GRANT PROPOSAL SUBMISSION

I. INTRODUCTION AND PURPOSE

Research & Development (R&D) functions as the curator of Carilion Clinic's research portfolio and is responsible for ensuring that all research proposals, program grants and projects comply with Carilion Clinic, federal, and sponsor regulations, policies, and procedures. R&D manages administrative aspects such as contracting, finance, regulatory support, grant management and research coordination. This procedure establishes sufficient guidelines for timely proposal submission to Research & Development.

II. SCOPE

This document establishes Carilion Clinic's standards and expectations for preparing and submitting proposals for externally sponsored awards. It applies to all Carilion Clinic principal investigators, non-Department of Medicine departments, and offices involved in any aspect of proposing, utilizing, or supporting the implementation of sponsored award agreements or subawards regardless of the primary source of funding. All grants must be submitted through Research & Development unless otherwise indicated by the parent announcement.

These guidelines cover all proposals that request external funding and/or commit Carilion Clinic resources (including personnel time, patient involvement, funds, equipment, or facility use). This policy applies whether Carilion Clinic is submitting the proposal directly or participating as a subcontractor or collaborator under another organization's submission.

III. APPLICABLE REGULATIONS AND GUIDELINES

As a reminder, 2 CFR 200.460 clearly states that the costs of preparing bids, proposals, or applications on potential federal and non-federal awards or projects, including the development of data necessary to support the non-federal entity's bids or proposals, is not allowable as a direct cost.

IV. REFERENCES TO OTHER APPLICABLE SOPS

Proposal Submission Rules and Responsibilities

V. ATTACHMENTS

None.

VI. RESPONSIBILITY

This SOP applies to:

- Principal Investigators (PIs): have the primary responsibility for development of the statement of work, developing staffing/subcontracting plans, and assuring timely and complete documents submission to R&D to allow for a timely review of the proposal.
- Department Personnel: Department-based staff who support proposal development and submission on behalf of the Principal Investigator. This includes, but is not limited to, Research Directors, department administrators, project managers, clinical research staff, and other designated personnel involved in preparing grant applications. Department Personnel may assist with coordinating internal timelines; gathering and routing required documents (e.g., biosketches, other support, compliance items); developing and/or compiling proposal components (e.g., budgets, budget justifications, letters of support, facilities/resources, and subcontractor documentation); facilitating departmental and institutional approvals; and serving as a liaison between the PI, collaborating entities, and Carilion R&D) to ensure complete and timely submission materials.
- Research & Development: monitors and administers proposal and award activity in accordance with Carilion contractual obligations; specific compliance with 2 CFR Part 200; associated federal laws, rules and regulations; and Carilion policies and procedures. The Pre Award Associate processes accurate, timely and complete proposal submissions in accordance with this procedure.

VII. KEY WORDS

Proposal Submission; Grants;

VIII. PROCESS OVERVIEW

A. Reason for the Procedure
B. Proposal Submission Timeliness
C. Proposal Prioritization
D. Principal Investigator Availability
E. Timely Submission of Proposals to R&D
F. Late or At-Risk Proposal Submissions
G. Unauthorized Proposal Submissions
H. R&D Staff Availability
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IX. PROCEDURES

A. Reason for the Procedure

Carilion is strongly committed to its sponsored research mission and to ensuring that all sponsored activities are conducted in full accordance with the requirements of each award, applicable federal, state, and local laws and regulations, and Carilion's internal policies and procedures. In addition, Carilion ensures that all clinical trial activities adhere to governing rules and regulations, including human subject protections, Good Clinical Practice standards, and oversight requirements to safeguard ethical and compliant research conduct.

These guidelines are established to ensure sufficient time for R&D to conduct a basic quality control review of proposals submitted by Carilion. When lead time permits, R&D will provide guidance and recommendations to Principal Investigators to help ensure that submissions are responsive to sponsor requirements and comply with applicable solicitation instructions. Principal Investigators are also expected to review and understand the responsibilities outlined in the Rules and Responsibilities table and to proactively fulfill their defined obligations within the grant submission process.

