RCRA Policy Updates

Deepika Bhatia, Associate VP, Research Integrity Officer
LeBrit Nickerson, Administrator, Research Compliance Effectiveness Program
Research Compliance & Regulatory Affairs

Ask RCRA

February 15, 2024

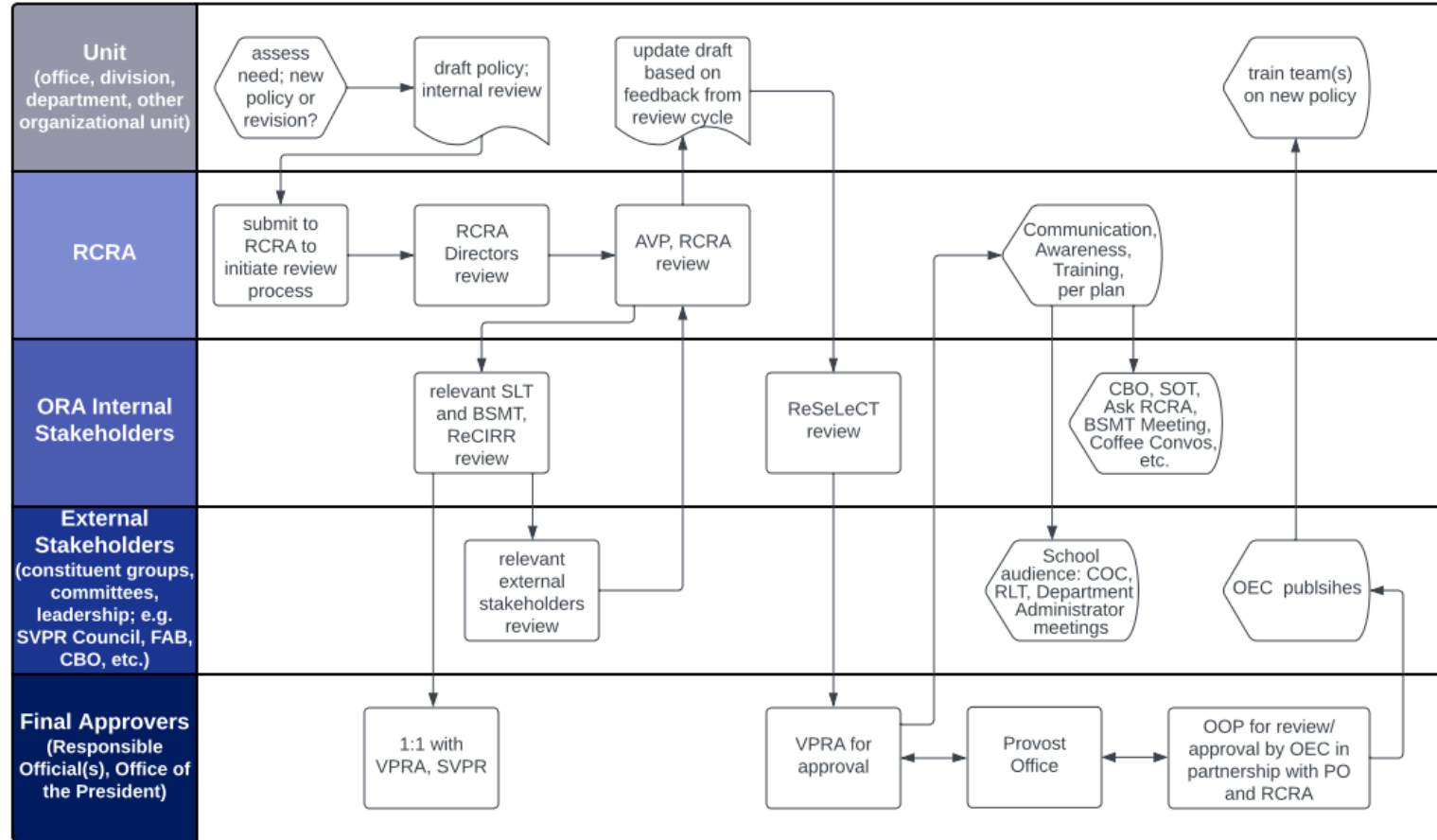# Research Policy Review and Approval Workflow

