Post Details	Last Updated: 04/10/2021		
Faculty/Administrative/Service Department	Faculty of Health & Medical Science Department of Clinical and Experimental Medicine		
Job Title	Clinical Data Coordinator		
Job Family	Professional Services	Job Level	3
Responsible to	Clinical Project/Trial Manager		
Responsible for (Staff)	n/a		

Job Purpose Statement

To accurately and efficiently manage data throughout the lifetime of a clinical trial in compliance with Standard Operating Procedures (SOPs), laws and guidelines, supporting the Trial Management Team and the activities of Surrey Clinical Trials Unit (CTU) to successfully complete human clinical research studies by ensuring the accurate collection and reporting of study data.

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)

1. Ensure data is managed effectively and efficiently to the appropriate SOP, laws and guidelines governing clinical trial data such as GCP.
2. Act as the data lead to ensure that work is completed to required standards in the CTU and liaise with the Trial Manager and external sites to ensure that work flow and quality are maintained and timelines are met.
3. Develop procedures relating to data entry and verification in conjunction with the Clinical Trial Manager and Data Systems Team.
4. Ensure data is entered in a timely and accurate manner, recording and coding of incoming forms and letters and of data brought back from monitoring visits to centres, checking for inconsistencies, violations and unusual or adverse clinical events.
5. Chase missing data and forms, preparing information for monitoring purposes and preparing data reports for the trial team, working with trial sites to ensure that data are clean and being reported in the appropriate manner.
6. Work with the team to have complete documentation filed in TMF and ensure CRFs are appropriately completed
7. Assist with monitoring, quality assurance and audit exercises.
8. Assist the Clinical Project/Trial Manager with preparation of reports by the provision of information and basic analysis of data, and with other essential tasks in support of clinical trial delivery.

N.B. The above list is not exhaustive.

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.
- Work to achieve the aims of our Environmental Policy and promote awareness to colleagues and students.
- Follow University/departmental policies and working practices in ensuring that no breaches of information security result from their actions.
- Ensure they are aware of and abide by all relevant University Regulations and Policies relevant to the role.
- Undertake such other duties within the scope of the post as may be requested by your Manager.
- Work supportively with colleagues, operating in a collegiate manner at all times.

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.

Elements of the Role

This section outlines some of the key elements of the role, which allow this role to be evaluated within the University's structure. It provides an overview of what is expected from the post holder in the day-to-day operation of the role.

Planning and Organising

- The post holder will work with and under the supervision of the Clinical Project/Trial Manager. The post holder will be responsible for ensuring that data is managed effectively and efficiently to the appropriate SOP, laws and guidelines governing clinical trial data such as Good Clinical Practice (GCP).
- They will liaise with the trial site staff to ensure that data is complete, up to date and accurate, using various methods to monitor, query and verify the data, including central and on-site monitoring. They will have the responsibility for planning their workload to ensure that this is done on a regular basis and provide the necessary reports to both sites and the in-house trial team, they must be able to react positively to changing demands.

Problem Solving and Decision Making

- The post holder will analyse how new data should be processed, and validate and carry out QC checks in the trial database order to maintain the integrity of the scientific data.
- The appropriate course of action will usually be a matter of choice, influenced by the application of established procedures and precedents and their previous experience/exposure to similar problems. However, they are also expected to exercise discretion and judgement when addressing and resolving these problems or issues.
- Proactive problem solving, creativity and lateral thinking are therefore a key element of this role.
- The post holder is required to identify and address the majority of problems/issues faced with assistance from the Trial Manager however, more complex problems should be referred up, either for advice/guidance or for resolution.

Continuous Improvement

- 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.

Accountability

- The post holder is expected to support the Trial Team in the performance of their duties. They will also provide advice to other staff members with regard to specific aspects of data management procedures within Surrey CTU.
- Within their role, the post holder is held accountable for the accuracy and integrity of the clinical trial data.

Dimensions of the role

- The post holder will not have any direct line management responsibilities, but will be expected to provide guidance and training to staff who may be required to assist the team if necessary, including Clinical Data Assistants or data entry staff.

Supplementary Information

- As part of the role you may be required to travel within the UK and abroad
- All staff including the post holder will have a role in implementing the practices and collaborative culture which define the success of the essential clinical research functions housed within the Clinical Research Building and across the Department of Clinical and Experimental Medicine.