B. Proposal Submission Timeliness

Timely submission of proposals is required to allow Research & Development to complete all necessary review, compliance, and approval activities. The growing complexity of sponsor and federal regulations has significantly increased the administrative workload associated with proposal development. R&D conducts a comprehensive review of each proposal to confirm alignment with sponsor requirements, verify budget accuracy, identify missing components, evaluate cost-sharing commitments, and ensure completion of all required assurances, representations, and certifications. In addition, R&D is responsible for obtaining the authorized organizational signature when required, preparing cover letters, and submitting proposals through the sponsor's designated submission mechanism.

All Principal Investigators are **required to submit an R&D application for each proposal to obtain the necessary departmental approvals** from the Department Chair and Chief, when applicable. PIs are responsible for ensuring that departmental leadership is fully informed of all relevant aspects of the proposed project prior to approval, including the project budget, the PI's anticipated effort and time commitment, and any implications related to physician participation in research activities.

Electronic submission platforms used by some sponsors may experience system instability or congestion as deadlines approach. To mitigate the risk of technical delays or submission failures, R&D strongly encourages PIs to build in additional time when planning electronic submissions. These procedures are intended to provide adequate time

to confirm compliance with all regulatory and sponsor requirements and to reduce the likelihood of proposal rejection due to administrative or procedural deficiencies. PIs or their designated departmental representatives should notify R&D of their intent to submit a proposal and request budget development as soon as the decision to pursue funding is made. This notification should occur no later than four weeks prior to the sponsor's submission deadline.

C. Proposal Prioritization

At times, multiple Principal Investigators may submit proposals in response to the same funding opportunity. In these situations, Research & Development will prioritize proposal processing on a first-come, first-served basis. Proposals received by R&D well in advance of the sponsor's deadline will be given priority for review and submission. Proposals submitted after the deadlines outlined in Section E, Timely Submission of Proposals to R&D, will be reviewed and processed only as staffing capacity and time permit. PIs will be notified if a proposal is considered "at risk" (see section F.) or if it cannot be submitted by the intended sponsor deadline, allowing the PI an opportunity to request a deadline extension from the sponsor when feasible.

D. Principal Investigator Availability

To ensure a smooth proposal review and on-time submission, the PI and/or designated project staff must remain accessible to R&D for questions, clarifications, and timely correction of any issues identified during review. Providing adequate lead time allows R&D to address necessary revisions without jeopardizing the deadline. Accordingly, the PI or designated team member should complete required information promptly and be available for consultation throughout proposal development and submission. If the contact information listed in the Carilion directory is not the most reliable way to reach a team member during the review period, it is the responsibility of that individual to inform the assigned Pre-Award Administrator of an alternative method of communication.

E. Timely Submission of Proposals to R&D

To ensure adequate time for review and institutional approval, proposals must be submitted to R&D according to the following schedule:

- Finalized budget and Key Personnel biosketch(es): At least 10 business days before the sponsor deadline.
- All other administrative components: At least 8 business days before the sponsor deadline.
- Final technical narrative: At least 5 business days before the sponsor deadline.

For scheduling purposes, eight working days is defined based on standard business days. If a sponsor's deadline falls before 5:00 p.m., the finalized administrative materials must be completed eight working days prior to that earlier cutoff.

Meeting these timelines provides R&D with sufficient opportunity to:

- evaluate the proposal for completeness, budget accuracy, and alignment with sponsor requirements;
- review all sponsor-specific forms and documentation.

R&D will assist PIs with questions about completing sponsor forms and review the proposal for these required documents. Eight days is the minimum time period required for R&D to identify, and for PIs to correct, any items that could prevent proposal submission and acceptance by a sponsor.

F. Late or At-Risk Proposal Submissions

Proposals submitted to R&D fewer than eight working days before the sponsor's deadline are considered late or at-risk. Because of the limited time available, R&D cannot guarantee a full quality review. Any review that is provided will be restricted to essential checks and will occur only if workload and time allow.

Scope of R&D Review for At-Risk Proposals
For late submissions, R&D's review will be limited to:

- Verifying compliance with university policies, applicable regulations, and federal requirements
- Confirming budget calculations for accuracy
- Correcting administrative or system-related errors necessary for electronic submission

R&D will not complete a comprehensive review of proposal content, scientific narrative, or responsiveness to the solicitation. If the proposal is found to be non-compliant with sponsor requirements, R&D will not proceed with submission.

