CARILION CLINIC

Facility: System-wide
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Sponsor: Research and Development

Policy / Procedure:

Principal Investigator (PI) Eligibility

KEY TERMS: Principal Investigator, Responsibilities, Program Director, Sponsored Research, Eligibility)

I. PURPOSE:

The purpose of this policy is to:

- Position the Organization, PIs, and Co-PIs to reduce the organizational risk involved in accepting and carrying out a sponsored project, or in carrying out regulated activity within any project;
- Establish criteria permitting individuals to fulfill the role of PI or Co-PI on a sponsored project and/or project which includes a regulated activity; and
- Ensure that sponsored projects and/or regulated activities are conducted by those who have the requisite training, competencies, skills, commitment, and resources, as well as the appropriate relationship to the Organization.

As a condition of its acceptance of sponsored project awards from external sponsors, or its engagement in a project that involves a regulated activity, the Organization is obligated in its role as the recipient of the award and/or overseer of regulated activities to ensure that:

- Sponsored projects and/or other projects including regulated activities are adequately administered by the PI;
- Only individuals meeting the eligibility requirements of this policy are listed as PIs, and that proposed projects are submitted through the Organization following approved Organization procedures in place at the time of the submittal;
- All proposals and projects involving regulated activities are reviewed and approved by the Department Chair and by an authorized individual in the Research & Development Office acting on behalf of the Organization; and
- All submitted proposals or projects involving regulated activities meet the requirements of the sponsor and/or the Organization. If sponsor requirements are less restrictive than Organization policies, Organization policy shall take precedence.

II. SCOPE:

This policy applies to:

- all proposals for projects submitted to external sponsors seeking monetary or non-monetary support for a sponsored project which, if awarded to the Organization will be governed by a contract, grant, cooperative agreement, or other binding agreement;
- to all projects, irrespective of the source of funding or other support, including activities that are subject to federal, non-financial compliance regulations and are overseen at the Organization by the Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), and/or Export Controls (EC).

This policy does not apply to consultant agreements or the procurement of goods or services from vendors.

III. DEFINITIONS:

Principal Investigator (PI) or Project Director (PD)
A PI or PD is the primary individual responsible for the preparation, conduct, and administration of a sponsored project or a project which includes a regulated activity to ensure it is in compliance with applicable laws, regulations, and institutional policy governing such projects. More specifically, this individual is directly responsible and accountable to the Organization for the proper programmatic, scientific, technical and/or professional conduct of the project, and its financial and day-to-day management. The PI/PD retains the majority of the responsibility to meet the requirements of the sponsorship and/or aspects of a project which involve regulated activities. For the purposes of this policy, the term PI will be used to indicate both PIs and PDs.

Co-Investigator
Co-Is or Co-PDs are key personnel who have responsibilities similar to that of a PI (or Site Investigator, if a participating site). While the PI has ultimate responsibility for the project, the Co-I/Co-PD(s) are also obligated to ensure the project is conducted in compliance with applicable laws, regulations, and institutional policy governing the conduct of sponsored projects or other regulated activities. For the purposes of this policy, the term Co-I will be used to indicate Co-Is and Co-PDs.

Other Key Study Personnel: Other Key Study Personnel (KSP) are individuals outside of the PI and Co-I who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. This includes, but is not limited to, individuals involved in conducting the research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; and those who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study. Other Key Study Personnel who are involved in a regulated activity are responsible for the appropriate conduct/performance of that activity.

Sponsored Project: For the purpose of this policy, a sponsored project is any project or portion of a project, in which the Organization is engaged through its faculty, staff, or students that involves an interaction between the Organization and another party which may be an entity, unit, or individual inside or outside of the Organization. Normally, the agreement involves a transfer of funds, a non-monetary exchange, or payment for

services and/or products. Sponsored projects include interactions such as awards, sub-awards, grants, research contracts, outreach contracts, instruction contracts, cooperative agreements, capacity building contracts, public service work, community service project agreements, class projects with communities, task orders, extension projects, etc. where the Organization is committed to deliver a service or product.

Regulated Activity: For the purpose of this policy, a regulated activity is any project or portion of a project, in which the Organization is engaged through its faculty, staff, or students that is subject to one or more federal, non-financial compliance regulations. Such regulations may include: human subject protection regulations, biosafety and select agents regulations and export control regulations. At the Organization, such activities are overseen by the IRB, IBC, or EC.

For multisite research or research involving external collaborations:

Lead Multi-Site Principal Investigator:
Lead Multi-Site PI is typically the individual who has initiated the project or has applied for and received sponsorship. This individual has the ultimate responsibility for the conduct and integrity of research across all sites including the responsibilities as listed under Principal Investigator.

