

**To:** Legislative History

**From:** IACUC Administrator and IRB Administrator

**Policy Owner(s):** Administrator for the Institutional Animal Care and Use Committee and  
Administrator for the Institutional Review Board

**Date:** September 29, 2022

**Re:** Policy 7-100 University Research Committees

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## Introduction and Background

Policy 7-100 describes the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB). This policy was created in 2014, and currently includes a note that as of 2014 it was under examination for further revising. These two committees must meet requirements in federal regulations. The proposed substantive changes are a result of changes in federal regulations.

## Proposed Substantive Changes

### IACUC

- Reduces the minimum number of IACUC members from six to five
- Specifies that at least one member must be a practicing scientist and at least one member must not be a scientist
- Deletes “participate in the University’s submission of an annual Animal Welfare Assurance to the Office for Protection from Research Risks, National Institutes of Health” from IACUC’s duties
- Updates appointing authority to match current practice of Vice President for Research appointing the members.

### IRB

- Deletes “conduct continuing review of research involving human subjects at least once each year, and shall have authority to observe or have a third party observe the consent process and the research” from the IRB’s duties.

## University of Utah Regulation Revision

General Regulation Information	
<b>Regulation proposed for enactment/revision</b>	Policy 7-100: University Research Committees
<b>Policy owner(s)</b>	Administrator for Institutional Animal Care and Use Committee and Administrator for the Institutional Review Board
<b>Policy officer(s)</b>	Vice President for Research
<b>Contact person(s)</b>	IACUC Administrator and IRB Administrator
<b>Other related regulations with proposed revisions</b>	None
<b>Planned effective date of revisions</b>	October 11, 2022
<b>Brief (1-2 sentence) description of revisions and reason for revision</b>	Makes minor revisions to the responsibilities of the IACUC and IRB in response to changes in federal regulations.

Consultation and Approval	
<b>Groups and Stakeholders Consulted</b>	
<b>Required Approval Steps and Date (if applicable)</b>	
Council of Academic Deans (if applicable)	Not applicable
Institutional Policy Committee	September 9, 2022
Academic Senate Executive Committee	September 19, 2022
Vice President or Designee	July 14, 2022
Academic Senate (if applicable)	October 3, 2022
Board of Trustees (if applicable)	October 11, 2022

# Policy 7-100: University Research Committees

Revision ~~42~~. Effective date: ~~October 14, 2014~~ October 11, 2022

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## I. Purpose and Scope

### A. Purpose.

This Policy describes the membership structure and functions of certain University ~~Committees~~committees which have responsibilities regarding academic research conducted by members of the University community.

### B. Scope.

[reserved]

## II. Definitions

[reserved]

### III. Policy

#### A. Institutional Animal Care and Use Committee

~~[User Note: As of 2014 this Part III-A regarding the IACUC is under examination for extensive revising, for further information contact the administrator associated with this 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~~7, USC 2131 et. seq.), Department of Agriculture Animal Welfare Regulations, 9 CFR 2, and all other applicable ~~Federal, State~~federal, state, and local laws and regulations.

#### 2. IACUC Membership

a. The IACUC consists of at least five members of varying professional and personal backgrounds, appointed by the vice president for research, including at least:

~~2. The IACUC consists of at least six faculty and one citizen member. At least one faculty member shall be a one 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:~~~~

i. one non-scientist;

ii. one practicing scientist experienced in research involving animals; and

iii. ~~not be~~ at least one person who is not affiliated in any way with the University, in any way 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~~who should represent general community interests in the proper care and treatment of animals. ~~Not~~

- b. ~~No~~ more than three members ~~shall~~may 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.~~

c. Members shall be appointed for three-year terms.

d. The IACUC reports to the vice president for research.

3. The IACUC shall:

- a. ~~Review~~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~~ ensure that the proposed activities are conducted in accordance with applicable laws and regulations;
- b. ~~Review~~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~~ ensure that the proposed changes are in accordance with applicable laws and regulations;
- c. ~~At~~at least once every six months, review the University's program(s) for humane care and use of animals;
- d. ~~At~~at least every six months, inspect all University animal facilities;
- e. ~~Submit~~submit reports of its evaluations of the University's programs and animal facilities to the ~~Vice President~~vice president for ~~Research~~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;~~

~~f. g. Review~~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;

~~g. h. Make~~make recommendations to the ~~Vice President for Research~~vice president for research regarding any aspect of the University's animal programs, facilities, or personnel training; ~~and~~

~~h. i. Suspend~~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~~An IACUC member may not 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

1. The Institutional Review Board (IRB) for Research with Human Subjects is federally mandated to monitor review and approve research involving humans as subjects in accordance with applicable law.

2. Each IRB panel consists of at least five members who are sufficiently qualified to execute the IRB's charge based on experience, expertise, and diversity. The IRB shall consist of members from more than one profession. IRB membership is determined consistent with federal regulations. Members shall be appointed for three-year terms. The IRB reports to the ~~Vice President~~vice president for ~~Research~~research.

3. The IRB shall:

- a. ~~Approve~~approve research activity, specify modifications required to secure IRB approval of the research activity, or disapprove any research activity ensure 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~~;~~;
  - b. ~~Conduct~~conduct continuing review of approved protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk;
  - ~~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;~~
  - ~~c.~~ ~~d.~~ ~~Suspend~~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.~~ ~~e.~~ ~~Review~~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 University personnel; and
  - ~~e.~~ ~~f.~~ ~~Consult~~consult with the University administration as necessary regarding the Federal Wide Assurance required by the Department of Health and Human Services Office for Human Research Protections.
4. ~~No~~An IRB member may not 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. Other research-related committees.~~

~~[Reserved]~~

*Sections IV- VII are for user information and are not subject to the approval of the Academic Senate or the Board of Trustees. The Institutional Policy Committee, the Policy Owner, or the Policy Officer may update these sections at any time.*

#### **IV. Policies/ Rules, Procedures, Guidelines, Forms and other Related Resources**

- A. Policies/ Rules. [ *reserved* ]
- B. Procedures, Guidelines, and Forms. [ *reserved* ]
- C. Other Related Resources. [ *reserved* ]

#### **V. References**

[reserved]

#### **VI. Contacts**

The designated contact officials for this Regulation are

- A. Policy Owner(s) (primary contact person for questions and advice):  
[Administrator for Institutional Animal Care and Use Committee and Administrator for the Institutional Review Board](#)
- B. Policy Officer(s): Vice President for Research

See Rule 1-001 for information about the roles and authority of policy owners and policy officers.

#### **VII. History**

Revision History.

- A. Current version. Revision ~~1~~2.
  - 1. Approved by Academic Senate ~~September 8, 2014~~[October 2, 2022](#) and Board of Trustees ~~October 14, 2014~~[October 11, 2022](#) with Effective Date ~~October 14, 2014~~[October 11, 2022](#).
  - 2. Legislative History
  - 3. Editorial Revisions



~~a. Editorially revised July 5, 2022 to move to current regulations template.~~

B. Previous versions.

1. Revision ~~0~~1. Effective ~~May 15~~October 14, 2014.

2. Revision 0. Effective May 15, 2014

C. Renumbering

1. 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.