



Senior Scientist, Governance Sage Bionetworks, Seattle WA

Sage Bionetworks is a world-leading nonprofit biomedical research organization dedicated to building and supporting open communities of collaborative research in human health and genomics. We are developing multiple initiatives designed to facilitate scientific collaborations and enable direct contributions to research projects of ideas and data from citizens. These initiatives require the development of technology platforms, governance policies and procedures, and novel approaches to collaborative and crowd-sourced research projects.

We are seeking creative and passionate people with experience in the ethical, legal, and/or regulatory framework for conducting research on human data and who are keen to work on open science initiatives that sit at the intersection of research, patient/citizen engagement and technology. This position assists in the development, implementation and evaluation of effective data protection policies and procedures for the open research initiatives within the organization, including outreach to all involved partners in the US and abroad. Activities must be carried out with the goal of compliance with all applicable federal and state regulations for protection of Human Research Subjects and use of human data in research.

Responsibilities:

Specific responsibilities may include but are not limited to:

- Design and develop goals, policies, and procedures to support the organization's open research initiatives in accordance with privacy and security laws.
- Provide subject matter expertise on initiatives involving the collection, use, and disclosure of personal information in biomedical research.
- Prepare and review protocols, consent documents and procedures for research projects involving human subjects/data.
- Provide support for and coordinate all submissions to the IRB (e.g. Full, Expedited, Cooperative, Exempt, etc.) and other regulatory authorities.
- Assess and mitigate regulatory compliance risks for internal and external research initiatives.
- Interact with a diverse group of colleagues including scientists, software engineers, and ethics experts as well as external partners, contributors and advisors.
- Review and evaluate existing and emerging privacy regulations (HIPAA, GINA, etc) to assess impact on projects and develop recommendations for appropriate implementations.
- Advise and educate staff regarding regulatory, legal, and other requirements of research protocols.
- Plan and coordinate data privacy training programs for users of our technology platforms.

Desired Qualifications:

- MS or other advanced scientific degree or BS with 5 years relevant experience in human data protection, medical research, or legal/regulatory matters.
- Demonstrated knowledge of ethical principles and privacy regulations as well as federal and state law pertaining to the ethical conduct of human subjects research.
- Ability to interpret and apply complex and changing regulatory requirements from multiple sources.
- Effective and efficient communication skills.
- Ability to write clear, detailed technical correspondence.
- Strong organizational and critical thinking skills.
- Project management experience, preferably with software or scientific teams.