Policy 7-100: University Research Committees

Policy: 7-100 Rev: 0
Date: May 15, 2014

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I. Purpose and Scope

[reserved]

II. Definitions

[reserved]

III. Policy

[User note: As of 2014 this Policy is under examination for extensive revising. For further information contact the office of the Senate, office of the Associate Vice President for Faculty, or administrators for each of these research committees.]

A. Institutional Animal Care and Use Committee

1. The Institutional Animal Care and Use Committee (IACUC) is federally mandated to monitor the care, treatment, housing, and use of animals in University laboratory and research programs to assure that animals are treated humanely and in accordance with the Animal Welfare Act of 1966, as amended (7 USC 2131 et. seq.), Department of Agriculture Animal Welfare Regulations, 9 CFR 2, and all other applicable Federal, State, and local laws and regulations.
2. The IACUC consists of at least six faculty and one citizen member. At least one faculty member shall be a Doctor of Veterinary Medicine, with experience or training in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the University. The citizen member shall not be affiliated in any way with the University, other than as a member of the IACUC, and shall not be a member of the immediate family of a person who is affiliated with the University. It is intended that the citizen member will represent general community interests in the proper care and treatment of animals. Not more than three members shall be from the same administrative unit of the University. Members shall be appointed for three-year terms by the University President, upon nomination by the Personnel and Elections Committee, with one-third of the membership changing each year. The chair of the IACUC shall be designated by the University President, upon recommendation by the Personnel and Elections Committee. The IACUC reports to the Vice President for Research.
3. The IACUC shall:
    a. Review and approve, require modifications in (to secure approval), or withhold approval of proposed research and teaching activities involving the care and use of animals to insure that the proposed activities are conducted in accordance with applicable laws and regulations;
    b. Review and approve, require modifications in (to secure

approval), or withhold approval of proposed significant changes involving the care and use of animals in ongoing activities to insure that the proposed changes are in accordance with applicable laws and regulations;

c. At least once every six months, review the University's program(s) for humane care and use of animals;

d. At least every six months, inspect all University animal facilities;

e. Submit reports of its evaluations of the University's programs and animal facilities to the Vice President for Research;

f. Participate in the University's submission of an annual Animal Welfare Assurance to the Office for Protection from Research Risks, National Institutes of Health;

g. Review and, if warranted, investigate concerns involving the care and use of animals at the University resulting from public complaints or from reports of noncompliance received from laboratory or other University personnel;

h. Make recommendations to the Vice President for Research regarding any aspect of the University's animal programs, facilities, or personnel training;

i. Suspend or terminate approval of activities that are not being conducted in accordance with the IACUC's requirements or that has been associated with unexpected pain or discomfort to the animals.

4. No IACUC member may participate in the IACUC's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IACUC.

B. Institutional Review Board for Research with Human Subjects (General University)

1. The Institutional Review Board (IRB) for Research with Human Subjects (IRB) (General University) is federally mandated to monitor review and approve research involving humans as subjects in accordance with the Department of Health and Human Services, Protection of Human Subjects Regulations, 45 CFR 46, and other applicable Federal, State, and local laws and regulations applicable law.

2. Each IRB panel The IRB (General University) consists of at least six faculty and two citizen five members who are sufficiently qualified to execute the IRBs charge based on experience, expertise, and diversity. The IRB shall consist of members from more than one profession. The IRB shall include at least one member who is a nonscientist and at least one citizen member who is not affiliated with the University, other than as a member of the IRB, and who is not a member of the immediate family of a person who is affiliated with the University. IRB membership is determined consistent with federal regulations. Members shall

be appointed for three-year terms. by the University President, upon nomination by the Personnel and Elections Committee, with one-third of the membership changing each year. The chair of the IRB shall be designated by the University President, upon recommendation by the Personnel and Elections Committee. The IRB reports to the Vice President for Research.

