LEHIGH UNIVERSITY	SOP: Creating and Revising University Policies, SOPs, and Forms Responsible Office: Research Integrity			
	ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
	30-Nov-2018	n/a	N. Coll	1 of 7

I. Purpose

This SOP outlines the steps involved in creating or revising research administration policies, SOPs, and forms, as outlined in Policy: Developing, Revising, and Posting Research Administration Policies.

II. Scope

This SOP must be followed during the creation, revision, and approval of all policies, SOPs, and forms owned by research administration offices in the OVPR stem: Office of the Vice President and Associate Provost for Research and Graduate Studies; Office of Research and Sponsored Programs; Research Integrity, and; Office of Technology Transfer. This policy also applies to all university-wide policies pertaining to the planning, funding, conduct, and reporting of research.

III. Relevant University Policy/(ies)

Policy: Developing, Revising, and Posting Research Administration Policies

IV. Procedure

1. Identifying the Need for a New Policy or Major Revisions to an Existing Research Administration Policy

Any individual or OVPR department who identifies the need for a new policy, SOP, form, or revision to an existing policy, SOP, or form, should contact the Director of Research Policy and Compliance. The Director of Research Policy and Compliance coordinates the process of developing, reviewing, approving, and posting research administration policies, SOPs, and forms.

The Director of Research Policy and Compliance can, if needed, help to identify an appropriate Policy Sponsor. The Director of Research Policy and Compliance provides the Policy Sponsor with the following information:

- An overview of the policy, SOP, and form development and approval process and the Policy Sponsor's role in the process, as outlined in the Policy: Developing, Revising, and Posting Research Administration Policies.
- For a new policy, SOP, or form: the appropriate document template.
- For revisions to an existing policy, SOP, or form: an editable version of the existing document.
- The number of the policy, SOP, or form. All research administration policies, SOPs, and forms must follow a standard numbering system.
- The identities of other known policies, SOPs, forms, or stakeholders that the Policy Sponsor should be aware of because they may affect or be affected by the new or revised policy, SOPs, or form.

2. Proposing a New Policy or Major Revisions to an Existing Research Administration Policy

Every new research administration policy, or major revision to an existing research administration policy, begins with the development, submission, and approval of a formal proposal using the Form: Research Administration Policy Proposal. Policy proposal are not required for minor revisions to existing research administration policies. The Policy Sponsor develops a policy proposal that contains, at minimum, the following information:

- Background establishing the need for a new or updated policy, including an outline of the events or conditions that give rise to the new policy or update.
- A policy statement that includes the requirement(s) of the university community that establish the need for a new or updated policy, and that may also include the university's commitment to a relevant principle.
- The reason for the new or updated policy, including any legal, regulatory, financial, operational, accreditation, technological, and/or social requirements the policy addresses, and any advantages the policy will bring to the university.
- An overview of the policy content, including the problem the policy addresses, the way the policy solves the problem, and a general outline of the policy's scope.

	SOP: Creating and Revising University Policies, SOPs, and Forms Responsible Office: Research Integrity			
	ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
	30-Nov-2018	n/a	N. Coll	2 of 7

- The likely impact of the university, including identification of the resources (human, financial, physical, operational, technical, etc.) that will be needed to implement and maintain compliance with the policy; identification of changes to Lehigh's culture or behaviors that may be involved, and; identification of operational activities that may be affected.
- The stakeholders (those who will be affected by the policy, as well as subject matter experts) to be consulted when drafting the policy.
- The planned timing for implementation of the policy.
- The communication plan, including format and audience, that ensures that the campus community is informed of the new or revised policy.
- The Responsible Official(s) and Policy Sponsor, as defined in Policy: Developing, Revising, and Posting Research Administration Policies.

The Policy Sponsor presents the policy proposal to the Responsible Official and the Director of Research Policy and Compliance. The Policy Sponsor considers all comments and incorporates revisions, as appropriate, prior to proceeding to the next step. Only after approval by the Responsible Official and the Director of Research Policy and Compliance may the Policy Sponsor proceed to the drafting phase.