Risks Associated with Late Submission
Because insufficient time is available to correct errors or gather missing information:

- Proposals involving complex elements—such as subawards, cost sharing, or non-standard indirect cost rates—are unlikely to be submitted successfully.
- There may not be time to revise budgets, finalize documentation, or address compliance issues before the sponsor's deadline.
- R&D cannot assure the quality of the proposal or its adherence to sponsor guidelines.

R&D tracks all late submissions and documents the reasons when a proposal cannot be submitted by the sponsor's deadline.

G. Unauthorized Proposal Submissions

Proposals may not be submitted directly to any external sponsor without the prior authorization of R&D. Any award granted as a result of an unauthorized proposal submission is subject to rejection.

Before acceptance of an award resulting from an unauthorized submission is considered, the PI must submit an explanation to the Director of Grants Management describing the nature of and reasons for the unauthorized submission. Awards will not be accepted until the explanation has been received/approved by the Director of Grants Management, the proposal details have been entered, an R&D budget has been approved, and the complete set of proposal documents is uploaded and approved. The package must include an exact copy of the proposal that was submitted to the sponsor.

H. R&D Staff Availability

Regular office or working hours for R&D staff are 8:00 a.m. until 5:00 p.m. Monday through Friday. For sponsor deadlines that occur on days when inclement weather forces the Carilion to close or on scheduled Carilion holidays or closings, the last day before the closing or holiday will become the effective sponsor submission deadline.

I. References

2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)

J. Contacts

Director of Grants Management Administration: Vera Hollen, MA
Grants Management Administrator: Melissa Mercure, PhD

X. DEFINITIONS

Administrative documents – Budgets, and other required proposal documentation, including sponsor required forms and subrecipient forms.

R&D office hours – Monday through Friday, 8:00 a.m. to 5:00 p.m. Proposals cannot be submitted by R&D electronically outside of R&D office hours.

Principal Investigator (PI) – The Principal Investigator is the primary individual responsible for the scientific, technical, fiscal, and administrative conduct of an award,

grant, contract, cooperative agreement, or other externally sponsored activity. While applications may include multiple investigators, federal agencies and Carilion require that one individual be formally designated as the PI, as both the sponsor and Carilion must identify a single person who holds ultimate accountability for the execution, integrity, and oversight of the project. The PI is responsible for ensuring compliance with sponsor requirements, institutional policies, human subjects, reporting obligations, and stewardship of awarded funds. In addition, the PI is expected to review and understand the responsibilities outlined in Carilion's Rules and Responsibilities table and to actively fulfill their obligations throughout proposal development, submission, and award management.

Proposal – A proposal is a formal request for external funding that is prepared in alignment with the sponsor's specific instructions. It serves as the official record of the commitments and deliverables Carilion agrees to provide in exchange for the funding outlined in the proposal budget. For grant proposals, this may include scientific or programmatic aims, personnel effort, compliance requirements, and assurances related to human subjects, data management, or other regulatory elements as applicable. A complete submission includes the proposed statement of work, detailed budget and cost breakdown, and all required supporting documents, and must be submitted using final versions of all materials. Additionally, proposals represent Carilion's institutional endorsement and therefore must follow internal review, approval, and submission processes.

Late Proposal or At-Risk Proposal – Proposal packages completed less than eight working days before a sponsor deadline and partial proposal packages that have been emailed to R&D but are incomplete (not ready to submit) eight working days before a sponsor deadline.

Science and Technical documents – The statement of work, scope of work, project narrative/summary portions of the proposal package.

Sponsor – A sponsor is any external entity that issues a grant, contract, cooperative agreement, or other funding mechanism directly to Carilion to support research, scholarly, educational, or programmatic activities. Sponsors may include federal agencies, state or local governments, foundations, corporations, nonprofit organizations, and other funding bodies. The award document issued by the sponsor and accepted by Carilion establishes the official agreement and outlines the terms, conditions, compliance requirements, and performance expectations under which the funded activity must be conducted. Sponsors may also impose reporting, regulatory, financial, and audit obligations that Carilion and the designated Principal Investigator are required to meet throughout the lifecycle of the award.

Sponsor deadline – The specific deadline, including date and time, by which the proposal must be submitted to and received by the sponsor, as stated in the Request for Proposal (RFP) or other official sponsor communication.

Target submission date – The date by which the proposal is to be submitted to the sponsor in cases where there is no official sponsor deadline or when the PI would like it submitted earlier than the sponsor deadline.