

## **POLICY CONCEPTS: INSTRUCTIONS AND GUIDELINES**

**All policy proposals – including new policy concepts, proposed revisions, or suggested repeals – must be submitted via the form on page 2 to the Office of the University Secretary with appropriate supporting information and documents.** Completed submissions are forwarded to the University Senate (academic policies) or the President’s Policy Advisory Council (PAC), which ensures proper routing through the policy-making process. (See UO Policy I.03.01 for more information.)

**Please keep the following definition of a university policy in mind as you develop your concept:**

*A University Policy (“Policy”) is a policy that (1) has broad application or impact throughout the University community, (2) must be implemented to ensure compliance with state or federal law, (3) is necessary to enhance the University’s mission, to ensure institutional consistency and operational efficiency, or to mitigate institutional risks; or (4) is otherwise designated by the Board [of Trustees] or the President [of the University] as a University Policy.*

*A policy establishes rights, requirements or responsibilities. Excluded from this definition are things such as, but not limited to, implementation guides, operating guidelines, internal procedures, and similar management controls and tools.*

**To help facilitate as smooth a process as possible, please consider the following:**

1. Consult as many stakeholders as possible *prior to submitting* your concept. A primary role for the PAC is to ensure that appropriate offices, departments or groups are consulted.
2. Run your concept by the Office of General Counsel (OGC) *prior to submission*. OGC review is a required step in policy-making.
3. Please use the proper template – email [uopolicy@uoregon.edu](mailto:uopolicy@uoregon.edu) to obtain either (a) the new policy template (new proposals) or (b) the Word version of the existing policy in its proper template (for redlines/revisions).
4. A “redlined” version of your concept in Word is required for proposed revisions. This must be done using the appropriate Word version (see #3, above).
5. Include any appropriate related resources that will be useful to those reviewing the concept. Links are preferred, but supplemental documents are of course acceptable for items not online. Examples of such items include any associated procedures or unit level policies (even if in draft form), or other policies or procedures related to, overridden by, necessary as a result of, or otherwise affiliated with your concept;
6. Please submit all documents as individual files.
7. Someone from the responsible office or proposing unit will need to attend a PAC meeting to explain the concept and answer any questions.

**Please email [uopolicy@uoregon.edu](mailto:uopolicy@uoregon.edu) if you have any questions. Thank you!**

## POLICY CONCEPT FORM

<b>Name and UO Title/Affiliation:</b>	Emily Tanner-Smith, Associate Professor, Thomson Professor, Associate Vice President for Research
<b>Policy Title &amp; # (if applicable):</b>	n/a
<b>Submitted on Behalf Of:</b>	Office of the Vice President for Research and Innovation
<b>Responsible Executive Officer:</b>	Vice President for Research and Innovation

**SELECT ONE:**  **New Policy**       **Revision**       **Repeal**

*Click the box to select*

**HAS THE OFFICE OF GENERAL COUNSEL REVIEWED THIS CONCEPT:**  **Yes**       **No**

**If yes, which attorney(s):** Jessica Price

### GENERAL SUBJECT MATTER

*Include the policy name and number of any existing policies associated with this concept.*

**The new proposed policy is entitled “Human Research Protection Program.” There are no existing policies associated with this concept.**

### RELATED STATUTES, REGULATIONS, POLICIES, ETC.

*List known statutes, regulations, policies (including unit level policies), or similar related to or impacted by the concept. Include hyperlinks where possible, excerpts when practical (e.g. a short statute), or attachments if necessary. Examples: statute that negates the need for or requires updates to an existing policy; unit level policy(ies) proposed for University-wide enactment; or existing policies used in a new, merged and updated policy.*

There are no known statutes or regulations related to or impacted by the concept.

