Policy on Designated Individuals

Version 3

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

POLICY STATEMENT
The purpose of this policy is to identify individuals who have the authority to review and approve documentation related to human subjects research on behalf of the MD Anderson IRB.

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

Office of Human Subjects Protection – office designated by MD Anderson to provide administrative support for the IRB

IRB Member Designee – IRB member(s) that have been granted the authority by an IRB Chair(s) to review and approve documentation related to human subjects
research on behalf of the MD Anderson IRB system.

Administrative staff may be appointed to the IRB solely for the purpose of performing expedited/exempt reviews, administrative reviews or review of responses to contingent approval of research with non-substantive changes.

**Signatory Official** - a senior institutional official who has the authority to commit the entire institution named in the FWA form to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the FWA. This individual also has the authority to assure compliance of the institution and all of its components to the Terms of the FWA. Generally, this is someone at the level of President, Chief Executive Officer (CEO), Vice President of a company, or at the level of President, Provost, Chancellor, Vice President, or Dean of an academic institution, unless another official has been specifically delegated with this authority.

**IRB GUIDANCE**

The MD Anderson IRB has granted authority to IRB member designees to review and approve documentation related to human subjects research. These designees are appointed as members or associate members of each IRB, and may hold the following titles or positions: IRB Vice-Chair, IRB Co-Chair, OHSP Director, IRB Associate Director, IRB Manager and IRB Supervisor.

These individuals will have the authority to perform the following actions on submissions to the IRB, on behalf of the IRB based on their level and area of expertise:

1. Approve
2. Approve with modifications
3. Refer for full board review

These individuals do not have the authority to disapprove any documentation submitted for IRB review.

**The following documents may be reviewed by IRB member designees:**

1. Amendments including minimal risk informed consent changes;
2. Research eligible for exemption per the federal regulations;
3. Adverse Event (AE) submissions;
4. Grants or contracts created in support of human subjects research;
5. Protocols, amendments and/or waivers of informed consent and authorization which can typically be reviewed using the expedited review category as defined by the code of federal regulations;
6. Continuing review forms and related documentation;
7. Deviation/Violation submissions;
8. Reports of unanticipated events;
9. Conflicts of interest;
10. Study recruitment materials or advertisements;
11. Other study documentation required to be reviewed by the IRB; and/or
12. Documentation sent to the PI, Sponsor or Regulatory agencies.

**OHSP Staff may create and sign on behalf of the IRB:**

1. Routine correspondence between the PI and the IRB (Examples: acknowledgement of investigator’s brochure, IRB committee outcome letters, related correspondence which may be specific for the OHSP staff’s defined duties.)

**Signatory Official:**

1. Correspondence sent to the PI, Sponsor or Regulatory agencies
2. Certificates of Confidentiality
3. Institutional Certifications related to IRB review or oversight

**REFERENCES**

- 21 CFR 56.109
- 21 CFR 56.110
- 45 CFR 46.109
- 45 CFR 46.110
- 45 CFR 46.117

**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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