GENERAL CHARGE

The Executive Institutional Review Board (IRB) on Human Subjects in Medical and Nonmedical 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 the Executive IRB is to address complex human subjects protection issues, serious non-compliance cases, research subject concerns and complaints, requests from investigators for reconsideration of previous IRB reviews, conflict of interest issues referred from the regular IRB or the Institutional Conflict of Interest Committee, and reports of unanticipated problems that occur in the research involving risks to subjects or others. The Executive IRB may also conduct specific high-risk and/or controversial protocol reviews, set pertinent institutional IRB policy and develop and continually update the institution’s definitions of key concepts such as “risk”, “serious non compliance”, or “continuing non compliance”.

The Executive IRB may approve research protocols with or without modifications, or may withhold approval of all or any portion of a protocol assigned to it.

The Executive IRB is 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 Executive IRB also has 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 Executive IRB will immediately notify the affected investigator(s), the Department Chair or appropriate institutional official, the Vice President, Clinical Research Administration, and others as required by the HRPP Manual, MD ANDERSON policies and external regulations (e.g., Food and Drug Administration).

Upon request, the Executive IRB shall review and comment on proposed external regulations dealing with human subjects in medical research. When appropriate, the Executive IRB will review and approve policies and guidance from documents from the IRB and seek promulgation by the Vice President, Clinical Research Administration.
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 Executive IRB 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 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. The activities of the Executive IRB are subject to “Confidentiality of Institutional Review Board Proceedings.”

DECISIONS OF THE EXECUTIVE IRB

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

MEMBERSHIP
The Executive IRB membership is comprised from the membership of the medical and nonmedical IRBs and shall be made up of at least five members. The members must include an individual whose primary concern is in a nonscientific area and at least one member of the local community not otherwise affiliated with the Institution. A quorum shall consist of ten or more members with the intent that all required categories of expertise, as listed above, be represented at convened meetings.

Non-voting ex officio members include but are not limited to representatives of the: Office of the Vice President, Clinical Research Administration. Membership is explained in Chapter 6 of the HRPP Manual.

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

REPORTING OBLIGATIONS
The Executive IRB reports to the Vice President, Clinical Research Administration, 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.

EXECUTIVE IRB MEETINGS
The Executive IRB shall meet as necessary to conduct business but not less than monthly.

STAFF SUPPORT
The Office of Clinical Research Administration shall provide the necessary staffing for the Executive IRB through the Office of Human Subjects Protection.

Versions

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