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| 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

1. **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

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

1. **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).**

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| **Name/Credentials** | **Role in Study Monitoring** | **Expertise** | **Title/Organization** |
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General description if individuals monitoring not known:

1. **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:**
   1. Who records the data?
   2. Who verifies data accuracy, by what method, and how frequently (examples: double data entry, outside audit, visual verification)?
   3. Who verifies that procedures are conducted per the approved protocol?
   4. Who conducts periodic assessments?
   5. 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?
   6. How will confidentiality be maintained?
   7. How will the data be evaluated and by whom?
2. **Describe the data and/or events that will be monitored, assessed, and reported to/by the monitoring entity and indicate the frequency with which the monitoring entity will review and assess the data and/or events and the procedures and methods the monitoring entity will use to evaluate the data and/or events, such as statistical analysis.**
3. **Describe the criteria and plan for taking action in response to monitoring entity findings, such as reporting, stopping rules, or implementing protocol changes.**