Research Compliance Consulting Scope of Work

Overview

The Institute for Systems Biology (ISB) is seeking experienced research compliance consulting support to assist institutional leadership with research compliance operations, regulatory oversight, and institutional risk management activities. The consultant or consulting team will provide strategic guidance, operational support, and subject matter expertise across multiple compliance domains relevant to federally funded biomedical and translational research environments. This engagement is intended to provide flexible, senior-level compliance expertise in support of ISB's evolving institutional research compliance infrastructure.

1. Conflict of Interest (COI/FCOI) Program Support

- Provide guidance related to institutional investigator Conflict of Interest (COI) and Financial Conflict of Interest (FCOI) compliance programs.
- Support COI/FCOI disclosure review processes and identification of actual, potential, or perceived conflicts.
- Assist with development, implementation, and monitoring of COI management plans.
- Support sponsor reporting obligations, including NIH FCOI reporting requirements.
- Advise institutional leadership regarding emerging COI-related risks and best practices.
- Support COI committee operations, meeting preparation, documentation, and process improvement.

2. Human Subjects Research (HSR) and IRB Support

- Provide advisory and operational support related to Human Subjects Research compliance and IRB administration.
- Assist with determinations regarding exempt, non-human subjects research, and IRB-reviewable activities.
- Support interactions with external IRBs and IRB reliance arrangements.
- Assist investigators and research staff with IRB submission processes and documentation requirements.
- Support study maintenance activities including modifications, continuing reviews, closures, and reportable events.
- Assist with development and maintenance of HSR policies, SOPs, and compliance tracking processes.

3. Research Data Governance, Privacy, and Biospecimen Oversight

- Provide guidance regarding research data governance, privacy compliance, and biospecimen oversight.
- Advise on HIPAA, GDPR, and related regulatory requirements.
- Support compliant sharing and transfer of human-derived data and biospecimens.
- Assist with review of data use, material transfer, and related research agreements.
- Support institutional data governance and de-identification practices.

- Assist with dbGaP and related controlled-access data processes.

4. Research Compliance Program Development and Risk Management

- Advise leadership regarding research compliance risks, regulatory developments, and sponsor requirements.
- Assist with development and refinement of institutional policies, SOPs, workflows, and governance structures.
- Support research security and export control awareness efforts, as applicable.
- Recommend scalable compliance infrastructure improvements and operational efficiencies.
- Support onboarding and compliance training activities for investigators and research staff.

Desired Qualifications

- Approximately 10+ years of relevant research compliance experience.
- Significant expertise with NIH and NSF regulatory environments.
- Experience with COI/FCOI administration and management plans.
- Strong Human Subjects Research and IRB administration expertise.
- Familiarity with HIPAA, GDPR, dbGaP, and research data governance requirements.
- Experience supporting institutional officials, compliance committees, and executive leadership.
- Demonstrated ability to develop scalable compliance processes and policies.
- Experience operating in complex federally funded research environments.

Engagement Structure

ISB anticipates this engagement may be structured as a flexible part-time consulting or advisory arrangement. The level of effort, scope prioritization, and operational model may be refined collaboratively based on institutional needs and consultant recommendations.