Post Details	Last Updated: 06/02/2017	
Faculty/Administrative/Service Department:	Faculty of Health and Medical Sciences (FHMS) / Surrey Clinical Research Centre (Surrey CRC)	
Job Title:	Project Manager	
Job Family & Job Level	Professional Services	Level 4
Responsible to:	Senior Project Manager	

Job Purpose Statement

To take responsibility for the planning, preparation, execution, and reporting of clinical research projects to ensure that clinical trial data is acquired effectively and efficiently to the appropriate Standard Operating Procedures (SOPs) of the Surrey Clinical Research Centre.

Problem Solving, Accountability and Dimensions of the role

The post holder will work within established departmental processes and procedures with minimum day-to-day supervision in the organisation and delivery of work objectives. As a member of the team the Project Manager has responsibility for the planning, preparation, execution, and reporting of clinical research projects. This includes responsibility for ensuring that clinical research projects are conducted according to relevant regulatory guidelines and good clinical practice (GCP). There is scope for the post holder to apply judgement and initiative when managing their workload, including any medium-term priorities and when responding to any conflicting demands. They must apply a sound understanding of the staffing, facility and equipment requirements of the clinical trial in order to effectively schedule the study and facilitate the smooth operation of clinical research projects.

The post holder is required to liaise daily with the client company, Principal Investigator (PI) and co-investigators (where appropriate) to ensure they are fully briefed on study status at all times. In addition the Project Manager is responsible for effectively communicating to Surrey CRC, FHMS and other faculties within the University on the study's status; highlighting areas of resource concern and issues and actions relating to the ongoing status and successful completion of the project. The Project Manager is responsible for the completion of regulatory forms; including Clinical Trial Applications (CTA) and research ethics submissions. Alongside the PI and study Physician, the Project Manager is expected to inform the research Ethics Committee of all target milestones during the clinical trial and to alert the committee to any protocol deviations or serious adverse events, in accordance with the timelines specified by UK law/ICH GCP.

They are expected to provide advice and solutions to routine day-to-day problems within the specialist area in which they are familiar, such as project scheduling, training and competence of research staff and conduct of clinical research. Resolution for these issues will usually be found through referring to their previous experience of similar problems or through making reference to and applying departmental policies and procedures. When faced with new issues, the post holder is required to identify the nature of the problem or issue through analysis and to apply reasonable personal initiative and judgement (where past experience does not apply) to identify a suitable and timely resolution. The post holder is expected to refer more complex issues or those outside of the remit of their role to more experienced/senior colleagues including the study Principal Investigator or their line manager for guidance and direction, but in these cases they are expected to have a degree of involvement in finding and implementing resolutions to the case.

The post holder is expected to take a pro-active approach to review and evaluate work practices/materials in order to identify areas for improvement. This will include writing and assisting in the development and updating of Unit SOPs and Work Instructions to ensure compliance with GCP and governing law.

This role is highly responsible and impacts significantly on the validity and integrity of clinical trial data, study budgets and staff management.

Background Information/Relationships

The Surrey Clinical Research Centre (Surrey CRC) is a world-renowned clinical research facility, pivotal to maintaining and enhancing the University of Surrey's research excellence in the biomedical/clinical

research interface. Surrey CRC is involved with conducting human clinical research to Good Clinical Practice (GCP) standards. The unit is managed by the Head of Clinical Research with a core of clinical research and study management staff trained to a high level in conducting clinical research.

The Project Manager is responsible ultimately to the Principal Investigator and Head of Research and Study Management. Their direct line management is to the Senior Project Manager.

They will liaise, communicate and build relationships with senior colleagues including senior staff in the University of Surrey, pharmaceutical industry, regulatory bodies and NHS Trusts.

They will be required to attend departmental meetings and to represent the CRC at external meetings including ethical review board meetings and client meetings.

This job purpose reflects the core activities of the post. As the Department/Faculty and the post-holder develop, there will inevitably be some changes to the duties for which the post is responsible, and possibly to the emphasis of the post itself. The University expects that the post-holder will recognise this and will adopt a flexible approach to work. This could include undertaking relevant training where necessary.

Should significant changes to the job purpose become necessary, the post-holder will be consulted and the changes reflected in a revised job purpose.

Person Specification This section describes the sum total of knowledge, experience & competence required by the post holder that is necessary for standard acceptable performance in carrying out this role.