EMORY UNIVERSITY | Research Compliance and Regulatory Affairs

RESEARCH POLICY REVIEW AND APPROVAL WORKFLOW

Unit (office, division, department, other organizational unit)	assess need; new policy or revision? → draft policy; internal review ... update draft based on feedback from review cycle ... train team(s) on new policy
RCRA	submit to RCRA to initiate review process → RCRA Directors review → AVP, RCRA review ... Communication, Awareness, Training, per plan
ORA Internal Stakeholders	relevant SLT and BSMT, ReCIRR review ... ReSeLeCT review ... CBO, SOT, Ask RCRA, BSMT Meeting, Coffee Convos, etc.
External Stakeholders (constituent groups, committees, leadership; e.g. SVPR Council, FAB, CBO, etc.)	relevant external stakeholders review ... School audience: COC, RLT, Department Administrator meetings ... OEC publsihes
Final Approvers (Responsible Official(s), Office of the President)	1:1 with VPRA, SVPR ... VPRA for approval ↔ Provost Office ↔ OOP for review/ approval by OEC in partnership with PO and RCRA

ORA: Office of Research Administration
BSMT: Broader Senior Management Team
OGC Office of General Counsel
COC: Council of Chairs
ReSeLeCT: Research Senior Leadership Compliance Team

RCRA: Research Compliance & Regulatory Affairs
VPRA: Vice President for Research Administration
OEC: Office of Ethics & Compliance
RLT: Research Leadership Team

AVP: Associate Vice President
SVPR: Senior Vice President for Research
CBO: Chief Business Officer
FAB: Faculty Advisory Board
ReCIRR: Research Compliance Investigations, Reporting, & Regulatory Updates

SLT: Senior Leadership Team
OOP: Office of the President
SOT: Strategic Operations Team

ORA Policy
Approvals Webpage

EMORY UNIVERSITY
Research Compliance and Regulatory Affairs

Research Administration

ABOUT ⌄ | ANIMAL CARE AND USE ⌄ | CONFLICT OF INTEREST AND COMMITMENT ⌄ | EXPORT CONTROL ⌄ | RESEARCH INTEGRITY & COMPLIANCE ⌄ | RESEARCH SECURITY ⌄

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ORA Policy Approvals

Research Policy Approval Goals

- Comprehensive and consistent review workflow for research policies
- Adequate communication, awareness, and training plans for policy socializing efforts
- Ensure that research policies reflect current procedures, objectives, and functions

Policy Elements

ALL RESEARCH POLICIES SHALL INCLUDE THE FOLLOWING MANDATORY ELEMENTS:

- A statement of the policy
- Who has authority to approve and make changes to the policy
- To whom or to what the policy applies
- Effective date
- Who has administrative responsibility for the policy

RESEARCH POLICIES MAY INCLUDE THE FOLLOWING ADDITIONAL PROVISIONS, AS APPROPRIATE:

- Reference to other relevant policies and procedures
- Definitions of terms
- Enforcement mechanism and appeal process, where necessary

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Policy Communication, Awareness, and Training

Upon final approval, the policy will be disseminated according to the Communication, Awareness, and Training plan including the following:

- Policy presentations
- ORA audience: CBO, Ask RCRA, BSMT Meeting, Coffee Convos etc.
- School audience: Council of Chairs (COC), Research Leadership Trainings (RLT), Department Administrator meetings

Policy Review

Policy will be reviewed at least every 3 to 5 years or as needed depending on regulatory changes. Substantive revisions to the policy follow same process as above. Non-substantive revisions can be made with the approval of the policy sponsor.

- Policy Review Cover Sheet (including Review Tracking Sheet)
- Policy Review Review and Approval Workflow
- Policy Reivew SOP

Research Senior Leadership Compliance Team (ReSeLeCT) Committee

The ReSeLeCT Committee is comprised of senior leadership in ORA and Emory's research, university and healthcare compliance teams. This committee is responsible for reviewing research policies at Emory. Other collaborative initiatives of the committee are illustrated below:

RCRA Policy Review Cover Sheet

EMORY UNIVERSITY | **Research Compliance and Regulatory Affairs**

Policy Review Cover Sheet

SUBMISSION INFORMATION		
Responsible ORA Office	**Responsible AVP**	**Contact Information**
RCRA	Deepika Bhatia	dbsivak@emory.edu

POLICY INFORMATION	
Policy Name	**Policy No. (assigned by RCRA)**
Intellectual Policy Property	Policy 7.6
Submission Date	**Target Implementation Date**
	June 2024

For revisions to existing policies, provide the following information. For new policies, write "N/A".		
Effective Date	**Current Version No.**	**Date of Last Revision**
• March 15, 2011		• March 16, 2011

Overview

1. **Policy Statement and overview of content**

   Emory encourages faculty to pursue areas of study of their choice, to share the results of their intellectual efforts with colleagues and students and recognizes their need to retain traditional academic freedoms in the conduct of scholarly and scientific work. Although the University does not undertake research or developmental work principally for the purpose of commercial application, patentable inventions and other commercializeable works sometimes result from the activities carried out by Emory Personnel. To address these needs and support the University's mission and its commitment to use knowledge to improve human well-being, the University has established this Intellectual Property Policy.