3. Drafting a New Policy

After a policy proposal for a new policy is finalized and approved by the Responsible Official and the Director of Research Policy and Compliance, the Policy Sponsor is responsible for:

- Drafting the new policy and working with the Director of Research Policy and Compliance to set a schedule for completion.
- Obtaining input from stakeholders during the drafting phase.
- Seeking assistance from the Director of Research Policy and Compliance with any of the tasks involved in developing the draft policy, including researching, writing, reviewing, editing, establishing timelines, and arranging meetings with stakeholders.
- Apprising the Responsible Official of progress and issues, as appropriate.
- Indicating to the Director of Research Policy and Compliance when the draft is ready to present to the RPRC or other appropriate advisory committee.

The draft of a new policy should be prepared with the Research Administration Policy Template and with the Research Administration Policy Style Guide as a reference. The Research Administration Policy includes full instructions on the type of information that may be needed for each research administration policy and the appropriate layout to ensure consistency among research administration policies. Only include the sections that are relevant to the specific policy.

4. Making Major Revisions to an Existing Research Administration Policy

For a policy with major revisions, after the policy proposal is finalized and approved by the Responsible Official and the Director of Research Policy and Compliance, the Policy Sponsor is responsible for:

- Drafting the revised policy and working with the Director of Research Policy and Compliance to set a schedule for completion.
- Obtaining input from stakeholders during the drafting phase.
- Seeking assistance from the Director of Research Policy and Compliance with any of the tasks involved in developing the revised policy, including researching, writing, reviewing, editing, establishing timelines, and arranging meetings with stakeholders.
- Apprising the Responsible Official of progress and issues, as appropriate.
- Indicating to the Director of Research Policy and Compliance when the draft is ready to present to the RPRC or other appropriate advisory committee.

Revisions to an existing policy are only permitted after obtaining a current, authorized, editable document from the Director of Research Policy and Compliance. Revisions to other documents are not accepted.

5. Policy Review and Approval Process

Once the Policy Sponsor indicates to the Director of Research Policy and Compliance that a new or revised draft policy is ready for review, the draft policy undergoes the following review process:

LEHIGH UNIVERSITY	**SOP: Creating and Revising University Policies, SOPs, and Forms** **Responsible Office: Research Integrity**			
	ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
	30-Nov-2018	n/a	N. Coll	3 of 7

- The Policy Sponsor submits the draft to the Director of Research Policy and Compliance.
- The Director of Research Policy and Compliance reviews it for editorial content and to ensure proper formatting.
- The Director of Research Policy and Compliance checks for compliance with relevant laws and regulations and check for consistency with existing research administration and other applicable university policies.
- As appropriate, the Director of Research Policy and Compliance submits the draft to any relevant stakeholders for review and comment.
- When applicable, stakeholders return feedback, which the Director of Research Policy and Compliance relays to and discusses with the Policy Sponsor.
- When applicable, the Policy Sponsor incorporates the stakeholders' feedback into subsequent revisions, as appropriate.
- When applicable, the Director of Research Policy and Compliance then re-submits the draft to any relevant stakeholders' for review and comment, and the process is repeated until the Policy Sponsor is satisfied with the draft.
- The Director of Research Policy and Compliance schedules a meeting of the RPRC or coordinates with another appropriate advisory committee and sends the draft document(s) to the committee for review at least two weeks in advance of the meeting.
- At the committee meeting, the Policy Sponsor presents the policy to the committee and discusses the members' comments with them. Committee meeting minutes document controverted issues and any recommended revisions and are provided to the Policy Sponsor.
- During the conferral process, the committee provides input to the Policy Sponsor and Director of Research Policy and Compliance regarding the appropriate communication plans to ensure that that the campus community is informed of new policies or major revisions to existing policies.
- The Policy Sponsor incorporates recommended revisions into a revised draft, as appropriate.
- When appropriate, the Policy Sponsor returns a revised draft to the Director of Research Policy and Compliance for further conferral with the RPRC or other appropriate advisory committee. This process may be completed by email.
- Once further conferral with the RPRC or other appropriate advisory committee is completed, or if it is not necessary, the Policy Sponsor and the Director of Research Policy and Compliance submits the final draft to the Responsible Official for approval. Committee meeting minutes and documentation of subsequent reviews conducted by email are provided to the Responsible Official as needed.
- If the policy has the potential to have a major, campus-wide impact, or if it directly affects faculty, the Responsible Official, may choose, at their discretion, to discuss it with relevant University officers or a senior-level committee (or assign this task to a designee) before providing final approval.
- The Policy Sponsor submits the final approved draft to the Director of Research Policy and Compliance, along with a draft communication to the Lehigh community explaining the new or revised policy, pointing out any major changes, and inviting comments.
- The Director of Research Policy and Compliance posts the draft policy to the Policy Drafts section of the Lehigh University Research and Graduate Studies: Research and Research-Related Policies website for a 30-day review period by the Lehigh community and issues a communication inviting review and comment.
- The Policy Sponsor and the Director of Research Policy and Compliance review the comments from the Lehigh community and as appropriate, revise the draft policy.
- If the Policy Sponsor or the Director of Research Policy and Compliance determine that the revisions are significant, the Director of Research Policy and Compliance may confer with the RPRC or other appropriate advisory committee to determine whether it should be re-posted to the Policy Drafts section of the Lehigh University Research and Graduate Studies: Research and Research-Related Policies website for review. This process may be completed by email. If there are no comments, or if the Policy Sponsor and the Director of Research Policy and Compliance determine that revisions are not significant, then no further review and approval is necessary.
- The Director of Research Policy and Compliance indicates to the Policy Sponsor that the draft policy is finalized and approved.