3. The IRB (General University) shall:

    a. Approve research activity, specify modifications required to secure IRB approval of the research activity, or disapprove any research activity Review and approve, require modifications in (to secure approval), or withhold approval of proposed research activities involving the use of human subjects in projects outside the health sciences to iensure that the proposed activities are conducted in accordance with applicable laws and regulations and, that the rights and welfare of the human subjects are protected, that adequate and informed consent is obtained, that confidentiality is maintained, and that potential benefits of the research are commensurate with the possible physical, psychological, social, and/or legal risks involved;

    b. Conduct continuing review of approved protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk; Conduct continuing review of research involving human subjects

    c. Have Conduct continuing review of research involving human subjects at least once every year, and shall have authority to observe or have a third party observe the consent process and the research;

    d. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects;

    e. Review and, if warranted, investigate concerns involving the use of human subjects at the University resulting from public complaints or from reports of noncompliance received from laboratory or other University personnel;

    f. Consult with the University administration as necessary regarding the Multiple Project Assurance of Compliance, required by the Office for Protection from Research Risks, National Institutes of Health. Federal Wide Assurance required by the Department of Health and Human Services Office for Human Research Protections.

4. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.

C. Institutional Review Board for Research with Human Subjects (Health Sciences)

1. The Institutional Review Board for Research with Human Subjects (IRB) (Health Sciences) is federally mandated to monitor research involving humans as subjects in accordance with the Department of Health and Human Services, Protection of Human Subjects Regulations, 45 CFR 46, and other applicable Federal, State, and local laws and regulations.
2. The IRB (Health Sciences) consists of at least six faculty and two citizen members who are sufficiently qualified to execute the IRBs charge based on experience, expertise, and diversity. The IRB shall consist of members from more than one profession. The IRB shall include at least one member who is a non-scientist and at least one citizen member who is not affiliated with the University, other than as a member of the IRB, and who is not a member of the immediate family of a person who is affiliated with the University. In addition, one citizen member recommended by the Utah State Board of Corrections shall serve as a prisoner advocate. Members shall be appointed for three-year terms by the University President, upon nomination by the Personnel and Elections Committee, with one-third of the membership changing each year. The chair of the IRB shall be designated by the University President, upon recommendation by the Personnel and Elections Committee. The IRB reports to the Vice President for Research.
3. The IRB (Health Sciences) shall:
    a. Review and approve, require modifications in (to secure approval), or withhold approval of proposed use of human subjects in projects in the health sciences to insure that the proposed activities are conducted in accordance with applicable laws and regulations that the rights of the subjects are protected, that adequate and informed consent is obtained, that confidentiality is maintained, and that potential benefits of the research are commensurate with the possible physical, psychological, social, and/or legal risks involved;
    b. Conduct continuing review of research involving human subjects at least once every year, and shall have authority to observe or have third party observe the consent process and the research;
    c. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects;
    d. Review and, if warranted, investigate concerns involving the use of human subjects at the University resulting from public complaints or from reports of noncompliance received from laboratory or other University personnel;
    e. Consult with the University administration as necessary regarding the Multiple Project Assurance of Compliance, required by the Office for Protection from Research Risks, National Institutes of Health.

4. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.

Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information - the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.

IV. Rules, Procedures, Guidelines, Forms and other related resources.

A. Rules [reserved]

B. Procedures [reserved]

C. Guidelines [reserved]

D. Forms [reserved]

E. Other related resource materials [reserved]

V. References:

[reserved]

VI. Contacts:

The designated contact officials for this Policy are:

A. Policy Owners (primary contact person for questions and advice): [_____Reserved]

B. Policy Officers: Vice President for Research.

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provided in University Rule 1-001:

"A 'Policy Officer' will be assigned by the President for each University Policy, and will typically be someone at the executive level of the University (i.e., the President and his/her Cabinet Officers). The assigned Policy Officer is authorized to allow exceptions to the Policy in appropriate cases...."

"The Policy Officer will identify an "Owner" for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the Policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to whom the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... .[and] bears the responsibility for determining which reference materials are helpful in understanding the meaning and requirements of particular Policies...." University Rule 1-001-III-B & E

VII. History:

Renumbering: The contents of this Policy 7-100 regarding research-related

committees previously appeared as parts within another Policy, which as of 9/15/2008 was renumbered as Policy 6-300, and was formerly known as PPM 9-2, and previously as Faculty Regulations Chapter II. The contents were moved out of 6-300 and into the newly created Policy 7-100 effective May 15, 2014.

Revision History:

1. Current version: Revision 0.

   Approved: Academic Senate April 7, 2014

   Approved: Board of Trustees April 8, 2014, with designated effective date of May 15, 2014.

   Legislative History of Revision 0.

2. Earlier versions:

   For history of the contents of this Policy 7-100 during the years prior to 2014 while the contents were housed within Policy 6-300, see the History information for Policy 6-300 at http://regulations.utah.edu/academics/6-300.php.