

Job Description

Job Code	102213-0
Job Title	Research Compliance Director
Effective Date	04/30/18
FLSA Status	Exempt

Job Summary

Manages the implementation of MedStar Health Research Compliance and Privacy programs and oversees the operation of that function in all MedStar facilities. Serves as the privacy liaison for research across all facilities, in coordination with the local entity compliance officer. Implements MedStar Health annual compliance work plans, systems, processes and policies as they relate to research which are designed to ensure compliance with Federal healthcare and research program requirements at the system level.

Minimum Qualifications

- Education/Training:** Bachelors degree in relevant field required, Masters or advanced degree (e.g., JD) is strongly preferred.
- Experience:** 5 years experience in research compliance or administration/human subject protection, preferably in a clinical research environment. Experience in conducting research investigations and knowledge of clinical research billing compliance reviews and auditing. In depth knowledge of human and non-human subject research compliance and privacy laws, regulations, and guidance.
- License/Cert/Reg:** Certification in healthcare research compliance, healthcare compliance, or another comparable compliance certification from a recognized industry professional association preferred.
- Knowledge, Skills & Abilities:** Strong knowledge of regulations governing human research is required including but not limited to OHRP and FDA regulations governing federal research grants such as OMB Circular A-21, A-133, A-110. Strong written and oral communication skills. Strong analytical and problem-solving skills. Proficiency in working with Microsoft Office products, and other health care related applications. Proven ability to manage multiple projects and deadlines.

Primary Duties and Responsibilities

1. Contributes to the achievement of established department goals and objectives and adheres to department policies, procedures, quality standards, and safety standards. Complies with governmental and accreditation regulations.
2. Advises and educates MedStar leadership and associates on research compliance matters and stays current on new developments in federal, state and local research regulations, laws and guidance documents.
3. Advises entity leadership on issues concerning compliance, including developing and implementing controls designed to ensure compliance with MedStar Health and OCBI policies and procedures. Works collaboratively with entity leadership in the development or restructure of a compliance program and its implementation.

4. Assists research leaders and managers in the development, review, approval and education of research policies and standard operating procedures and ensure they remain contemporary with federal, state and local regulations.
5. Collaborates with OCBI/Corporate to oversee the coordination of internal and external governmental compliance/privacy investigations or reviews (and the Legal Department as necessary) to ensure investigations/reviews are conducted appropriately and/or that responses to external entities are appropriate and consistent with OCBI standards and expectations.
6. Collects and provides data for monthly compliance data requests, dashboards and scorecards. Communicates and works collaboratively with AVP of Hospital Compliance, Privacy Director, OCBI staff, system Compliance Directors and Legal Counsel on research compliance and privacy issues, resolutions and identified trends.
7. Coordinates with the hospital Legal Counsel on legal compliance matters and government investigations of research, as appropriate.
8. Ensures distribution, implementation and education regarding compliance policies, procedures and the Code of Conduct (e.g. annual conflict of interest disclosure process, monthly healthcare exclusions screenings, Business Associate Agreement updates, etc).
9. Establishes a Research Compliance Committee to provide guidance and support to compliance initiatives. Chairs the research compliance committee and report to the MedStar research leadership and appropriate Board on compliance matters and progress on a regularly established frequency.
10. Identifies potential areas of system wide research compliance risk and set priorities for internal reviews, site monitoring (of investigative sites and administrative departments) and review and approve corrective actions needed.
11. Implements and oversees MedStar Health compliance and privacy programs at the system level to ensure the program meets the requirements of the seven elements for an effective compliance program as it relates to research and are aligned with the OCBI/Corporate compliance and privacy program.
12. Implements corporate/OCBI fiscal year compliance work plan and initiatives. As needed, develops research specific fiscal year work plan items in addition to the corporate/OCBI work plan.
13. Investigates independently or supervises the investigation of research compliance concerns raised through MedStar's Integrity Hotline or other reporting mechanisms.
14. Oversees periodic audits of research across all areas (all areas of research and all MedStar entities / activities) which will include, at a minimum, CMS billing compliance, human subject protection, privacy and security of research-related PHI and, where appropriate, adherence to IACUC and other regulations/oversight of pre-clinical subject protection and/or GLP adherence.
15. Participates in research-related meetings (IRB, IACUC, COI, MHRI management meetings) as necessary or appropriate to advise and educate research leadership on issues of research compliance. Participates in meetings and on committees and represents the department and hospital in community outreach efforts.
16. Participates in assisting entity leadership and local management education on research compliance. Participates in the development and implementation of annual research compliance work plan, enterprise risk management program and aligns research risk assessment with enterprise risk management plans.

17. Responds to, investigates and resolves reports of potential research misconduct and/or compliance issues with respect to research. As appropriate, works with relevant department heads to ensure that all reports of specific research non-compliance are thoroughly investigated and resolved.
18. Works with research leadership, hospital leadership and corporate leadership to ensure proper communication and consistency is being maintained across all MedStar facilities with respect to research policies, procedures and standards.
19. Works with system and entity-level leadership, compliance committee members and department heads to establish a culture of compliance for research
20. Performs other duties as assigned.

Patient Population

Where applicable, refer to the competency validation documents for population(s) served.