6. Issuance of Approved Policies

Once the draft policy is finalized and approved, the Director of Research Policy and Compliance does the following:

	SOP: Creating and Revising University Policies, SOPs, and Forms			
	Responsible Office: Research Integrity			
LEHIGH UNIVERSITY	ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
	30-Nov-2018	n/a	N. Coll	4 of 7

- Posts the policy and any related SOPs and forms on the Lehigh University Research and Graduate Studies: Research and Research-Related Policies website and/or the Responsible Office's website.
- With input from the Policy Sponsor, or their designee, issues the appropriate form of communication informing the community of the new or revised policy. The type of communication may vary based on the impact of the new or revised policy.
- The Director of Research Policy and Compliance drafts an executive summary for future inclusion in the research handbook (once developed), and will update the handbook with the new or revised policy as necessary.

7. Making Minor Revisions to an Existing Research Administration Policy

Minor revisions to existing policies are not required to go through the formal review and approval process as outlined above in Policy Review and Approval Process, **(**section 5). Minor revisions include, but are not limited to, clarifications, non-substantive changes, and updates to reflect, for example, new position titles, new contact information, or new website addresses. Minor revisions to existing policies are coordinated between a Policy Sponsor and the Director of Research Policy and Compliance. Contact the Director of Research Policy and Compliance for assistance determining whether a revision is major or minor.

Minor revisions to existing policies are only permitted after obtaining a current, authorized, editable document from the Director of Research Policy and Compliance. Revisions to any other documents are not accepted. The Director of Research Policy and Compliance is responsible for editorial content, formatting, and versioning.

Once the Policy Sponsor and the Director of Research Policy and Compliance approve the minor revisions, the Director of Research Policy and Compliance posts the revised policy on the Lehigh University Research and Graduate Studies: Research and Research-Related Policies website.

8. New or Revised SOPs

Policies typically have associated Standard Operating Procedures (SOPs) to facilitate compliance with and accomplish the goals of the policy.

The Policy Sponsor creates and revises the SOP. Newly created SOPs should use the template available on Lehigh University Research and Graduate Studies: Research and Research-Related Policies website to ensure consistency. Revisions to existing procedures are only permitted after obtaining a current, authorized, editable document from the Director of Research Policy and Compliance. Revisions to any other documents are not accepted. Director of Research Policy and Compliance is responsible for editorial content, formatting, and versioning. All SOPs follow the same numbering scheme as their related policies. If an SOP has the potential to have a major, campus-wide impact, or if it directly affects faculty, the Responsible Official, may choose, at their discretion, to discuss it with relevant University officers or a senior-level committee (or assign this task to a designee) before providing final approval. Approval of such new or revised SOPs follows the process as detailed in the Policy Review and Approval section above.

