ Protocol ID: _____

Study Title: _____

1. Indicate the entity that will monitor the study data for safety:

- Investigator: complete 3-6 below
- Individual monitor independent of the study team (such as sponsor's medical monitor): complete 3-6 below
- Data Safety Monitoring Board or Committee (DSMB/C): Required for phase 3 studies, see #2 below
- UICC Data and Safety Monitoring Committee (DSMC): Required for UIC investigator initiated interventional studies with no external DSMB, leave the remainder of the form blank

2. If the study is being monitored by a DSMB, attached the DSMB charter or, if the study is NIH funded, the DSMP submitted to NIH. A DSMB charter should, at a minimum, contain the following information:

- A list of the DSMB members and a description of the DSMB composition
- Meeting frequency, structure and procedures
- A description of to whom, how, and with what frequency findings will be communicated
- A description of the safety reporting process
- Procedures for stopping rules and conducting interim analyses, as required by the protocol



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Please complete the following if the study is not being monitored by a DSMB, including the UICC DSMC:

3. If known, list the monitor(s) in the table below. If not known, provide a general description of the expertise of the anticipated monitor(s).

Name/Credentials	Role in Study Monitoring	Expertise	Title/Organization

General description if individuals monitoring not known:

4. Describe the roles of the investigators, research coordinators, sponsor, monitoring entity, statistical consultant, etc. in gathering and monitoring the data, specifically addressing the following responsibilities:
- a. Who records the data?
 - b. Who verifies data accuracy, by what method, and how frequently (examples: double data entry, outside audit, visual verification)?
 - c. Who verifies that procedures are conducted per the approved protocol?
 - d. Who conducts periodic assessments?
 - e. Who will evaluate events to determine if any represent unanticipated problems involving risks to subjects or others and the appropriate action as a result of those events?
 - f. How will confidentiality be maintained?
 - g. How will the data be evaluated and by whom?