Physical Requirements

- DIRECT PATIENT CARE/CONTACT:** Visual acuity including color vision. Ability to hear and orally communicate. Ability to read, comprehend, and write English language. Manual dexterity. Moderate physical effort: Physical mobility with ability to lift, push or pull up to and including 35 lbs. Walking, standing, sitting for prolonged periods. Handling of patients including lifts, rolls, transfers, etc. with the use of mandatory Safe Patient Lifting Equipment. Ability to perform CPR and respond to emergency situations including potential takedowns or restraints. Ability to appropriately wear Personal Protective Equipment (PPE).
- INDIRECT PATIENT CARE/CONTACT:** Visual acuity. Ability to hear and orally communicate. Ability to read, comprehend and write the English language. Manual dexterity. Moderate to heavy physical effort: Physical mobility with ability to lift, push or pull up to and including 35 lbs. Walking, standing, sitting for prolonged periods. Handling of patient and or equipment including lifts, rolls, transfers, etc. with the use of mandatory Safe Patient Lifting Equipment. Ability to appropriately wear Personal Protective Equipment (PPE).
- LABORATORY STAFF:** Visual acuity including color vision. Ability to hear and orally communicate. Ability to read, comprehend and write the English language. Manual dexterity. Light physical effort: Physical mobility with ability to lift, push or pull up to and including 15 lbs. Walking, standing, sitting for prolonged periods. Ability to appropriately wear Personal Protective Equipment (PPE).
- NO PATIENT CARE/CONTACT:** Visual Acuity. Manual dexterity. Light physical effort: Physical mobility with ability to lift, push or pull up to and including 15 lbs. Walking, standing, sitting for prolonged periods. Ability to hear and orally communicate. Ability to read, comprehend and write the English language.
- NO PATIENT CARE/CONTACT:** Visual Acuity. Manual dexterity. Light physical effort: Physical mobility with ability to lift, push or pull up to and including 35 lbs. Walking, standing, sitting for prolonged periods. Ability to hear and orally communicate. Ability to read, comprehend and write the English language.

Working Conditions

ADA: Some skills/physical requirements can be altered and appropriate accommodations or use of adaptive equipment will be made in accordance with the ADA. Associates should discuss accommodations and provide medical documentation to Occupational Health.

ATTENDANCE: Regular job attendance is an essential job function.

DIRECT PATIENT CARE/CONTACT: Exposure to patients, visitors and family members with a variety of physical and psychiatric/mental health conditions. Potential for exposure to contagious diseases, blood and body fluids, chemicals, medicinal preparations, potential ionizing radiation, unpleasant odors, and other conditions common to a clinical environment. Mandatory requirement for use of Personal Protective Equipment (PPE) when indicated per policy. Position may require flexible scheduling, off-shifts, weekend, holiday, on-call and/or overtime hours of work in accordance with department policy or procedures.

INDIRECT PATIENT CARE/CONTACT: Exposure to patients, visitors and family members with a variety of physical and psychiatric/mental health conditions. Potential for exposure to contagious diseases, blood and body fluids, chemicals, medicinal preparations, potential ionizing radiation, unpleasant odors, and other conditions common to a clinical environment. Mandatory requirement for use of Personal Protective Equipment (PPE) when indicated per policy. Position may require flexible scheduling, off-shifts, weekend, holiday, on-call and/or overtime hours of work in accordance with department policy or procedures.

LABORATORY STAFF: Exposure to infection from disease-bearing specimens and contagious diseases, hazards of handling diseased organs and tissues, risk of bloodborne diseases, hazardous anesthetic and chemical agents, body fluids and wastes, unpleasant elements and other conditions common to a clinical laboratory environment. Mandatory requirement for use of Personal Protective Equipment (PPE) when indicated per policy. Position may require flexible scheduling, off-shifts, weekend, holiday, on-call and/or overtime hours of work in accordance with department policy or procedures.

NO PATIENT CARE/CONTACT: Mostly sedentary work in office type setting. Use of office equipment on a regular basis including computers, phones, etc. Potential for incidental exposure to patients, visitors and family members with a variety of physical and psychiatric/mental health conditions. Position may require flexible scheduling, off-shifts, weekend, holiday, on-call and/or overtime hours of work in accordance with department policy or procedures.

Working at another site and/or other MedStar departments or programs may be required.

May be required to travel to various locations as needed. Reliable transportation may be required.

Must be willing to carry a pager/cell phone and be available for 24 x 7 on-call support to include weekdays, evenings, weekends, and holidays. Frequency of rotation will vary depending on need/size of department.

Works from home.

May be exposed to assaults and/or hazards from internal/external disasters.

May experience exposure to extreme temperature changes.

May involve working in precarious or high locations such as ladders and scaffolding.

Reporting Relationships

Report To: Assistant Vice President for Hospital Compliance, Office of Corporate Business Integrity

Supervises: Assigned staff.

I have read, understand and accept that the duties and responsibilities in this job description provide a general summary of the work to be performed and are not intended to be an exhaustive list of all responsibilities, duties and skills required. Responsibilities may be augmented from time to time as management may require. This job description does not establish contract for employment and is subject to change at the discretion of the employer.

Employee Signature: _____

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