In cases where Carilion is not the initiating or lead site, the Carilion IRB application should list the **Lead Multi-Site Principal Investigator** as a Co-Investigator.

Site Investigator
Site Investigator is responsible for the conduct of the regulated activities at his/her participating institution when the project has been initiated by an individual at another site, or another site is recipient of the sponsorship. The Site Investigator is responsible for ensuring the fulfillment of their Organization's obligation under the sponsored contract, grant, or cooperative agreement as well as all regulated activities at their Organization, including but not limited to their Organization's IRB approval, compliance, data security and oversight of their Organization's research team members.

In the cases where Carilion is not the initiating or lead site, the Carilion IRB application must list the **Carilion Site Investigator** as the **Principal Investigator** and this individual must meet the PI eligibility criteria as listed above. The **Lead Multi-Site Principal Investigator** should be listed as a Co-Investigator.

IV. PROCEDURE:

To ensure that sponsored projects and/or projects which include a regulated activity are conducted by those who have the requisite training and competencies and who have the appropriate relationship to the Organization, PIs and Co-PIs must generally be employed by the Organization in a faculty or staff status.

Therefore, only Carilion Clinic employees holding a full-time position may be designated as PI or Co-Investigator in applications for externally sponsored funding or for other projects which require carrying out a regulated activity.

Those ineligible to serve as Principal Investigator at Carilion unless a special exception, as described below, has been granted include:

- Part-time employees
- Employees who are also students and are submitting their student projects
- Undergraduate and graduate students
- Post-doctoral fellows
- Residents and Fellows
- Flex time employees
- Volunteers

Exceptions

For all other members of the Carilion Clinic community other than a full-time employee of Carilion Clinic, special exception approval from the Vice President of Academic Affairs and Research and Development is required. Requests for special approval require that such projects have another Carilion Clinic employee who meets the standard PI requirements serve as Co-Investigator. In granting special exception approval, the chairperson assures that the department will assume responsibility for the conduct of the research should the Principal Investigator not remain with Carilion for the duration of the project. Research and Development and the IRB retain the right to reject, suspend, or remove any proposed PI or Co-PI, based upon previous evidence of inadequate project or financial management.

A request for exception to this policy should be made in writing to the Department of Research and Development to Serve as Principal Investigator/Project Director, and will be considered under the following conditions:

1. The individual must have the necessary experience and independence to conduct his/her own research project and to administer the project should it be funded, as judged by the faculty sponsor/ and department chairperson and demonstrated by the requesting individual's CV.
2. The individual must obtain written commitments of support from the

department chairperson or center director, and any other individual required to guarantee necessary lab space or other resources or support

3. The department chairperson or center director and a specifically identified Carilion Clinic professional or research staff must agree to assume responsibility for the awarded sponsored program should the individual leave Carilion or otherwise be unable to complete the proposed project. A plan should be developed for administering the research project in this case and should, at a minimum, include the identification of a specific individual who will assume the responsibilities of PI, and whether or not the project will stay at the Institution.
4. Completed and signed applications to serve as Principal Investigator shall be submitted to Research and Development no less than 20 business days prior to any required proposal submission date or prior to IRB submission if the project is unfunded.
5. Once agreed, the granted exception will be shared with the R&D Senior Director and IRB Director, if the project involved human subjects, documentation of the granted exception must be provided with the IRB application.

Other Academic Titles

Titles modified with the terms of "acting", "adjunct", "courtesy", or "visiting" do not confer the right to serve as a Principal Investigator. When these modifiers are used, special one-time approval for a specific project and duration may be provided under the Exceptions provision. Since "visiting" and "courtesy" appointments are for individuals whose primary responsibilities rest outside the Organization, these modified titles would require exceptional justification. (Example: professor on sabbatical)

V. OTHER ISSUES / CONCERNS:

Organization Conflict of Interest Disclosure Statement

As a matter of Carilion Clinic policy and federal regulation, it is required that Principal Investigators and other key study personnel on sponsored projects must have completed a "Disclosure of Interests" questionnaire. Information pertaining to the disclosure process/ questionnaire may be obtained from the Organizational Integrity and Compliance Office.

Recognition of Authorship in Proposals

The title of Site Investigator is primarily a designation of institutional responsibility for the conduct of a research study. As such, the title does not necessarily represent the principal authorship of the proposal document nor eligibility to receive Intellectual Property.

Name	Title	Dept./Committee	Date
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