Executive IRB By-Laws

Version 2

PURPOSE
To constitute an Executive IRB Committee composed of the most senior, experienced members of the institutional IRB Committees to:

- address complex human subjects protection issues, serious non-compliance cases referred from the Institutional Official or the individual IRB Chair;
- review requests from individual IRB Chair’s for reconsideration of previous IRB’s reviews;
- review conflict-of-interest issues referred from the regular IRBs or from the Institution’s Conflict of Interest Committee (COIC);
- provide guidance and regulatory oversight for specific high-risk and/or controversial protocol reviews;
- provide regulatory oversight for protocols where significant non-compliance has been identified;
- set pertinent Institutional IRB policy and procedures;
- review adverse events for the Institution; and
- develop and continually update the Institution’s definitions of key concepts such as “risk,” “serious non-compliance,” “continuing non-compliance”.

AUTHORITY
The Executive IRB Committee shall act as a fully constituted IRB Committee under federal regulations (45 CFR 46 and 21 CFR 56) and the Institution’s Federalwide Assurance, as filed with the Department of Health and Human Services’ Office of Human Research Protections (OHRP), to ensure that all research involving human participants meets the federal, state and local statutory requirements for human subjects’ protection, and complies with Institutional policy and procedure.

MEMBERSHIP
Membership on the Executive IRB Committee shall include the Executive IRB Chair, IRB Vice Chairs from IRB1, 2, 4, and 5, and the senior IRB members to
provide expertise related to key research disciplines. Institutional Administrators may be requested to provide guidance as needed on regulatory issues. In these cases, depending on the role of the Institutional Administrator(s) they may or may not be a voting member. The voting members shall possess an advanced level of regulatory knowledge and experience as IRB members, expertise to review complex or high-risk studies, and expertise with research involving complicated ethical considerations and participant safety concerns. The Executive IRB Committee may, at its discretion, invite consultants with competence in specialty areas to assist with the review of issues that require expertise beyond, or in addition to, that of the Committee, or for a perceived or real conflict of interest on the part of the IRB member possessing the expertise required to review a particular issue.

The committee will be comprised of the chair, a co-chair, and an appropriate number of members to assure compliance with the regulations. A quorum will be met if the majority of members are present. Associate members with comparable background and experience will replace members as needed or to maintain quorum.

FUNCTIONS

1. Review and recommend revisions to pertinent Institutional policies and procedures regarding human subjects research and protection. May implement new policies, as needed.

2. As requested by the Institutional Official or individual IRB Chairs review specific issues related to areas of research that may be perceived as high risk and provide guidance to the individual IRB.

3. Consider and take action on potential serious and/or continuing investigator non-compliance with regulations and/or with the requirements of the IRB of record.

4. Receive, evaluate and act upon reports, concerns or allegations from research subjects, and allegations or complaints of investigator non-compliance from any source.

5. Provide expert guidance and advice to internal departments, external agencies and other entities on issues regarding human subjects research and protection.

6. Receive and act upon decisions of the Institutional Conflict of Interest Committee (COIC) under the Institution’s Investigator Conflict of Interest Policy concerning its assessment of significant interests, as defined by Institutional policy, which are disclosed by investigators, namely whether such significant interests constitute or appear to constitute a conflict of interest, and which conditions or restrictions, if any, should be imposed to manage, reduce or eliminate such conflicts of interest or appearances of conflict, or the decision that the research cannot proceed at M.D. Anderson.

7. Receive and act upon information concerning risks to human subjects, deviations in IRB-approved protocols, or other breaches of Institutional policy regarding human subjects.

8. Work with staff of the Office of Human Subjects Protection to develop the Institution’ definitions of pertinent human research concepts, such as “risk,”
“serious non-compliance,” “continuing non-compliance”.
9. Review internal and external serious adverse events, safety reports or other new information that may pose a safety risk to research participants and make determinations as to whether informed consent documents should be revised, participants should be reconsented. The committee may take additional actions within their purview.

PROCEDURES
The IRB Executive Committees shall meet monthly on a published schedule.

A. For review of Institutional policies and procedures regarding human subjects research and development of definitions of pertinent human subjects research concepts:
   1. The IRB Executive Committee may address procedural and policy matters on its own initiative or as a result of submissions from various sources (e.g., the Institutional Official, OHSP staff, and/or investigators or research staff).
   2. The IRB Executive Committee will communicate their findings/recommendations to the Vice President for Clinical Research Administration and the Director of OHSP to provide guidance and education to those who may be impacted by the recommendations.

B. For reviews of research subject concerns, allegations or complaints:
   1. Concerns may be submitted to the Executive IRB Committee through various sources.
   2. The IRB staff will provide the Executive IRB Committee with all available information regarding the concern as voiced by a study subject, study staff or any concerned party.
   3. The Executive IRB Committee may initiate an investigation, to be conducted by the appropriate auditing staff or individual, and/or other independent auditor/audit group as deemed necessary by the Executive IRB after preliminary fact finding by the Chair of the Executive IRB or designee.
   4. If appropriate, procedures for review of potential investigator non-compliance may be initiated.

C. For reviews of potential serious and/or continuing investigator non-compliance:
   1. The Chair of the Executive IRB or designee shall conduct an initial fact-finding or review of regulatory documentation. The Chair of the Executive IRB will determine whether the report of events is a matter for immediate review by the IRB Executive Committee. In the event of an immediate concern that would impact participant safety, the Chair of the Executive IRB or Vice Chair will be consulted to assess whether immediate suspension of study
recruitment and/or the research activity is warranted. Regulatory requirements to protect human subjects involved in the research will be followed and may be implemented by the Institutional Official, Chair of the Executive IRB or Vice Chair (in the absence of the IRB Chair). In the event of a conflict of interest at the IRB, the initial fact-finding and/or review will be conducted by or under the oversight of the Director of OHSP and may be referred to the Office of Institutional Compliance, or an independent consultant.

2. The IRB Executive Committee will follow due process procedures in allowing the Investigator in question full opportunity to address the findings of the IRB and to respond in writing or in person.

D. For initial review of certain areas of research by Executive IRB Committee:

1. The individual IRB Chair may request that the Executive IRB Committee review special circumstances related to a specific study. The IRB Chair or designee shall determine whether the study is such as to require the specific expertise for review which can be provided by the IRB Executive Committee. The IRB Executive Committee may refer to an independent expert when it is determined that this expertise is needed either for additional expertise or due to a conflict of interest. Any non-member who participates in review of an IRB matter will be bound by the same confidentiality obligations as the members and associates.

2. If a determination is made that the requested review is appropriate for IRB Executive Committee deliberation, the Principal Investigator may be notified of the meeting date and the appropriate procedures by the IRB administrative staff. These procedures may include additional reference materials, number of copies to be provided for reviewers and a request for the Principal Investigators presence at the meeting. The Executive IRB Chair or designee who will conduct the meeting will make the determination whether the Principal Investigator must be present.

E. For review of potential conflict of interest:

1. In cases of investigator conflict of interest where the COIC has made a determination and informed the IRB of record of such decision, the Executive IRB Committee will review the decision and reasons provided by the COIC prior to making its final determination. After a discussion and vote, the Executive IRB Committee may accept the decisions of the COIC, require additional requirements or restrictions, or find that the conflict cannot be managed, reduced or eliminated and therefore may not proceed. The Executive IRB Committee will provide the investigator, the investigator's Chair, and the COIC with its final decision in writing.

2. Where the investigator's interests are beneath the threshold of a significant interest, as defined in Institutional policy, the Executive IRB may request a review and recommendation from the COIC.
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