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		
HNC, A level, NVQ 3, HND level or equivalent in relevant subject or relevant formal training plus proven experience in a similar or related roles Or: Broad vocational experience, demonstrating development through the acquisition of appropriate professional or specialist knowledge		E
Technical Competencies (Experience and Knowledge) This section contains the level of competency required to carry out the role (please refer to the Competency Framework for clarification where needed and the Job Matching Guidance).	Essential/ Desirable	Level 1-3
Proven experience in a similar role, ideally in multi-centre clinical trials	E	2

Good working knowledge of MS Office, including Word, Excel, Outlook and PowerPoint and other database software used for managing clinical trials	E	2
Ability to understand and work with figures with attention to detail	E	2
Ability to work under supervision to ensure the data is managed professionally and effectively	D	n/a
Working knowledge of UK Clinical Trials Regulations, ICH Good Clinical Practice, the European Directives on Clinical Trials and Good Clinical Practice and the Department of Health's Research Governance Framework	D	n/a
Familiarity with standard coding dictionaries such as MedDRA and WHO-DRUG	D	n/a

Special Requirements:	Essential/ Desirable
Willingness to undertake CPD to ensure that they remain up to date with developments and changes in legislation and regulations in the area of clinical trials	E
Core Competencies This section contains the level of competency required to carry out this role. (Please refer to the competency framework for clarification where needed). n/a (not applicable) should be placed, where the competency is not a requirement of the grade.	Level 1-3
Communication	3
Adaptability / Flexibility	2
Customer/Client service and support	3
Planning and Organising	2
Continuous Improvement	2
Problem Solving and Decision Making Skills	2
Managing and Developing Performance	n/a
Creative and Analytical Thinking	2
Influencing, Persuasion and Negotiation Skills	1
Strategic Thinking & Leadership	n/a

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.

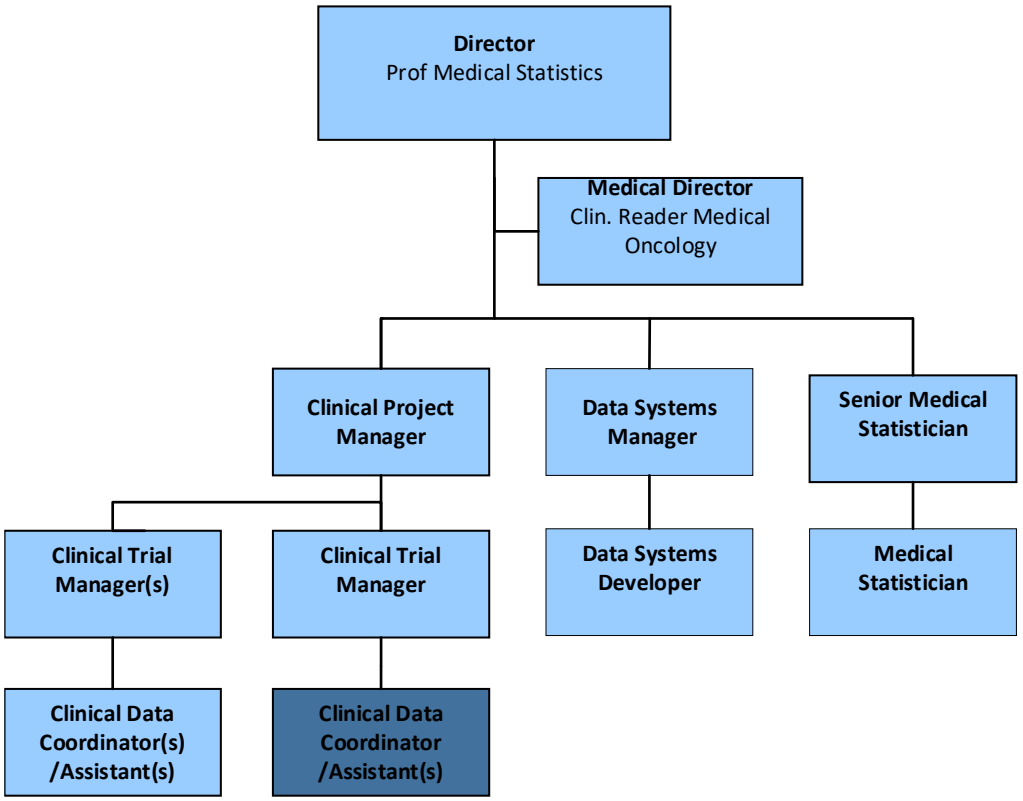
Organisational/Departmental Information & Key Relationships

Background Information

Surrey Clinical Trials Unit is a UK CRC registered CTU, with the expertise and infrastructure to design, develop, manage, analyse and report clinical studies through a core of academic, clinical, research, project and data systems/management staff and statisticians. The CTU is associated with the NIHR Research Design Service SE and works closely with Surrey Health Economics Centre to support the design and delivery of clinical trials and other well designed studies to the highest quality and to Good Clinical Practice (GCP) standards.

The CTU is co-located within the Clinical Research Building with Surrey Clinical Research Facility and Surrey Sleep Research Centre; synergistic units with skilled teams committed to excellence in clinical research and digital health innovation including in sleep/wake research.

Structure Chart



Relationships

Internal

- The Clinical Data Coordinator is responsible to a Clinical Trial Manager and ultimately to a clinical Project Manager and the CTU Director.
- They will liaise, communicate and build relationships with senior and immediate colleagues in the CTU and across the essential research functions within the Clinical Research Building.
- They will be required to attend internal meetings at various levels as required

External

- The post holder will liaise, communicate and build relationships with staff at various levels at external sites
- They may be required to attend external meetings