THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Principal Investigator/Study Team Checklist When Requesting Termination of IRB Oversight

This form can be utilized as a checklist when requesting termination of IRB oversight of your protocol. Please ensure that all applicable requirements are met prior to requesting study closure through the IRB.

NOTE: This form does not need to be submitted to the IRB Office.

MD Anderson Protocol Number: _____

Principal Investigator Name: _____

Protocol Title: _____

Please mark an "X" by the criteria that applies to your protocol:

☐ **Human Subjects Research carried out at a single site may be terminated if all of the following conditions are met: (Please affirm by checking all boxes)**

- ☐ 1. The research is permanently closed to enrollment of new subjects;
- ☐ 2. All subjects have completed all research-related interventions;
- ☐ 3. Long-term follow-up of all study subjects has been completed; and
- ☐ 4. All data analysis is complete.

Note: It is permissible to terminate IRB oversight if the final manuscript(s) or report(s) have not yet been prepared and preparation of such document(s) will not require further access or use of PHI of participants, *i.e.* it will only involve the use of data that meets HIPAA de-identification standards.

☐ **Human Subjects Research where MD Anderson is one of multiple sites and is not the lead site, may be terminated if all of the following conditions are met: (Please affirm by checking all boxes)**

- ☐ 1. The research is permanently closed to enrollment of new subjects at MD Anderson and there are no plans to enroll new subjects;
- ☐ 2. All MD Anderson subjects have completed all research-related interventions;
- ☐ 3. Long-term follow-up of all MD Anderson subjects has been completed; and
- ☐ 4. MD Anderson has no data analysis or other data management responsibility, *e.g.* all data queries have been addressed, and close-out visit has been completed, and MD Anderson data has been locked.

☐ **Human Subjects Research that is conducted at multiple sites and MD Anderson is the lead site, may be terminated if all of the following conditions are met: (Please affirm by checking all boxes)**

☐ 1. The research is closed to enrollment of new subjects at all study sites and there are no plans to enroll new subjects;

☐ 2. All subjects at all sites have completed all research-related interventions;

☐ 3. Long-term follow-up of all subjects at all sites has been completed; and

☐ 4. All data analysis or other data management responsibility for all sites is complete, *e.g.* all data queries have been addressed, and close-out visits have been completed, and the databases at all sites has been locked.

☐ 5. MD Anderson research team has received documentation from the applicable IRBs from each of the non-MD Anderson sites confirming that such Human Subjects Research at each such site has been terminated.

If the above criteria does not apply to your protocol, please select by marking "X" which of the following reasons termination of IRB oversight is being requested:

Human Subjects Research may be terminated prior to completion of the research described in the Human Subjects Research Protocol under the following circumstances.

☐ At the request of the PI, Department Chair or Division Head, data safety monitoring board, the FDA, study sponsor, MD Anderson, or IRB; or

☐ Upon or in preparation for termination of the PI's employment at MD Anderson or association with MD Anderson if the PI responsibilities have not or will not, be transferred to another MD Anderson employee; or

☐ When the PI is not able to fulfil his/her duties, e.g. extended leave, death, and the PI responsibilities will not be transferred to another MD Anderson employee; or

☐ Upon loss or unavailability of funding.

Ensure you have documentation for the following, if applicable:

1. Is the protocol a multicenter trial and MD Anderson is not the lead site?

☐ Yes

☐ No

If yes, please ensure you have received approval from the lead site that the study may be closed at MD Anderson.

2. **Is the protocol a sponsored study, data has been locked and no analysis of identifiable data will occur?**

   ☐ Yes

   ☐ No

   If yes, please ensure you have received approval from the sponsor that the study may be closed at MD Anderson. Please attach this approval with the continuing review form.

3. **Is this an MD Anderson sponsored protocol?**

   ☐ Yes

   ☐ No

   If yes, please ensure you have received approval from the IND office that the study may be closed. Please attach this approval with the continuing review form.

4. **Is this protocol monitored by the MD Anderson Data Safety Monitoring Board (DSMB)?**

   ☐ Yes

   ☐ No

   If yes, please ensure you have received approval from the DSMB that the study may be closed. Please attach this approval with the continuing review form.

5. **Is this protocol currently being audited by the Office of Protocol Support and Management (OPSM) or an external entity (ie. Regulatory agency or sponsor)?**

   ☐ Yes

   ☐ No

   If yes, please ensure that the final audit report has been submitted to the IRB prior to requesting study closure.

6. **Please confirm that there are no outstanding compliance issues related to this research.**

   ☐ There are compliance issues related to this protocol.
   If selected, please explain.

   ☐ There are no compliance issues related to this protocol.

7. **Are off dates entered in CORe for all participants that were registered on this protocol?**

   ☐ Yes

   ☐ No

   If No, the protocol cannot be closed until this is complete.

8. **Please attach a final report for the MD Anderson participants registered on this protocol with the continuing review form. The final report should include the following:**

   - Total number of participants enrolled on the protocol
   - Total number of MD Anderson participants enrolled on the protocol
   - Overall description of serious adverse events or toxicities and that were experienced on the protocol
   - Overall all response for all participants enrolled on the protocol
   - Conclusion/Outcomes of the research

Please note that once the IRB has approved your request to terminate IRB oversight, there are actions that are still allowable. Please reference section 3 of the "IRB Policy on Human Subjects Research Termination, Termination of IRB Oversight and Activities that are not subject to IRB Oversight" for a complete list of these actions.