

 Research & Sponsored Programs UNIVERSITY OF DENVER	Office of Research and Sponsored Programs Policy Manual Policies Generally
	Policy Number: ORSP-01
Recommended By: Director, Research and Financial Operations; Director, Sponsored Programs Administration; Director, Research Integrity and Education; Director, Intellectual Property and Technology Transfer; Regulatory Compliance Officer; Sponsored Programs Academic Research Council Approved By: Senior Vice Provost for Research and Graduate Education	Effective Date: 08/15/2023

1. PURPOSE

To align ORSP policy with the provisions of the University [Policy on Policies \(FINA 1.10.040\)](#) and provide for consistency in ORSP policy and University policy. Enables the Vice Provost for Research to promulgate an administrative and operational ORSP policy manual. Provides a consistent process by which ORSP policy will be adopted.

2. DEFINITIONS

- 2.1. ORSP is the Office of Research and Sponsored Programs which serves to promote and administer research, scholarship and creative works, providing project administration, proposal development, financial reporting, oversees human subjects, biosafety and animal welfare compliance, oversees intellectual property protection and technology transfer and works to prevent issues of scholarly misconduct and unethical research.
- 2.2. SPARC is the Sponsored Programs Academic Research Council, which is comprised of University Faculty that have demonstrated distinction in their field and prominence as a Principal Investigator in Sponsored Program research.
- 2.3. Faculty is a person appointed to employment by the University to fulfill teaching and/or scholarly activities.
- 2.4. Principal Investigator is the University employee that leads an externally funded program or project and is responsible for the proper conduct of research or other activity described in the proposal, grant, contract or other instrument of agreement.
- 2.5. Sponsored Programs are programs or projects that are funded by an external entity through a written agreement (grant, agreement, or other instrument) with the University. Sponsored Programs include specific research, training, or service programs and projects.

- 2.6. Recommending Officials are the University administrators and employees that recommend a particular policy for adoption.
- 2.7. Non-Substantive Revisions are revisions that are administrative and general in nature and do not fundamentally change any specific portion of a policy.
- 2.8. Human Subjects are living individuals about whom a researcher, whether professional or student, conducts research that obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 2.9. Biological Agents are DNA molecules as defined by the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), infectious and potentially infectious agents, human and non-human primate materials, and biological toxins.

3. POLICY

- 3.1. Section I of the University [Policy on Policies \(FINA 1.10.040\)](#) enables divisions to adopt policies and procedures for administrative and operational purposes. The [Policy on Policies \(FINA 1.10.040\)](#) reads as follows:

Administrators of University divisions are responsible for providing policies that ensure consistency, efficiency, and comply with pertinent local, state and federal laws. This Policy authorizes senior administrators to develop policies and outlines processes and procedures for doing so. Approved policies and procedures promulgated by senior administrators will apply to all members of the University community.

- 3.2. Section IV.2 of the University [Policy on Policies \(FINA 1.10.040\)](#) delegates authority to the Vice Provost for Research to adopt an ORSP policy manual as follows:

Policies formulated by the Provost and Executive Vice Chancellor and the appropriate Vice Chancellor or Associate Provost overseeing functional areas that articulate administrative and operating policies and procedures specific to a division or administrative unit of the University.

- 3.3. In Section II.D.7 of the University [Policy of Limits of Authority \(FINA 2.10.030\)](#) the Board of Trustees delegates general authority to ORSP for matters relating to research-related agreements and research administration.
- 3.4. In keeping with the provisions of the [Policy on Policies \(FINA 1.10.040\)](#) ORSP adopts a standardized process for reviewing and approving administrative and operational policies that comply with all other University policy and applicable local, state and federal laws, rules, regulations, ordinances and executive orders.
- 3.5. ORSP will use a standard policy format and a uniform review and approval process for ORSP policies to improve communication, promote administrative consistency and efficiency, and achieve compliance with all local, state and federal laws, rules, regulations, guidance's, ordinances and executive orders and accreditation requirements.
- 3.6. All ORSP policies must be consistent with existing University policies, state and federal laws and

regulations, internal control guidelines, and must not contradict any other operating policies or procedure.

