

**Mater Misericordiae University Hospital
Dublin (“MMUH”)**



Job Description & Person Specification

**Grade VII
Contracts and Regulatory Affairs Manager**

Job Title - Grade

As above

Reports to

Direct Report MMUH General Counsel

Location

Mater Hospital, Eccles Street, Dublin 7

JOB DESCRIPTION

JOB PURPOSE

The Contracts and Regulatory Affairs Manager will be employed on a permanent contract and will work with the Hospital's General Counsel who is responsible for providing legal advice and assistance to the Hospital's Chief Executive Officer and the Hospital's Clinical Research Support Office (CRSO).

1. PRINCIPAL DUTIES & RESPONSIBILITIES

The post holder will be a key member of the Legal team and will be mainly responsible for addressing all contract and regulatory queries arising from the CRSO to include:

- Reviewing and editing the terms of a range of Hospital contracts, including clinical trial agreements and data protection agreements, to ensure compliance with applicable legislation and regulatory guidelines.
- Lead the development of clinical trial agreement templates to facilitate research collaboration between MMUH and key stakeholders to include academic institutions and the pharmaceutical and medical devices sector.
- Ensuring the accuracy and maintenance of contract documents under the remit of the Legal team.
- Where applicable, assist in negotiations with third party providers and research sponsors to ensure contracts meet with the relevant legal and regulatory requirements.
- In collaboration with the Hospital's Data Protection Officer and Information Governance Manager, the post holder will assist the CRSO in the review of relevant Data Protection Impact Assessment (DPIAs) and in the development and implementation of an Information Governance Framework for research.

2. GENERAL DUTIES AND RESPONSIBILITIES

2.1

- The ability to take personal responsibility to initiate activities and drive objectives through to a conclusion.
- Ensure the efficient administration of area of responsibility.

- An ability to prioritise conflicting demands, and to address medium and long term goals while also managing short term objectives.
- Demonstrate pro-active commitment to all communications with internal and external stakeholders, including the development of effective working relationships with professional groups.
- Strong team work skills including the ability to build and maintain relationships in a multidisciplinary team / multi-stakeholder environment.
- Make appropriate use of technology to advance the quality and efficiency of service provision.
- Understand, identify with and be committed to the core values of the Hospital.
- Demonstrate striving for excellence and achieving quality outcomes.
- Represent the Legal Department on committees and groups as required.
- Provide analysis and regular timely reports on function activities and performance as required.
- Maintain continuous professional development in order to build on and develop expertise and professional knowledge in areas of responsibility.

2.2

- You will be aware of the confidential nature of Hospital work and in particular, the right of patients to confidentiality.
- You are required to familiarise yourself with and adhere to all policy and procedural documents relevant to your position.
- The highest standard of hygiene must be maintained in the Hospital at all times and all staff members are responsible for ensuring compliance with the Hospitals requirements and standards with regard to hygiene. It is the responsibility of all staff to have a fundamental understanding of their individual responsibility in maintaining departmental & site hygiene standards.
- Ensure that effective safety procedures are in place to comply not only with the Safety, Health and Welfare at Work Act 2005 but also within the spirit of the Hospital's mission, vision and values, and they are known and followed by staff. You are required to familiarise yourself with the requirements of employees under the Safety, Health and

Welfare at Work Act 2005 and to promote a work environment that is compliant with the Safety, Health and Welfare at Work Act 2005. Each staff member is individually responsible for ensuring that the Hospital remains a safe place to work.

Business Continuity Management (BCM) is a holistic management process that identifies potential impacts that threaten an organisation and provides a framework for building resilience and the capability for an effective response that safeguards the interests of its key stakeholders and reputation” (BS 25999) All Staff employed in the Mater Misericordiae University Hospital are obliged to:

- make themselves familiar with the Organisational Business Continuity Plan,
 - attend BCM education sessions provided for them,
 - make themselves familiar with their individual roles as set out in their departmental business continuity plan if applicable and / or the Organisational business continuity plan.
- Carry out any other appropriate duties or assignments as requested by MMUH General Counsel.

The above Job Specification is not intended to be a comprehensive list of all duties involved and consequently, the post holder may be required to perform other duties as appropriate to the post which may be assigned to him/her from time to time and to contribute to the development of the post while in office.

3. Eligibility Criteria - Qualifications and/ or experience

Candidates must have on or before the date of application:

- Hold a bachelor’s degree from a third level university.
- Knowledge of Irish and EU Health Research and Clinical Trials legislation.
- A minimum of 3 years’ experience in the review and management of contracts, including clinical trial contracts and data protection agreements.
- Proficiency in IT skills and experience with a broad range of systems and reporting tools.
- Healthcare industry experience advantageous subject to overall experience / skillset.

4. Desirable Criteria

- Hold a Degree in Law
- Hold a Certificate and/or Diploma in Data Protection Law and/or relevant experience in the area

Enquiries to Ms Ruth Adams by email radams@mater.ie