Job Description

1. Job Details

Job title: Clinical Trial and Research Governance Manager
School/Support Department: College of Medicine & Veterinary Medicine
Unit (if applicable): n/a
Line manager: Professor

2. Job Purpose

To ensure the University meets its obligations as sponsor for clinical research and to minimise potential risks to the University. Furthermore, the post also provides support to principal investigators in navigating and complying with new regulatory and research governance requirements.

3. Main Responsibilities

1. Ensure the University and Principal Investigators comply with the Medicines for Human Use (Clinical Trials) Regulations and Good Clinical Practice (GCP). Introduce and manage administrative systems to meet the requirements of sponsorship such as protocol review, regulatory/ethical approval, indemnity and risk assessment, pharmacovigilance. 35

2. Establish and manage a central University Clinical Trials Unit and have line management responsibility for individuals within the unit. Network with other key UK Universities, particularly in Scotland, to share best practices and develop necessary tools, e.g. electronic Case Record Forms. 30

3. Be lead named University sponsorship signatory under the requirements of the Research Governance Framework. Risk assess individual projects and determine if University sponsorship or co-sponsorship is appropriate. 10

4. Ensure that clinical research studies are properly registered and covered under the University indemnity insurance. 5

5. Assist Investigators with protocol design, preparation of documents, applications to Ethics Committees and Regulatory Agencies, trial registration. 10

6. Generate and implement a core set of University Standard Operating Procedures for clinical research and set up a system to demonstrate compliance with these SOPs. Liaise with relevant departments, codify common practices and establish new ones to meet requirements. 5

7. Establish and maintain effective working relationships with NHS Lothian and MRC, ensuring systems are complementary and not duplicated. 5

8. Act as point of contact for MHRA if/when they inspect the University. 5
4. Planning and Organising
- Plan, develop and implement new systems to ensure the following:
  - Ethical/regulatory applications and monitoring, reporting and indemnity arrangements are in place as part of the sponsorship requirements.
  - Awareness is raised and research staff are proactively educated about regulatory and good practice standards surrounding the involvement of human subjects in research. Following discussion with other Universities, a website is the optimum way of achieving this.
- Streamline existing systems to ensure the following:
  - Processes for funding, ethics and regulatory applications are simplified. This will be planned in collaboration with ERI proposal administration and NHS Lothian to reduce the bureaucratic burden on researchers.
  - Establish and develop a Clinical Trial Unit with other key members of staff throughout the University.

5. Problem Solving
- Critically analysing existing systems and procedures, identifying gaps where new processes are needed.
- Implementing change within the University and encouraging a new research culture. Ensuring researchers appreciate the importance and view as a priority the implementation of standards of good practice and legislation in their research.
- Managing a dynamic and evolving legislative environment and formulating appropriate University policies for implementation of these requirements.
- Collaborating with ERI, NHS Lothian and MRC, overcoming bureaucratic and political obstacles.
- Identifying needs for IT systems or where ERI, NHS Lothian and University systems can merge.

6. Decision Making
- Working with the freedom to make decisions and implementing appropriate systems throughout the College, in particular for the following:
  - Risk assessing individual projects, deciding where the University will sponsor or co-sponsor.
  - Deciding and advising on required study management and monitoring mechanisms based upon risk assessment.
  - Implementing appropriate procedures to fill the identified gaps with sponsorship obligations.

7. Key Contacts/Relationships
Director of the Wellcome Trust Clinical Research Facility (Line Manager), Principal Investigators, members of the University Clinical Trial Unit, Head of the College of Medicine and Veterinary Medicine, College Director of Research, College Registrar and Senior Administrative Officer, Edinburgh Research and Innovation legal and grant proposal personnel, NHS Lothian Research and Development staff, MRC staff based at Little France, MHRA, Ethics Committees, Chief Scientist Office, AON Insurance Brokers, equivalent post holders in other Universities (member of the Brunswick Group) and NHS divisions.
8. Knowledge, Skills and Experience Needed for the Job

- **Skills**
  Organisational and project management skills; strong written and interpersonal skills; proven track record of clinical study delivery; problem solving; decision making; leadership; keeping abreast with new and evolving legislation; analytical skills to relate legislation and good practice to particular research scenarios; self motivation and self management; IT skills.

- **Experience and Knowledge**
  University life sciences degree; clinical trial management; working knowledge of GCP and relevant directives; working knowledge of regulatory and research governance concepts.

9. Dimensions

New legislation, standards and guidelines have recently brought significant changes to the way clinical research should be conducted. In particular:

- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Research Governance Framework (RGF) for Health and Social Care

As a consequence, the University needs a structure for authorisation and management of clinical research to ensure the University meets its obligations as sponsor. This post is within the College of Medicine and Veterinary Medicine primarily, however, it is evident that similar support is required within other Colleges and where necessary, the post holder will advise and support where possible. Furthermore the University is involved with a collaboration of Scottish Universities aiming to produce high quality research across Scotland. Developing and maintaining a network of researchers, statisticians and trial managers will be key to the success of this.

10. Job Context and any other relevant information