THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

IRB OVERSIGHT REQUEST FORM

This form must be submitted to the MD Anderson IRB for review for either of the following scenarios:

Scenario 1: An MD Anderson investigator or a Sponsor would like for an external IRB to provide oversight (cede oversight) for their protocol. All research activity and patient enrollment will occur at MD Anderson.

Scenario 2: An MD Anderson investigator or a Sponsor would like for the MD Anderson IRB to provide oversight to a collaborating site. The collaborating site will perform research procedures (e.g., data analysis, conducting the informed consent process, administration of an investigational drug/device, etc).

Please complete this section for Scenario 1 above.

Please complete the information below and submit via email to IRB_Help@mdanderson.org or you may also attach this form to a generic memo in the PDOL system.

MD Anderson Investigator:
Protocol Number:
Protocol Title:
IRB Approval date:

Please explain why MD Anderson is being asked to grant IRB oversight to an external IRB.

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Please provide the name, contact information and address for the external IRB.

Name of IRB:
Contact Person (Signatory Official):
Address:
Phone:
Fax:
Email address:
FWA number for the IRB:
IRB registration number:

Does the IRB have an oncology expert/IRB member on the Institutional Review Board (IRB)?

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Has the FDA issued any 483s to the IRB? If yes, please explain.

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Does the IRB have procedures for reporting non-compliance and any unanticipated problems? Please attach.

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Please confirm that MD Anderson's local context language will be included in the Informed Consent Document.

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Please attach the following documentation with this request.

- Written documentation from the Sponsor requesting that an external IRB be utilized for this research project, if applicable.

Please complete this section for Scenario 2 above.

Please complete the information below and submit via email to IRB_Help@mdanderson.org or you may also attach this form to a generic memo in the PDOL system.

MD Anderson Investigator:
Protocol Number:
Protocol Title:
IRB approval date:

Please provide a description of the activity that will be performed at the external site.

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If the external site will conduct the informed consent process, please describe the consenting procedures. Please include a description of who will conduct the consent process, how participants will be identified and if the external investigator has any conflicts of interest with the Sponsor.

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Please include a list of the research staff at the external site and describe their role in the research.

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Please provide the name and contact information for the person at the external site that is authorized to sign IRB agreements for the site. This person typically has a title such as: President, Chief Operating Officer, Vice President for Research, Institutional Official, IRB Director or IRB Administrator.

Name:
Title:
Address:
Phone:
Fax:
Email address:

Please explain why MD Anderson is being asked to provide IRB oversight at this location (e.g., the site does not have an IRB, the site's IRB does not wish to review this protocol, etc).

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Has the collaborating investigator been cited for non-compliance by the FDA/OHRP or their respective IRB within the last 12 months. If yes, please explain.

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Please confirm that the site has access to resources (ie. medical or laboratory services) required by the protocol.

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Please attach the following documentation with this request.

- *Curriculum vitae for investigators and research staff at the external site involved in the conduct of the study.*
- Written documentation from the person at the external site that is designated to sign IRB agreements for the site. The documentation must specifically state that the site is requesting MD Anderson to serve as the IRB of Record for this research.
- Documentation showing that investigators and research staff at the external site have attended a human subjects training and HIPAA course.
- Written documentation of IRB review at the external site, if available.
- Written documentation from the Sponsor that allows this site to participate in this research project, if applicable.

Additionally, the investigator should include the following information in the protocol and informed consent document:

- Local contacts for IRB questions;
- Local contacts for research participants;
- Local participant injury language; and
- Local HIPAA language