IRB Policy on Submission of Investigator's Brochures

Version 2

PURPOSE
It is the policy of The University of Texas MD Anderson Cancer Center Institutional Review Board (MD Anderson IRB) to comply with the regulations governing human subjects research.

POLICY STATEMENT
The purpose of this policy is to outline procedures for submitting Investigator’s Brochure for review.

SCOPE
This policy applies to all human subjects research at (or conducted with) MD Anderson.

DEFINITIONS
The Institutional Review Board (IRB) – means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

Human “study” subject/Research subject - a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable protected health information.

Research Protocol/Study – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Principal Investigator (PI)/Study Chair - the individual responsible for the conduct of the research study.

Research Team - co-investigators, collaborators, trainees, staff, and classified employees directly involved with the research.

Investigational Product – a drug that has not been approved by the Food and Drug Administration for use in human subjects.

PROCEDURE
Information on Investigator’s Brochures

“The Investigator’s Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale, for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial.”

Per the code of federal regulations, an Investigator’s Brochure must contain the following information:

1. A brief description of the drug substance and the formulation.
2. A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.
3. A summary of the pharmacokinetics and biological disposition of the drug in animals and, if known, in humans.
4. A summary of information relating to safety and effectiveness in humans obtained from prior clinical studies.
5. A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and or precautions or special monitoring to be done as part of the investigational use of the drug.

The information outlined in items 1-5 should be included in the protocol or related documents that are submitted for IRB review.

Investigator’s Brochures are required to be included in the protocol record for protocols utilizing investigational products prior to protocol activation.

IRB Review Guidelines For Submitting New or Updated Investigator’s Brochures

- Investigator’s Brochures may be submitted with the initial protocol during the scientific review process.
- Investigators may submit an updated Investigator’s Brochure for review at any time for IRB acknowledgement.

If the information listed in items 1-5 has been updated, investigators are responsible for assuring that the information remains consistent with the IRB-approved protocol and the informed consent authorization.

- Investigators should utilize the attached template or submit a cover letter which contains the following information when submitting Investigator’s Brochures for review:
  a) Principal Investigator
  b) MDA Protocol Number
c) Protocol Title

d) Version and Date of Investigator’s Brochure

e) Briefly summarize the changes in the updated Investigator’s Brochure

f) Statement as to whether or not the updated Investigator’s Brochure includes any new information which should be incorporated into the approved protocol or informed consent authorization. If an amendment is required, provide a plan to submit the amendment for IRB review. If an amendment will not be submitted, please explain why.

g) Dated signature of Principal Investigator

• Investigators may submit Investigator’s Brochures in any of the following formats:

  a) Using the Investigator’s Brochure Memo attach the document in the Protocol Document On-Line System
  b) CD or diskette with a cover letter
  c) Paper copy with a cover letter

• The IRB will issue an official notification letter to the PI acknowledging receipt of the Investigator’s Brochures. This notification letter should be kept in the PI’s regulatory binder.

Please note that based on the information in the Investigator’s Brochures, the IRB designee may request that the protocol and/or informed consent authorization be revised. If this occurs, the PI will be notified.

Possible Actions The IRB May Take

Should the Investigator’s Brochures reveal that there may be safety concerns with the study, the IRB may require actions that include but are not limited to:

• Close the protocol to new patient entry
• Revision of the protocol and the informed consent authorization document to address the safety risks
• Notification of research subjects that participation in the trial may have an impact on their safety

Assignment of additional oversight of the protocol to an independent monitoring board (e.g., Data Safety and Monitoring Board or outside entity, if appropriate).

Penalties for Non-Compliance

Failure to comply with this policy may result in temporary or permanent suspension of the research and/or the investigator’s research privileges.

In accordance with 45 CFR 46.113, any suspensions or terminations of approval will be reported promptly to the investigator, to the appropriate institutional officials, and possibly the federal department or agency head responsible for oversight or funding of the research.
REFERENCES

21 CFR 312.23(a)(5)
21 CFR 312.55
21 CFR 56.111(a)(1)
21 CFR 56.111(a)(2)
ICH Guidelines 7
ICH Guidelines 4.4.2

STRATEGIC VISION

From the following, please select the appropriate goal(s) applicable to this policy and identified in the 2005-2010 Strategic Vision:

Goal 2: Enhance the quality of existing research programs and develop priority programs for the future.

APPROVALS

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