PI Override Request/Planned Deviation Form

A planned deviation is any change from the IRB-approved protocol and/or informed consent document where the IRB is notified and approval is obtained prior to the deviation occurring.

NOTE: Studies that are set up with two-step registration, must use this form to complete the PI override process. If your protocol does not include a two-step registration process, please complete the electronic PI Override process in CORe.

Protocol#: _____________________ Sponsor: _________________________________

Have similar PI overrides been requested for this protocol in the past?

Yes ☐ No ☐

If yes, how many?_________________________________________________________

Department: _________________ Principal Investigator: ______________________

CORe Accession #: _________

Does this request involve the enrollment of a participant who does not meet the current IRB approved eligibility criteria?

Yes ☐ No ☐

If yes, please provide the following:

Inclusion ☐ Exclusion ☐  CORe Criteria Number: ______

Describe the inclusion/exclusion criteria as currently stated in the protocol.
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Describe how participant deviates from the eligibility.
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Provide adequate rationale for the planned deviation request.
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Will there be a modification submitted to the IRB?

Yes  □  No  □

If yes, please provide details about the changes that will be submitted.
__________________________________________________________________________
__________________________________________________________________________

Have other planned deviations been requested for this study?

Yes  □  No  □

If yes, then provide the number of planned deviations/PI overrides and the purpose.

Please provide Sponsor approval with PI override request.
REQUIRED SIGNATURES

Registering Physician: ___________________________  Date: _______________
Printed Name: _________________________________
Principal Investigator: ___________________________  Date: _______________
Printed Name: _________________________________
Sponsor Name: __________________________________ Date: _______________
Printed Name (email documentation acceptable): _______________________________
IRB Chair or Vice Chair: _____________________________ Date: _______________
Printed Name: _________________________________

IRB approval must be obtained before participant is consented and registered on this protocol.
PROCEDURE FOR PI OVERRIDE REQUEST FORM SUBMISSION

Criteria for IRB Approval

- Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (45 CFR 46.111(a)(1));
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(2));
- Selection of subjects is equitable (45 CFR 46.111(a)(3));
- Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, and appropriately documented in accordance with, and to the extent required by, HHS regulations at 45 CFR 46.116 and 46.117, respectively (45 CFR 46.111(a)(4) and (5));
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111(a)(6));
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111(a)(7));
- Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence (45 CFR 46.111(b)); and
- When the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations at subpart B, C, or D, respectively, of 45 CFR part 46.

If investigator submits a third PI overrides/planned deviation request, this will require an amendment to the protocol.

A warning note will be included in the second IRB approval of PI override/planned deviation to inform the investigator that the next PI override/planned deviation will not be approved and will require a change to the protocol.

A. Industry Sponsored Protocols:

1. Obtain written authorization from the Sponsor confirming that they approve enrollment of the patient who does not meet the specific eligibility criterion, but will be enrolled on the study with IRB approval. (Fax or Email copies are acceptable forms of documentation).

2. Complete PI Override/planned deviation Form.

Remember to obtain the following signatures:
- Registering Physician
- Principal Investigator (P.I.)
- IRB Chair or designee

Note: Please contact OHSP at 2-OHSP or send an email to IRB Help for assistance.
If PI Override/planned deviation request is not approved by the IRB Chair, enrollment of the patient on the protocol cannot proceed.

Attach supporting documentation (e.g., Sponsor approval, treatment notes or treatment plan, etc)

3. Proceed with and document the informed consent process.

4. Submit the completed form to the IRB Office by utilizing one of the following modes of communication:

   Fax: (713) 794-4589
   Email: IRB_Help@mdanderson.org
   Interoffice: IRB Office, Unit 1437

B. Non-Industry Sponsored, Grants or Investigator-Initiated Protocols:

   Refer to steps 2 and 3 as indicated above.

C. MD Anderson IND Studies:

   Please contact the monitor of your study with detailed information about the PI override/planned deviation request. Include in the e-mail patient medical number, protocol number, eligibility criteria and rationale for override. The IND Office will obtain written approval from the IND medical monitor. The written approval will be emailed to the PI and individual requesting the PI override/planned deviation and should be filed in the regulatory binder. Investigators should not submit a PI override/planned deviation request to the IRB until written authorization has been received from the IND Office.

   Once written authorization has been granted, proceed with steps 2 and 3 listed above.

   The PI Override/planned deviation process is not complete until IRB approval has been obtained.