

# Memorandum

**TO:** To Whom It May Concern

**FROM:** Aman U. Buzdar, M.D. *AUB*  
Vice President, Clinical Research Administration

**DATE:** January 4, 2019

**SUBJECT:** Use of the Single IRB Mechanisms for Federally Funded Research Projects

The MD Anderson IRB is pleased to participate in the single IRB mechanism for federally funded research projects. MD Anderson has 3 clinical IRBs that review drug, device, surgical and laboratory protocols; 1 psychosocial IRB that reviews population-based research, surveys and data reviews, and 1 Executive Session IRB that reviews policies and multi-faceted research-related matters that expand across the human research protection program (e.g., adverse events and conflict of interest).

MD Anderson maintains an FWA through OHRP (FWA00000363), each of our IRBs are registered through OHRP, and our policies and procedures are available to external sites and Sponsors as needed. MD Anderson is also in the process of publishing policies externally as part of the accreditation process.

The MD Anderson IRBs provide initial review, continuing review of research, and review of modifications to previously approved research as required by the Common Rule (45 CFR 46) when conducted under the Institution's FWA, and applicable FDA regulations (21 CFR Parts 50, 56, 312, 812) when governed by the FDA. The MD Anderson IRBs review all research, regardless of funding, in accordance with federal and state requirements. MD Anderson also applies the International Council on Harmonisation – Good Clinical Practice (ICH-GCP) standard to all clinical trials. MD Anderson IRBs will ascertain whether research is subject to the additional human subject protection requirements of federal agencies (Departments of Defense, Education, and Energy, and the Environmental Protection Agency), and if so, will follow the appropriate additional mandates of that agency. All research is either approved, disapproved, or returned noting which modifications are required for approval. The MD Anderson IRB review is compliant with NIH requirements.

In addition, MD Anderson's Office of Clinical Research Administration offers the following specialized services:

- **Consent and Patient Material Editorial Services** –The MD Anderson editorial services office edits or authors MD Anderson-specific consent documents and amendments and negotiates appropriate language with the sponsor on behalf of the study team in advance of IRB review.
- **IND Management** – The MD Anderson IND Office assumes many of the day-to-day sponsor responsibilities for INDs that are held by MD Anderson. The office is comprised of three groups in order to both assist investigators and provide oversight.
- **Auditing Support** – This office conducts clinical research audits and facilitate FDA, EMA and NCI inspections and audits.
- **Dedicated external IRB coordinators** – Provides single points of contact for intake and processing. Dedicated staff provide IRB regulatory support for protocols where the MD Anderson IRB has oversight at an external site. These staff function as liaisons with the external site to ensure that IRB agreements and approvals are secured prior to implementation of the research.
- **Electronic Systems** – Facilitates submission of protocols and informed consent documents from all sites.
- **Scientific Review Process** – Encompasses scientific review committees (SRCs) that have the responsibility of overseeing all aspects of the scientific research that is incorporated into a protocol plan.
- 
- **DSMB/eDSMB** – The DSMB convenes 10 months of the year and oversees the data and patient safety issues for phase II or higher randomized clinical trials that originate at MD Anderson and are not being monitored by any other DSMB; or trials that have been designated as requiring DSMB monitoring at the request of the IRB, institution, or principal investigator.
- **Research Education Program** – Develops and delivers clinical research education programs including Human Subject Protection Training and Clinical Research Training.

MD Anderson is qualified to serve as the single IRB for multi-center research projects in which MD Anderson faculty is leading the research. MD Anderson is also willing to partner with, or cede oversight to, human research protection programs to other IRBs at external sites to ensure that IRB oversight is maintained in accordance with federal grant requirements.

The MD Anderson IRB serves as the privacy board for research for projects conducted at MD Anderson. For external research projects where MD Anderson will provide IRB oversight at another site, MD Anderson is willing to partner with the external site's privacy board so that they may fulfill this function in lieu of the MD Anderson IRB.

MD Anderson is committed to continuous quality improvement to its human research protection program. To this end there are required research education certifications for research faculty and employees, as well as required annual IRB orientation for IRB members including IRB staff. Continuous education is provided through the use of research town halls or other mechanisms. The institution is currently seeking accreditation through the Association for the Accreditation of Human Research Protection Programs.