Once the Responsible Official and the Director of Research Policy and Compliance approve the new or revised SOP, the Director of Research Policy and Compliance posts the revised policy on the Responsible Office's website. The Policy Sponsor, or their designee, drafts an appropriate communication to the university community about the SOP, determines whether any training is required, and coordinates the provision of any required training. The Director of Research Policy and Compliance ensures that the communication is distributed to affected parties.

9. New or Revised Forms

Policies may have associated forms to facilitate compliance with, and accomplishment, of the goals of the policy. The Policy Sponsor or their designee creates and revises the form. Newly created forms should use the Research Administration Form Template to ensure consistency. Revisions to existing forms are only permitted after obtaining a current, authorized, editable document from the Director of Research Policy and Compliance. Revisions to any other documents are not accepted. The Director of Research Policy and Compliance is responsible for editorial content, formatting, and versioning. All forms follow the same numbering scheme as their related policies.

Once the Responsible Official and the Director of Research Policy and Compliance approve the new or revised form, the Director of Research Policy and Compliance posts the revised form on the Responsible Office's website. The Policy Sponsor drafts an appropriate communication to the university community about the form, determines whether any training is required, and

| | SOP: Creating and Revising University Policies, SOPs, and Forms |
| LEHIGH UNIVERSITY | **SOP: Creating and Revising University Policies, SOPs, and Forms**
Responsible Office: Research Integrity |

ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
30-Nov-2018	n/a	N. Coll	5 of 7

coordinates the provision of any required training. The Director of Research Policy and Compliance ensures that the communication is distributed to affected parties.

V.   Roles and Responsibilities

Responsible Party	List of Responsibilities
Director of Research Policy and Compliance	Responsible for the administration of this policy through the management of the policy development, review, approval, dissemination, and maintenance processes.
	Accepts and responds to inquiries from any individual or OVPR department that identifies the need for a new policy, SOP, form, or revision to an existing policy, SOP, or form. If needed, identifies an appropriate Policy Sponsor. Provides the Policy Sponsor with all necessary information detailed in the Identifying the Need for a New Policy or Major Revisions to an Existing Research Administration Policy subsection of the Procedures section above.
	Together with the Responsible Official, review and approve proposals for new policies or major revisions to existing policies.
	Oversees the drafting of new policies or major revisions to existing policies. Works with the Policy Sponsor to set a schedule for completing drafts. Reviews drafts for editorial content, to ensure proper formatting, to check for compliance with relevant laws and regulations, and to check for consistency with existing research administration and other applicable university policies. Coordinates the process for obtaining and incorporating stakeholder review. Coordinates the process for conferring with the RPRC or other appropriate advisory committee. Together with the Policy Sponsor, submits final version to the Responsible Official for final approval. Coordinates the process for issuing drafts to the Lehigh community for review and comment.
	Collaborates with the Policy Sponsor to make and approve minor revisions to existing policies.
	Collaborates with the Policy Sponsor to create/revise, review, and approve new or revised SOPs or forms. Follow the processes as described in the New or Revised SOPs and New or Revised Forms sub-sections of the Procedures section above for exceptions that require SOPs and forms to undergo the formal review process described in the Policy Review and Approval sub-section of the Procedures section above.
	Maintains the OVPR policy repository website and posts approved policies.
	Collaborates with Responsible Officials to ensure that the university community is informed of new and revised policies.
	Chairs the RPRC or liaises directly with the existing Chair of standing committees when they are used as appropriate advisory committees for conferral on the development of new or revised research administration policies.
	Provides consultation to individual OVPR departments to conduct needs assessments and identify policy priorities.
	Oversees process for regular periodic review of existing Research Administration policies.
	Controls the versioning of all official policy documents and maintains history of all revisions.
	Reviews requests for exceptions to this policy, and refers requests to the RPRC or other appropriate advisory committee or the Vice President and Associate Provost for Research and Graduate Studies as appropriate.

