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12-May-2020

Assistant Director, Research Administration, Compliance

Harvard Business School

52143BR

Job Code

358057 Admin Pro/Indiv Contrib

Job Summary

The Assistant Director, Research Administration, Compliance has primary responsibility to manage the Harvard Business School (HBS) program for the protection of research participants ensuring compliance with all HBS and Harvard University policies and procedures.

Job-Specific Responsibilities

Reporting to the Senior Director, Research Administration and Behavioral Research Services, and working closely with members of the research administration team, HBS faculty, and administrative partners at HBS and across Harvard University (HU), the Assistant Director, Research Administration, Compliance supports the research and scholarly activities of the HBS faculty by managing the administrative review process for the use of human subjects in HBS research and ensuring the ethical principles that apply to human research projects are adhered to.

Human Subjects Review

Analyzes and reviews all submissions to the HBS online human subjects system to ensure completeness and compliance with applicable federal regulations, State laws, Harvard, and HBS policies. Identifies protocols that meet regulatory criteria for exemption from human subjects review. Determines whether research projects are exempt from further review; reviews and approves certain research projects as a designated reviewer; corresponds with researchers, articulating required modifications to study documentation, including consent forms, in order to secure approval, and requesting additional information needed before approval can be considered.

- Is a subject matter expert on federal regulations, State laws, Harvard, and HBS policies related to the protection of research participants. Provides guidance to individual researchers regarding submissions, incomplete protocols, policy questions, and serves as a consultant on matters pertaining to the use of human subjects in HBS research. Serves as the point of contact on research related policies and procedures to HBS faculty, researchers and other administrators.
- Serves as the liaison to Harvard's Committee on the Use of Human Subjects (CUHS), attending staff meetings and ensuring policies and procedures are consistently applied at HBS. Serves as HBS point of contact for protocols involving ceding review with other institutions, international human subject's approval, and noncompliance. Ensures that all HBS policies, procedures and guidelines are current and documented.
- Maintains active knowledge of evolving laws, regulations, policies, and ethical norms that are applicable to human research activities through continuous professional development

Program Management and Delivery

- Manages the submission review process of protocols in the Harvard-wide electronic submission and tracking and reporting (ESTR) system. Reviews the ESTR queue, prioritizing and allocating submissions for review, ensuring goals relating to timely output, turnaround, accuracy, and customer service are met. Maintains up to date workflow documentation on all processes.
- Provides guidance to researchers and administrators on the use of the Electronic Submission Tracking & Reporting (ESTR) system used to manage applications for review and automate correspondence.
- Creates and maintains a system to monitor and track critical exceptions and changes to policies. Documents procedures related to HBS faculty research, and provides timely access to facilitate faculty work and decisions regarding exception requests.
- Creates and maintains a system of monitoring relevant metrics to inform strategic decision making and policies around the use of human subjects in HBS research.

Basic Qualifications

- Bachelor's degree required
- At least 5-7 years of experience in the application of human subject protection administration regulations required
- Knowledge of research regulations, HIPAA (regarding human subjects), and familiar with current NIH, DHHS, OHRP, and FDA guidelines.
- Demonstrated knowledge of human subject protection and related regulations normally acquired through employment with an Institutional Review Board (IRB).

Additional Qualifications

- Familiarity with Huron Research Suite (Formerly Click) software (or have used other similar IRB electronic-system software).
- Excellent judgment and sound decision-making skills.
- Experience in successfully managing projects from inception through completion.
- An understanding of and ability to manage highly confidential information.
- The ability to communicate with a diverse group of people with sensitivity.
- Demonstrated ability to work effectively in a complex organization and across multiple units and levels.
- Ability to take initiative and work independently with an entrepreneurial spirit, flexibility, and high-capacity assess priorities and to meet competing deadlines.
- A strong customer service orientation, and excellent interpersonal skills.

Certificates and Licenses

Current Certified IRB Professional (CIP) designation is strongly preferred. (In the absence of such a designation, CIP eligibility must be obtained within 1 year of hire.)

Additional Information

Cover Letter is Required.

Many HBS employees are eligible for Flexible Work Arrangements, which may be explored during the interview process.

Culture of Inclusion: The work and well-being of HBS are strengthened profoundly by the diversity of our network and our differences in background, culture, experience, national origin, religion, sexual orientation, and much more.

Explore HBS Work Culture at <http://www.hbs.edu/employment/>

Follow us on Twitter @HBSJobs

Harvard Business School will not offer visa sponsorship for this opportunity.

Job Function

General Administration, Research

Location

USA - MA - Boston

Time Status

Full-time

[Salary Grade](#)

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EEO Statement

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Pre-Employment Screening

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