2. **Reason for new policy/policy revision (legal, regulatory, operational, technological, social requirements addressed by policy)**

   The content of Policy 7.6 has not been updated since 2011. RCRA wants to ensure that Emory is following current standards in the industry. The Provost's office requires that policies are reviewed every five years, and this policy has not been reviewed in over 10 years.

3. **Affected individuals/groups/departments**

   Emory University faculty across all schools, but specifically in the School of Medicine.

4. **Include any information on peer comparisons, survey data, benchmarking, steering committee review, etc.**

   See attached benchmarking table comparing pertinent sections of comparable institutions' intellectual property policies.

5. **Additional comments/concerns**

Communication Plan
Provost Communication Plan

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REVIEW TRACKING SHEET				
Version (No. or Date)	Review/ Approval Date	Reviewer Role/Office	Reviewer Name	Comments/Description of Changes/Approval
		Office of General Counsel		
		Office of the Provost		

FINAL APPROVALS AND SUBMISSION	
Final Approvals	Date Approved
Dr. Robert Nobles, Vice President for Research Administration	
Office of the President	
Office of Ethics and Compliance Submission	Date Submitted
John Lawley, Deputy Chief Compliance Officer	

Approved ORA Policies

EMORY UNIVERSITY

Policy Number	Policy Title	Brief Overview
Policy 2.125	Cost Transfers and Payroll Reallocations	This policy establishes principles for cost transfers in accordance with 2 CFR 200, Federal and State regulations, and other agency-specific requirements.
Policy 7.27	Sponsored Award Overrun and Unallowable Cost Policy	This policy addresses the management of overruns and unallowable costs related to sponsored award administration at Emory University.
Policy 7.35	Small Balance Write-Off Policy	This policy promotes robust financial management by defining when minor revenue and expenses can be written off to an appropriate departmental account.
Policy 7.36	Residual Balance Transfer Policy	This policy sets forth the final disposition of unexpended residual balances related to fixed price, fixed rate, or nonrefundable agreements managed by Emory University.
Policy 7.37	Sponsored Award Close Out Policy	This policy addresses the management of award closeout related to sponsored award administration at Emory University.
Policy 7.39	Allocation Methodology for Sponsored Programs	This policy provides guidance for the allocation of costs that benefit two or more projects or activities
Policy 7.40	Program Income	This policy is intended to account for program income in accordance with 2 CFR 200, Federal, and State regulations, and other agency specific requirements.

Policy Number	Policy Title	Brief Overview
Policy 7.41	Provisional Award Number (PAN)	This policy provides guidance when establishing a PAN is allowable prior to receiving an official award document if certain criteria are met.
Policy 7.42	Supplemental Pay for Sponsored Programs Policy	This policy is established to expedite and facilitate certain salary payments for monthly paid employees.
Policy 7.43	Budget Revisions	This policy is intended to account for budget revisions in accordance with 2 CFR 200, Federal, and State regulations, and other agency-specific requirements.
Policy 7.44	Capital Equipment Policy	This policy is intended to account for capital equipment purchases in accordance with 2 CFR 200, Federal, and State regulations, and other agency-specific requirements.
Policy 7.45	Cost Principles for Federal and Non-Federal Sponsored Programs	This policy is intended to provide guidance on the appropriate budgeting and expenditure application of sponsored program funding whether the primary source is from federal or non-federal sources.
Policy 7.46	Institutional Base Salary	This policy is intended to provide guidance for determining the Institutional Base Salary used on sponsored awards and in accordance with 2 CFR 200, Federal, and State regulations, and other agency-specific requirements.
Policy 7.47	Internal Controls Policy	This policy is intended to document internal controls of sponsored awards in accordance with 2 CFR 200, Federal, and State regulations, and other agency-specific requirements.

Policy Number	Policy Title	Brief Overview
Policy 7.48	Invoicing and Financial Policy	This policy establishes billing and financial reporting requirements in accordance with 2 CFR 200, Federal and State regulations, and other agency-specific requirements.
Policy 7.49	No Cost Extension Policy	This policy establishes guidelines for requesting no cost extensions in accordance with 2 CFR 200, Federal and State regulations, and other agency-specific requirements.
Policy 7.9	Responsible Conduct of Research Training Policy	The policy is intended to ensure that every Emory University workforce member knows their Responsible Conduct of Research (RCR) responsibilities and protects Research integrity by completing training requirements and escalating potential issues.
Policy 7.7	Financial Conflicts of Interest in Research	This policy seeks to foster Research by providing requirements and procedures for identifying and managing financial conflicts of interest (FCOI) in Research.