Qualifications and Professional Memberships	**Essential/ Desirable**
Degree in Life Sciences or equivalent vocational qualifications plus a number of years' practical experience in a similar or related role(s) Or: Significant vocational experience, demonstrating development through the acquisition of appropriate professional or specialist knowledge	E

Technical Competencies (Experience and Knowledge)	**Essential/ Desirable**	**Level 1-3**
Experience of working in a clinical research facility	E	2
Working knowledge of Good Clinical Practice guidelines (ICH GCP) and the European Clinical Trial Directive and the UK legislation	E	2
Good working knowledge of MS Office, including Word, Excel, Outlook and PowerPoint	E	2
Special Requirements:	**Essential/ Desirable**	**Level 1-3**
Willingness and ability to work outside of regular office hours as the clinical studies run 24 hours a day, 7 days a week	D	n/a
Willingness to undertake CPD to ensure that he/she remains up to date with developments and changes in legislation and regulations in the area of clinical trials	E	n/a

Core Competencies	**Level 1-3**
Communication	3
Adaptability / Flexibility	2
Customer/Client service and support	2
Planning and Organising	2
Teamwork	2
Continuous Improvement	3
Problem Solving and Decision Making Skills	2

Leadership / Management	1
Creative and Analytical Thinking	2
Influencing, Persuasion and Negotiation Skills	2

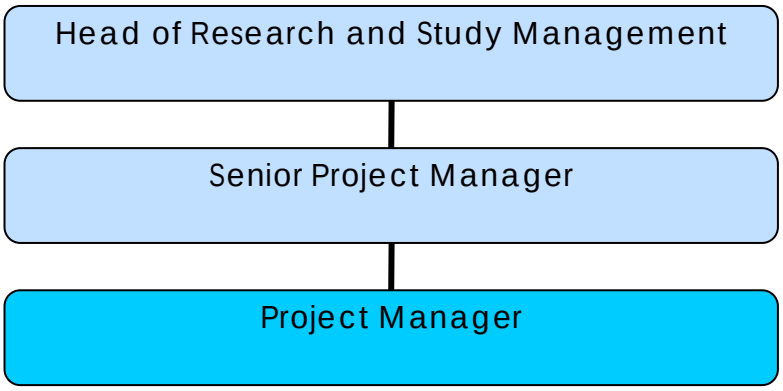
Organisational Information

All staff are expected to:

Positively support equality of opportunity and equity of treatment to colleagues and students in accordance with the University of Surrey Equal Opportunities Policy.

Help maintain a safe working environment by:

- Attending training in Health and Safety requirements as necessary, both on appointment and as changes in duties and techniques demand.
- Following local codes of safe working practices and the University of Surrey Health and Safety Policy.
- Excellent environmental performance is a strategic objective for the University of Surrey. All staff are encouraged to work to achieve the aims of our Environmental Policy and promote awareness to colleagues and students.
- Undertake such other duties within the scope of the post as may be requested by your Manager.



Key Responsibilities

This document is not designed to be a list of all tasks undertaken but an outline record of the main responsibilities (5 to 8 maximum) and should be read in conjunction with the accompanying Job Purpose.

1. Ensure that all departments involved in a study hold a clear understanding of and are in agreement with their responsibilities in the conduct of a study.
2. Maintain an exceptional working knowledge of, and ensure compliance with, UK law, ICH GCP, American clinical trial requirements (FDA), applicable regulatory and legal requirements, and CRC Standard Operating Procedures. Developing and updating those procedures as required.
3. Assist in the production and/or collation of all documentation for ethical committee submission, regulatory submissions and all study related documentation, including the maintenance of the site master file and subsequent archiving of documentation in accordance with GCP.
4. Responsible for project management (overview, direction, timelines, output, financial tracking, study scheduling and resource allocation).
5. Co-ordinate arrange and chair client pre-study visits, initiation meetings, study specific training , monitoring, close-out visits, audit inspections and other study related meetings.
6. To oversee, and be responsible for, the quality and integrity of all documents, data and reports generated in the course of a study through overseeing monitoring and quality control procedures to ensure compliance with UK law and appropriate regulatory requirements.
7. Monitor external sites that are responsible for study related tasks.
8. Assist with the development, review and maintenance of the Quality management systems including SOPs and Work instructions.

N.B. The above list is not exhaustive.