Office/Contact: Office of Research Assurance and Sponsored Programs
Source: Federal Policy for the Protection of Human Subjects (also referred to as the Common Rule) – codified at 45 CFR 46, Protection of Human Subjects, Subparts A-D; SDBOR Policy 4.8.1
Link: http

3. Policy

    a. At the University, the guiding principles for the protection of human research participants will be based on the Belmont Report. The Belmont Report establishes three basic principles essential when conducting any human research:

        i. Respect for persons: individual autonomy through informed consent, and protection for those with reduced autonomy;

        ii. Beneficence: through the maximization of benefits and the minimization of harm; and

        iii. Justice: through an equal selection of subjects and a sharing of risks and benefits.

    b. In accordance with National Institutes of Health (NIH) policy, all University personnel listed on an application as investigators (key personnel) conducting human subjects research that is supported by NIH funds are required to complete required education in the protection of human research participants. Although the scope of the policy is limited to research supported by the NIH, to adequately protect all human subjects in research, the University extends the NIH mandate to all research. The training module chosen by the University is an on-line training program for researchers developed by the Collaborative Institutional TrainingTw (.)Tj.2 (t)-21(i)8.3 (s)-7.6 (Ir)-3n (u)2 (n(he)-1.7U)4.6 (n)10.9 (ik

investigators (PIs) may not make a unilateral determination of a project's exempt status and must submit a protocol or research materials for review. A single trained individual—either the Chair of the Committee or a designee will make the determination as to exempt status. This individual may call on others to provide additional guidance, as needed. If a proposal is determined to be exempt from the Common Rule, no continuing review will be required, except that the PI must report any proposed changes to the protocol (such as those that may change the activity so it is no longer exempt) and report any unanticipated or anticipated but serious adverse events.

g. For research involving no more than minimal risk that appears on the Federal Register list of categories, or for minor changes to previously approved research, or research for which limited review is a condition of exemption, an expedited review process may be followed, in accordance with 45 CFR § 46.110. At the University, expedited review will consist of review by up to three members of the Committee for new protocols, for f

1. These records shall include all information required by 45 CFR § 46.115, including a current roster of all Committee members with detailed information per 45 CFR § 46.108(a)(2), files of all projects, and records of all correspondence between the PI and Committee. Files of projects should contain, at a minimum, the date the application for approval was submitted, the application and any related correspondence (including revised applications), a description of the location of the research activity, and review and oversight action and determination documentation (recorded in addition to a reference to the action or determination in the meeting minutes). Files shall be destroyed three (3) years after the close or completion of the project.

2. The minutes should contain a list of all of the individuals attending the meeting, including non-members, and should be actively updated throughout the meeting to reflect that a quorum does or does not exist at any given time; the number of members voting for, against, or abstaining on all votes; a description of each action taken by the Committee and the date of approval and the approval period, if applicable; the basis given for suspension or termination of approval, or changes in the research, if any; and a summary of the discussion on each matter.

iv. Committee members will have varying backgrounds with respect to experience, gender, race, culture, and sensitivity to community attitudes. Committee composition shall also be structured to reflect the types of research generally

members of the Committee. Members may participate via video or teleconferencing. The minutes of the meeting shall be made available to authorized representatives of the FDA and OHRP upon request.

j. At a minimum, Committee review (per the Common Rule) will ensure that:

   i. Risks to subjects are minimized by: (1) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

   ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result;

   iii. Selection of human subjects is equitable;

   iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR § 46.116;

   v. Informed consent will be appropriately documented or appropriately waived, with the rationale for the waiver properly recorded in accordance with and to the extent required by 45 CFR §§ 46.115 and 46.117;

   vi. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

   vii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

   viii. Additional considerations for vulnerable populations (e.g., those likely to be vulnerable to coercion or undue influence) are evident, as needed; and

   ix. The researcher is adequately trained and qualified.

k. A protocol under review shall be deemed approved by the Committee if accepted by a majority of those voting members present. The Committee may condition approval subject to modifications to the protocol. These modifications may be provided electronically or in writing; the Chair or a designee shall determine if the modifications follow Committee requirements. The Committee may require the resubmission of a protocol before action is taken, or may disapprove the research, with detailed comments/reasons for disapproval provided to the PI. The PI may appeal the decision for disapproval to the committee.

l. Any changes in protocols shall be reported to the Committee electronically or in writing prior to initiation, using forms approved by the Committee. The Chair, or designee, will make a determination as to accept the change using expedited procedures or through Committee review, in accordance with the Common Rule. The only exception to this requirement shall be when an investigator initiates a change to eliminate apparent immediate hazards to the subject. Unexpected or serious adverse events shall be reported

to the Committee by the PI.

v. In accordance with the Common Rule and federal policy and guidance, the University, through the IO, will promptly report to the appropriate federal agency officials any of the following when the activity involves the use of federal funds:

i. Unanticipated problems involving risks to subjects or others;

ii. Serious or continuing noncompliance with federal regulations or the requirements or determinations of the Committee; and

iii. Suspension or termination of Committee approval.

w. The University may serve as a point of review of human subjects research for other organizations. These organizations must first sign a memorandum of understanding agreeing to abide by the decisions of the University Human Subjects Committee. A fee may apply. Cooperative research projects will rely upon a single Institutional Review Board designated by the Federal sponsor.

x. When a researcher is alleged to be in noncompliance with the Common Rule or any other federal, state or University regulations, the RICO will review the allegation and recommend action to be taken if noncompliance is found. Such action may include verbal or written warnings, the suspension of research activities until all appropriate administrative activities have been corrected or completed; re-inspection to substantiate the facility/laboratory is subsequently in compliance; and the referral of the noncompliance issues to the Department Chair, Dean, and the IO. Allegations of conduct rising to the level of academic misconduct per SDBOR Policy 4.8.1 shall be reported and processed in compliance with SDBOR Policy 4.8.1 and the
In either case, the University President, upon consultation with other officials as necessary, shall have decisional authority as to disciplinary action.

4. Responsible Administrator

The Vice President for Research and Economic Development, successor, or designee is responsible for the annual and ad hoc review of this policy. The University President is responsible for approval of modifications to this policy.

SOURCE: Approved by President on 09/8 (e)-1.5.9 (.) Tl.065 -1.14.9 (o)1g8.5 (i)6.3 9 (s)8.53.3 (A)9.6 (d)11RC .3 (c)-1.