IRB SOP 506
Criteria for IRB Approval

Purpose

The purpose of this standard operating procedure (SOP) is to ensure that specified criteria are reviewed by the USA IRB and requirements determined to be adequate.

Scope

This SOP applies to all IRB administrative staff and board members.

Policy

All research projects that include human participants must meet certain criteria before the investigator can initiate research project-related procedures, which include the principles of respect for persons, beneficence, and justice as discussed in the Belmont Report. In addition, certain other criteria that are unique to the University of Souheeauhe Ua

meeting any of the below criteria must be registered with ClinicalTrials.gov before final approval is issued. The NCT# must appear on the IRB Application.

Studies involving drugs, devices, or biologics that are regulated by the FDA and meets the FDA definition of an Applicable Clinical Trial (ACT)
Studies receiving NIH funding and fit the NIH definition of a Clinical Trial **acal TrialnsSt5005 Tc 0005 Tw0**

evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the Research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the Research. The IRB should not consider possible long range effects of applying knowledge gained in the Research (e.g., the possible effects of the Research on public policy) as among those Research risks that fall within the purview of its responsibility
Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits Based on this assessment, risk associated with the research will be classified as either Minimal Risk or Greater than Minimal Risk.

1.2 Scientific Merit

To assess the risks and benefits of the proposed research, the IRB examines the research

persons; the scientific and ethical justification for excluding classes of persons who might benefit from the research; and the inclusion/exclusion criteria. At the time of the continuing review the IRB will determine that the PI has followed the subject selection criteria that he/she/originally set forth at the time of the initial IRB review and approval.

1.4 Recruitment of Subject's

The investigator will provide the IRB with all recruiting materials to be used in identifying participants including recruitment methods, advertisements, and payment arrangements. For specific details, see *SOP: Recruitment of Research Participant*.

An Investigator may contact potential research subjects for recruitment purposes using the following methods:

• The potential research subject may initiate the contact by responding to an IRB-approved advertisement or similar recruitment notice.

• A treating physician who is also an investigator may talk directly to the patient about recruitment into a research trial.

• If the treating physician is not the investigator, the treating physician must get an authorization to refer the patient to the investigator. The investigator may then rely on the authorization to contact the individual. The investigator [in(.)7 ( )1l0 (h)10.1 (e]TJ0.0)]TJ-b18 (t i)4 (v)

1.5.2 Significant New Findings

During the course of research, significant new knowledge or findings about the medication or test article and/or the condition under study may develop. The PI must report any significant new findings to the IRB and the IRB will review them with regard to the impact on the subjects' rights and welfare. Since the new knowledge or findings may affect the risks or benefits to subjects or subjects' willingness to continue in the research, the IRB may require, during the ongoing review process, that the PI contact the currently enrolled subjects to inform them of the new information. The IRB will communicate this to the PI. The informed consent should be updated and the IRB may require that the currently enrolled subjects be re-consented, acknowledging receipt of this new information and for affirming their continued participation.

1.6 Data Safety Monitoring

All interventional studies involving more than Minimal Risk must include a Data and Safety Monitoring Plan. A DSMP is established to assure that each research study has a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. The DSMP should specify whether there will be an independent Data and Safety Monitoring Board (DSMB). The primary purpose of an independent DSMB is to protect the research subjects through independent analysis of emerging data from the trial. This differs from adverse event reporting in that the DSMB can review aggregate and un-blinded data as the data accumulate, identify significant issues and trends during the study, and recommend changes in the study including recommending early termination of the study. The DSMB reviews data for both safety and efficacy. The protections afforded by this review apply to both current subjects and future subjects if the DSMB identifies the need to modify or even halt the trial. In addition to the above, an independent DSMB protects the credibility of the trial by virtue of its independence from the study sponsors, and helps to ensure the validity of study results by reviewing data on subject accrual and conducting interim reviews.

1.7 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy of subjects and to maintain the confidentiality of the data.

1.7.1 Privacy

The IRB must determine whether the activities in the research constitute an invasion of privacy. To make that determination, the IRB must obtain information regarding how the investigators are getting access to subjects or subjects' private, identifiable information and the subjects' expectations of

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to additionally protect research data. For further details, see *SOP: Certificate of Confidentiality*. In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harm that would be likely to result from a disclosure of collected information outside the research.

The IRB shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

1.8 Vulnerable Populations

At the time of initial review, the IRB will consider the inclusion of vulnerable subjects in research. To approve research involving vulnerable populations, the IRB must determine, where appropriate, that additional safeguards have been included to protect

University Related Documents

SOP: Certificate of Confidentiality
SOP: HIPAA Authorization
SOP: Recruitment of Research Participants

HISTORY

Effective Date:
Revisions: November 2018, August 2023