Legislative History—Policy 7-100 (Rev 1)

http://regulations.utah.edu/research/revisions_7/Policy%207-100.RI%20History.pdf

Prepared by Bob Flores, for the Institutional Policy Committee, Fall 2014.

The proposal for Revision #1 of Policy 7-100 was approved by the Academic Senate on September 8, 2014 and the Board of Trustees on October 14, 2014, with a designated effective date of October 14, 2014.

Contents  (copied from the agenda materials for the Academic Senate Meeting of September 8, 2014):

(i) Explanatory Memorandum.

(ii) Final version of the Policy revisions, as approved by Senate & Trustees.
MEMO

TO: Academic Senate Executive Committee

FROM: Thomas N. Parks, Jeffrey R. Botkin, John Stillman

SUBJECT: Research Committee Policy 7-100, Changes in University Policy Relevant to the Institutional Review Board

DATE: April 21, 2014

We have been informed of the proposed changes to University policy which would move research committee information from Policy 6-300 to Policy 7-100. We are in support of this decision. In addition, we are requesting that the text regarding the Institutional Review Board (IRB) in Policy 7-100 be updated to provide accurate information about the IRB as it has evolved over the last decade. The proposed changes do not affect any current processes for IRB management, IRB composition, or the IRB submission and review process.

Summary of Changes:

- Reference to separate “General” and “Health Sciences” IRBs have been removed. The IRBs were combined approximately 15 years ago and all of the University uses a single IRB.
- Direct reference to specific federal and state laws was removed in order to simplify the policy. As there are a large number of regulations and laws that the IRB follows, it is not prudent to list all of them in this policy. Additionally, any language that directly quotes regulation was removed to prevent erroneous quoting if requirements change or if additional standards are put into place by our accrediting body, the Association for Accreditation of Human Research Protection Programs (AAHRPP).
- Language was updated to accurately reflect the federal requirements for IRB membership and how members are appointed. As IRB members are appointed through a number of mechanisms, the specific process for appointing members was removed to allow for the multiple methods currently employed. The most common mechanism today is direct membership recruitment through department and division leadership based on the volume of research submitted to the IRB from a given department or division. The Personnel and Elections Committee model has
not been in place for several years and was not effective as a sole means of IRB membership appointment.

- Minor corrections for organization and grammar were made.

Thomas N. Parks, Vice President for Research

Jeffrey R. Dotkin, Associate Vice President for Research Integrity

John Stillman, IRB Director
1. Regulation(s) involved (type, number, subject): Policy 7-100 Revision 1.

2. Responsible Policy Officer (name & title): Vice President for Research, Thomas N. Parks

3. Contact person(s) for questions & comments (name, email, phone#): John Stillman, IRB Director, john.stillman@hsc.utah.edu, 801-587-9136

4. Presenter to Senate Exec (if different from contact person. name, phone#): John Stillman

5. Approvals & consultation status.
   a. Administrative Officers who have approved (VP/President, name & date): Thomas Parks, Jeffrey Botkin, John Stillman (signatures included on explanatory memorandum)

   b. Date(s) processed through Institutional Policy Committee: Multiple meetings throughout 2013 and 2014

   c. Other Committees/Councils/other Officers consulted: Vice President for Research, Institutional Review Board

6. Check YES or NA (not applicable) of documents submitted--- (In digital form. Preferred file format MS Word doc. Special exception allowed for PDF format if previously arranged.)
   
   Yes Explanatory memorandum (key points of proposal, rationale).
   
   Yes VP/Presidential approval signatures (separate sheet, or affixed to memo cover).
   
   Yes Text of proposed Regulation addition/revision.
   
   Yes (If revision of existing Regulation) text changes are clearly marked, using permanent font markings (not MS Word ‘Track’ Changes non-permanent markings unless special exception previously arranged).

Date submitted to Senate Office: May 29, 2014

After presentation the Executive Committee will consider whether the proposal is ready for the full Senate, schedule it on a Senate agenda if so, and categorize it either as i) a matter of academic significance—set on the “Intent” & “Debate” Calendars presumptively over two monthly meetings with final “approval” voting at the second, or ii) not academically significant—set on the “Information & Recommendations” Calendar for a single monthly meeting, with opportunity for questions and recommendations from senators to the presenter. See Policy 1-001 http://regulations.utah.edu/general/1-001.php; Rule 1-001 http://regulations.utah.edu/general/rules/R1-001.php; Senate procedures http://admin.utah.edu/academic-senate. Further information—Senate Secretary: Shawnee Worsley 581-5203 shawnee.worsley@utah.edu
Policy 7-100: University Research Committees. Revision 1. Effective date ___ {upon final approval}.

I. Purpose and Scope [reserved]

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

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

[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 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.

2. Each IRB panel The IRB (General University) consists of at least five 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 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 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, 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 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.

D. Other research-related committees. [Reserved]

Drafting note: Through later revisions, information may be added here regarding other research-related committees, such as the Institutional Biosafety Committee (IBC), or Radiation Safety Committee.

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]

[Drafting note: Need to decide upon and insert here which University official should be designated as the Policy Owner, or combination of two Owners--which should be whichever officer has front-line responsibilities for administering all of the research-related committees which will end up being encompassed in this Policy, now and in the future (i.e., for now encompassing the Animal committee and the IRB, and later any other such research-related committees).]

B. Policy Officers: Vice President for Research.

These officials are designated by the University President or delegatee, 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:
   Approved: Academic Senate ___??
   Approved: Board of Trustees ___?? with designated effective date of ___???.
   Legislative History of Revision 1. {create and link to legislative history file.}

2. Earlier versions:
   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. {create and link to legislative history file.}
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.