- 3.7. There is created an Institutional Review Board (IRB) which is charged with oversight of all research that involves human subjects (42 USC § 289(a); 45 CFR § 46). The IRB will develop policies and procedures, which will have the same force and authority as an ORSP policy, to implement the University's human research protection program (HRPP). The IRB will have the following responsibilities:
 - 3.7.1. Review, prior to its initiation, all research, whether funded or not involving Human Subjects.
 - 3.7.2. Protect the welfare, rights and privacy of Human Subjects.
 - 3.7.3. Approve, exempt, or disapprove, all research involving Human Subjects.
 - 3.7.4. Monitor on a continuing basis all research involving Human Subjects.
 - 3.7.5. Administer protocols and procedures for the conduct of Human Subjects research.
 - 3.7.6. Investigate suspected deviation from approved protocols or noncompliance with HRPP policies and procedures and report to the appropriate entity if appropriate.
 - 3.7.7. Understand and apply the principles of the Belmont Report and the federal regulations related to the protection of Human Subjects.
 - 3.7.8. Maintain compliance with all relevant laws, rules, regulations, guidance, policies and procedures relating to the protection of Human Subjects.
- 3.8. There is created an Institutional Biosafety Committee (IBC), which is charged with oversight of all research and teaching activities that involve the use of Biological Agents. The IBC will develop policies and procedures, which will have the same force and authority as an ORSP policy to implement the University's biological safety program. The biological safety program will be managed by the Department of Environmental Health and Safety, the IBC will be administered by the Office of Research Integrity and Education in ORSP. The IBC will have the following responsibilities:
 - 3.8.1. Review research involving biological agents conducted at or sponsored by the University and approves those projects that comply with NIH rules, regulations and guidelines as well as all applicable University polices.
 - 3.8.2. Develop and implement policies, procedures, and guidelines related to the use of biohazardous agents.
 - 3.8.3. Assist Principal Investigators in meeting their responsibilities for assessing risks, establishing policies and procedures, training personnel, and maintaining facilities and equipment.
 - 3.8.4. Provides guidance and support to the Department of Environmental Health and Safety in carrying out the requirements of the University's Biosafety program.
 - 3.8.5. Investigate any significant problems, suspected violation of NIH rules, regulations or guidelines, or any significant research-related accidents and illnesses and will issues reports to the NIH as necessary.
- 3.9. There is created an Institutional Animal Care and Use Committee (IACUC), which may adopt policies and procedures relating to the use and care of animals used in research (7 USC § 2131). The IACUC will develop policies and procedures, which will have the same force and authority as an ORSP policy to provide for the compliance of the University with all laws, rules, regulations, guidance, policies and procedures relating to animal welfare. The IACUC will provide for the supervision, coordination, and review of every project proposed to include the use of vertebrate animals.
- 3.10. All ORSP policies will be assigned a unique numbering architecture beginning with the ORSP abbreviation and the number of the policy (Example: Policies Generally (ORSP-01)).

- 3.11. All ORSP policies must be approved by the Vice Provost for Research.
- 3.12. An ORSP policy library will be made available on the ORSP website and will contain all approved policies in their most current form.
- 3.13. ORSP policies will remain up to date and be revised as needed to reflect current practice and/or procedures. Each ORSP policy will be reviewed by the Recommending Official and revised as necessary no less than once every two (2) years.

4. PROCESS

- 4.1. ORSP is charged with consulting with University offices on proposals for new, revised and repealed policies to consider whether they are necessary and aligned with institutional missions, goals and priorities; that policies are concise, consistent in format and scope, and easy to understand; to identify constituencies and other policies that may be affected; and to make recommendations to appropriate offices. SPARC may assist with dissemination and sharing feedback regarding policies.
- 4.2. Proposed drafts of new policies substantially revised policies and those policies recommended for repeal will be distributed to SPARC for review and comment prior to final approval.
- 4.3. New, substantially revised or repealed policies must be developed by ORSP with consultation from impacted stakeholders. Policies are developed to help improve communication, promote administrative consistency and efficiency, and promote compliance with state and regional accreditation requirements.
- 4.4. New, Substantially Revised or Repealed Policy Process
 - 4.4.1. The policy must conform to the standard template format.
 - 4.4.2. The Recommending Official will review and approve the draft following consultation with all stakeholders, this includes consultation with the Department of Enterprise Risk Management and the Office of General Counsel as appropriate.
 - 4.4.3. The draft ORSP policy will be forwarded to SPARC who will review and recommend approval and/or revisions to the Recommending Official.
 - 4.4.4. After this review, the policy draft will be submitted to the Vice Provost for Research for final approval.
 - 4.4.5. Once approved by the Vice Provost for Research the ORSP policy is posted to the ORSP policy website and distributed widely among the division.
- 4.5. Non-Substantive Revisions to existing policies, including those to align policy with practice may be approved directly by the Vice Provost for Research using an expedited approval process. The Vice Provost for Research may determine in their discretion the non-substantive revision would be better served by the process in Section 4.4 above and direct that process occur.
- 4.6. Expedited Policy Approval Process
 - 4.6.1. The policy must conform to the standard template format.
 - 4.6.2. A description of the revisions and the corresponding “red lines” are reviewed by the Recommending Official.
 - 4.6.3. The revised policy will be submitted to the Vice Provost for Research for final approval.
 - 4.6.4. Once approved by the Vice Provost for Research the ORSP policy is posted to the ORSP policy

website and distributed widely among the division.

5. RESOURCES

- 5.1. [University Policy on Policies – FINA 1.10.040](#)
- 5.2. [University Policy on Limits of Authority – FINA 2.10.030](#)
- 5.3. Institutional Review Boards; Ethics Guidance Program – 42 USC § 289(a)
- 5.4. Protection of Human Subjects – 45 CFR § 46
- 5.5. [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)
- 5.6. Animal Welfare Act of 1966 – 7 USC § 2131
- 5.7. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#)