Chapter	VPR Policy	Effective:	September 1, 2015
Section	Quality Program	Revised:	November 18, 2016
Policy	**Study Reviews for Human Research**	Responsibility:	Vice President for Research

STUDY REVIEWS FOR HUMAN RESEARCH

PURPOSE

To establish a standard operating procedure for the Office of Regulatory Affairs and Compliance (ORAC), Human Research Compliance Program. The ORAC Human Research Compliance program will provide a review of Institutional Review Board (IRB)-approved research conducted by UT Health Science Center at San Antonio researchers. The goal is to achieve and maintain compliance with organizational policies and applicable laws, regulations, codes and guidance. Through periodic compliance reviews and other quality improvement activities, the ORAC Human Research Compliance program will evaluate and make recommended improvements to increase compliance, when necessary.

BACKGROUND

The Handbook of Operating Procedures, HOP Chapter 7, authorizes the Office of Regulatory Affairs and Compliance to develop and implement a research review program to evaluate the functioning of the Human Research Protections Program (HRPP) and safeguards in place to protect human research subjects in institutional research. This policy provides details on the ORAC human research review program and how it is integrated with the greater HRPP.

In addition, ORAC reviews other aspects of human research such as good clinical practice, research billing, participant payments, conflict of interest and IRB and institutional operations according to applicable regulations and accreditation standards.

REVIEW PROCEDURES

A. In general, there are three triggers that initiate an ORAC human research review:
    1. For-cause reviews are conducted at the request of the IRB or an official of the institution

In addition, the ORAC reviews will include special situations and institutional responsibilities on a regular basis. Of the reviews conducted in a quarter, the goal is that at least two are reviewed for these additional elements, including:

1. Section 6 Billing and Participant Payments
2. Section 7, FDA Sponsor Investigator
3. Institutional Offices: IRB, Office of Clinical Research (OCR), Office of Sponsored Projects (OSP), Clinical Trials Office (CTO), or Conflict of Interest (COI)

E. An entrance meeting will be conducted at the start of all reviews. In addition to the PI (who is required to attend), other key research team members should attend at the discretion of the PI. If the PI will not be available for the duration of the review, another member of the study team should be designated and attend the entrance meeting.
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b. All Patient Source documents
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