GENERAL CHARGE

The Institutional Review Boards 1, 2, & 5 (IRB1, 2, & 5) on Human Subjects in Medical Research are assigned the authority and responsibility to perform, in an independent and autonomous manner, the key functions of the Human Research Protection Program (HRPP) of MD Anderson Cancer Center and its affiliates, (together referred to as “MD ANDERSON”) including Houston Area Locations and Cancer Network sites. Some functions are described in this General Charge. A full description of their duties and responsibilities is contained in the HRPP Manual.

The primary function of each IRB on human subjects in medical research is the prospective and continuing review and approval of all MD ANDERSON research involving human participants, except research reviewed by the Institutional Review Board on Human Subjects in Nonmedical Research. Their objective is to ensure that the rights and welfare of research participants are adequately protected and that all activities involving human subjects are in compliance with applicable MD ANDERSON policies and external regulations.

The IRBs are assigned the authority and responsibility for reviewing all protocols involving human subjects (as defined below and in Chapter 1 of the HRPP Manual) that are conducted at MD ANDERSON facilities or by MD ANDERSON faculty, staff, students or visiting scientists at any location. This includes the authority to observe the informed consent process and all aspects of the conduct of the research. All protocols that involve human subjects shall be reviewed at intervals appropriate to the degree of risk but not less than once per year. The IRBs may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol.

The IRBs are assigned the authority to, and shall review, suspected or alleged protocol violations, participant complaints, potential violations of applicable external regulations or MD ANDERSON policies and other potential non-compliance, and unanticipated problems involving risks to participants or others, as outlined in Chapter 3 of the HRPP Manual. The IRBs also have the authority to take action based on their reviews, including the authority to suspend or terminate a protocol or an investigator’s privilege to conduct human subject research, as outlined in Chapter 9 of the HRPP Manual. In cases of suspension or termination, the IRB will immediately notify the affected investigator(s), the Department Chair, the Vice President, Clinical Research Administration (VPCRA), and others as required by the HRPP Manual, MD ANDERSON policies and external regulations (e.g., Food and Drug Administration).

Upon request, the IRBs shall review and comment on proposed external regulations dealing with human subjects in medical research.
DEFINITIONS

**Human subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Per FDA:**

**Human subject:** An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

**Clinical investigation:** Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of 21 CFR 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of the FDA.

GUIDELINES

A number of the important policies discussed in the HRPP Manual to aid the IRBs in the exercise of their responsibilities are summarized below:

1. Research projects shall be reviewed in such a manner as to provide for the protection of the participant against undue or unnecessary invasion of privacy, disrespect for human dignity, and physical, psychological or social harm. In most cases, this will involve approval of a clearly-worded consent form to assure that the participant is fully informed of the risks inherent in participation and of the benefits which might be reasonably expected.

2(a). Conflict of Interest — Human subject research protocols shall be reviewed for potential conflicts of interest involving possible financial gain from research results versus obligations to human participants. This review process is set out in Chapter 3 of the HRPP Manual.

2(b). Under the Common Rule (45 CFR 46.107(e); 21 CFR 56.107 (e): "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB." The standards for determining if a conflict exists and the steps to take if it does are set out in Chapter 6 of the HRPP Manual.

3. All research protocols involving the use of human participants shall be available for review by any member of an assigned IRB. Any member of that IRB may, upon request, obtain convened board review of such protocols. Approval of a protocol may be granted at intervals appropriate to the degree of risk but not less than once per year. Except for life-threatening emergencies and protocols qualifying for expedited or exempt review, all protocols must be approved at a convened meeting of a quorum of the IRB (i.e., a majority of the voting members, including at least one member whose primary concerns are in non-scientific areas) with the affirmative vote of a majority of those present. The IRB review process and requirements are discussed in Chapter 7 of the HRPP Manual.
4. The activities of these IRBs are subject to the “Confidentiality of Institutional Review Board Proceedings.”

DECISIONS OF THE IRB
If an investigator has concerns with respect to procedures or decisions of the IRB, the investigator may discuss his/her concerns with the IRB Chair. The details and process for such discussions are set forth in Chapter 6 of the HRPP Manual. As this document makes clear, neither the VPCRA, Deputy Chief Academic Officer & Vice President of Clinical and Interdisciplinary Research, nor the IRB Chair, nor any other MD ANDERSON official or committee may approve a protocol that has not been approved by the decision of one of the IRBs, nor apply undue pressure on the IRB to reverse a decision (as further provided in Chapter 3 of the HRPP Manual).

MEMBERSHIP
The IRBs are appointed by the VPCRA. The members of each IRB include: MD ANDERSON faculty and staff, a member whose primary concerns are in non-scientific areas, a member of the local community not otherwise affiliated with the Institution, and any others who may be invited to serve when their expertise is required.

Non-voting ex officio members include but are not limited to representatives of the Office of the VPCRA, Office of Clinical & Interdisciplinary Research, Institutional Compliance Office and Legal Services Department. Membership is explained in Chapter 6 of the HRPP Manual.

The term of membership on the IRBs is a 12-month renewable period beginning September 1 through August 31.

REPORTING OBLIGATIONS
The IRBs report to the VPCRA, who is the institutional official responsible for assuring compliance with institutional policies and external regulations on the use of human subjects in medical research and providing oversight for the HRPP.

IRB MEETINGS
The IRBs shall meet twice a month to conduct business. The OHSP Director and the IRB Manager provide annual reports to the VPCRA, summarizing the nature and volume of MD Anderson’s IRBs’ activities and resources needed for the new fiscal year.

STAFF SUPPORT
The Office of the VPCRA shall provide the necessary staffing and administrative assistance for the IRBs through the Office of Human Subjects Protection.

Versions

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