	SOP: Creating and Revising University Policies, SOPs, and Forms			
LEHIGH UNIVERSITY	**Responsible Office: Research Integrity**			
	ORIGINALLY ISSUED	REVISED	AUTHOR	PAGE
	30-Nov-2018	n/a	N. Coll	6 of 7

Policy Sponsor	The Policy Sponsor is the staff person in the OVPR department responsible for the policy or process, or their designee. A Responsible Official may act as a Policy Sponsor.
	Develops a policy proposal to initiate a new policy or major revision to an existing policy that contains, at minimum, the information listed in the Proposing a New Policy or Major Revision to an Existing Research Administration Policy sub-section of the Procedures section above.
	Presents the policy proposal to the Responsible Official and the Director of Research Policy and Compliance. Considers all comments and incorporates revisions, as appropriate.
	Drafts the new or revised policy. Collaborates with the Director of Research Policy and Compliance with any of the tasks involved in developing the draft or revised policy, including researching, writing, reviewing, editing, establishing timelines, and arranging meetings with stakeholders. Apprises the Responsible Official of progress and issues, as appropriate.
	Presents the draft policy to the RPRC or other appropriate advisory committee and discusses the members' comments with them. Incorporates recommended revisions into a revised draft as appropriate and repeats the committee conferral process, as necessary.
	Submits a final approved draft to the Director of Research Policy and Compliance, along with a draft communication to the Lehigh community explaining the new or revised policy, pointing out any major changes, and inviting comments. Together with the Director of Research Policy and Compliance, follows the process for posting the draft policy for public comment by the Lehigh community.
	Collaborates with the Director of Research Policy and Compliance to make and approve minor revisions to existing policies.
	Collaborates with the Director of Research Policy and Compliance to create/revise, review, and obtain Responsible Official approval of new or revised SOPs or forms. Follow the processes as described in the New or Revised SOPs and New or Revised Forms sub-sections of the Procedures section above for exceptions that require SOPs and forms to undergo the formal review process described in the Policy Review and Approval sub-section of the Procedures section above.
Research Policy Review Committee (RPRC) or other appropriate advisory committee	Consists of senior-level representatives from academic and administrative areas who are, collectively, able to represent stakeholders and provided needed subject matter expertise as is needed to advise on policies in a given area. Standing committees may be used to serve as an advisory committee when appropriate. For example, the Conflict of Interest in Research Committee (CIRC), the Institutional Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC) are standing committees that serve as advisory committees for conferral on the development of new or revised policies in their respective areas.
	Reviews, provides comments/input, and confers on the development of new research administration policies, SOPs, and forms or major revisions to existing policies, SOPs, and forms.
	During the conferral process, provides input to the Policy Sponsor and Director of Research Policy and Compliance regarding the appropriate communication plans to ensure that that the campus community is informed of new policies or major revisions to existing policies.
	Reviews exceptions to this policy as appropriate.
Responsible Officials	The Responsible Official is typically the Director of the department that owns the policy and is responsible for the process governed by or affected by the policy. The Responsible Official may act as a Policy Sponsor.
	Together with the Director of Research Policy and Compliance, review and approve proposals for new policies or major revisions to existing policies.

	SOP: Creating and Revising University Policies, SOPs, and Forms				
LEHIGH UNIVERSITY	**Responsible Office: Research Integrity**				
	ORIGINALLY ISSUED	REVISED	AUTHOR		PAGE
	30-Nov-2018	n/a	N. Coll		7 of 7

	Approve the final draft of a policy, form, or SOP.
	Collaborate with the Director of Research Policy and Compliance to ensure that the university community is informed of new and revised policies, including developing and implementing appropriate training for those affected by a new or revised policy and ensuring compliance with a new or revised policy.
	Collaborate with the Director of Research Policy and Compliance to determine departmental policy priorities and participate in regular periodic reviews of existing Research Administration policies within their department.
Stakeholder	An individual, department, or function identified in the policy proposal affected by the policy or whose professional expertise relates to the subject of the policy. Stakeholders, and/or individuals or groups able to represent stakeholders' perspectives, are consulted during the policy drafting stage. The RPCR or other appropriate advisory committee is a stakeholder for all research administration policies.

VI.   References

Form: Research Administration Policy Proposal

Policy Style Guide

Policy Template

SOP Template

Form Template