Related University policies:

Allegations of Research Misconduct

<https://policies.uoregon.edu/vol-2-academics-instruction-research/ch-6-research-general/allegations-research-misconduct>

Conflict of Interest, Conflict of Commitment, and Outside Activities

<https://policies.uoregon.edu/vol-1-governance/ch-2-legal-affairs/conflict-interest-conflict-commitment-and-outside-activities>

Inventions, License Agreements, Educational & Professional Materials Development, Patents & Copyrights

<https://policies.uoregon.edu/vol-2-academics-instruction-research/ch-7-innovation-tech-transfer-economic-development/inventions>

Proprietary Research

<https://policies.uoregon.edu/vol-2-academics-instruction-research/ch-6-research-general/proprietary-research>

Research: Classified Research

<https://policies.uoregon.edu/vol-2-academics-instruction-research/ch-6-research-general/research-classified-research>

Research: Financial Conflict of Interest in

<https://policies.uoregon.edu/vol-2-academics-instruction-research/ch-6-research-general/research-financial-conflict-interest>

---

## **STATEMENT OF NEED**

*What does this concept accomplish and why is it necessary?*

This concept proposes a university policy to articulate the University's guiding principles and program elements for the ethical conduct of research involving human subjects/participants. This policy is necessary because the University does not currently have such a policy; instead, the University currently provides a Federal Wide Assurance to the Office of Human Research Protection programs that states the University will comply with federal regulations for any human subjects research that occurs at the university (regardless of funding source for that research). Anticipated federal rule making is expected to change the Federal Wide Assurance system, which may eliminate the University's ability to extend the federal regulations to non-federally funded research. The proposed policy thus formalizes the existing process at the University by clarifying that all human subjects research conducted at or on behalf of the University will be governed by a Human Research Protection Program that is guided by standard ethical principles, professional and ethical standards and codes, and in compliance with federal laws, state laws, and University policies/procedures.

---

## **AFFECTED PARTIES**

*Who is impacted by this change, and how?*

The following parties will be affected by the new policy: Employees, officials, students, and agents of the University, and anyone else while using university facilities or resources, who is engaging in the conduct of research involving human subjects/participants. Of note, these parties will not experience any changes due to the adoption of this policy, as the new proposed policy simply articulates the University's guiding principles and program elements that are already current in effect under the University's Federal Wide Assurance.

---

## **CONSULTED STAKEHOLDERS**

*Which offices/departments have reviewed your concept and are they confirmed as supportive? (Please do not provide a list of every individual consulted. Remain focused on stakeholders (e.g. ASUO, Office of the Provost, Registrar, Title IX Coordinator, etc.).)*

Review was conducted in several parts. First, during the month of December 2020, input was sought from the Senate Executive Committee, Research Compliance Services, and Office of General Counsel for initial outreach. An initial discussion draft of the policy was created in response to that outreach.

Next, a joint administration-senate ad hoc committee was formed in February 2021 to further consider and revise the draft. The committee met in February and March 2021 to further revise the policy. The committee was comprised of the following representatives:

### Chair:

Emily Tanner-Smith, Associate Professor, Counseling Psychology and Associate Vice President for Research

### Members:

Hans Dreyer, Associate Professor, Human Physiology (Senator)

Charlotte Alverson, Research Associate Professor, SSET

Aaron Gullickson, Associate Professor, Sociology (Senator)

Sara Hodges, Professor, Psychology

Renee Irvin, Associate Professor, PPPM (Senator)

Jessica Price, Associate General Counsel, OGC

Sheryl Johnson, Director, Research Compliance Services

### Staff:

Brittney de Alicante, Executive Assistant, Office of the Vice President for Research and Innovation

Third and finally, the revised policy, approved unanimously by the committee, was submitted to Senate President Berkman in March 2021 and presented to the Senate Executive Committee in March 2021.

<b>Name</b>	<b>Office</b>	<b>Date</b>
Elliot Berkman	UO Senate	Multiple reviews during December 2020 – April 2021
Senate Executive Committee	UO Senate	January 6 & March 30, 2021
Senate Membership	UO Senate	January 13, 2021
Ad hoc Policy Committee	UO Senate	Multiple reviews during February – March 2021
Charlotte Alverson	UO Institutional Review Board	Multiple reviews during February – March 2021
Jessica Price	Office of General Counsel	Multiple reviews during December 2020-April 2021
Executive Leadership Team	Office of Vice President for Research and Innovation	Multiple reviews during February-March 2021
Research Compliance Leadership Team	Research Compliance Services	Multiple reviews during January-April 2021

---