Candidate Information

Position:	Clinical Trials Assistant
School/Department:	NI Clinical Research Facility
Reference:	21/109306
Closing Date:	Monday 15 November 2021
Salary:	£21,686 - £24,174 per annum
Anticipated Interview Date:	Wednesday 24 November 2021
Duration:	2 years

JOB PURPOSE:

To work as a member of the Northern Ireland Clinical Research Facility team to support and promote the practice of clinical research in the NICRF. The main area of work will be in Ophthalmology and Vision related studies.

To work unsupervised/supervised in day-to-day practice supporting a portfolio of clinical trials and other high-quality research studies. The post holder will provide technical and administrative support relating to vision clinical trials, co-ordinating volunteer recruitment and assist with management of clinical trials. They will carry out clinical tasks/assessments and assist in implementation of research programmes, supporting other clinical research and audit as agreed with the NICRF Director/delegate. They will be required to assist with the coordination of the daily running of the NICRF and support NICRF staff as required.

The postholder will be responsible for agreed functions within the delivery of a study that may include, but is not limited to, screening and recruitment, care, management and follow-up of a caseload of patients in clinical trials adhering to local and national regulatory research guidelines, policies and standard operating procedures.

MAJOR DUTIES:

1. Assist and support research optometrists/ophthalmologists/PIs with accurate completion of trial paperwork including transcribing/exporting data from medical records to Case Report Forms(CRFs) (paper or electronic) as required by clinical trial protocols, checking eligibility of patients for entry into trials and randomising/registering patients into trials according to protocol requirements.
2. Act as first telephone contact for enquires about trials/research and be confident to provide advice /information to participants. Where appropriate and for specific trials, the post holder may be expected to work autonomously obtaining patient informed consent to participate in a study, provide information and support to patients on clinical trials.
3. Assist with maintenance of databases of patients screened and recruited to trials and provide general administrative support including filing, typing, fielding telephone calls and arrange patient appointments as required by protocol timelines. Support the team in preparing documentation required for participant study visits.
4. Ensure clinical areas are ready for participant arrival. This includes switch on/set up of equipment and collection of appropriate drops/consumables required for the visit. Ensure clinical areas are cleaned following visits and equipment shut down at the end of the day if necessary. Ensure a safe, clean and comfortable environment is provided for patients, staff and other users.
5. Ensure specialist ophthalmic equipment used within the clinic is in working order, rectify and/or report faults in research equipment, and organise repair as necessary.
6. Following induction and a period of training, assist with clinical observations as required by study protocol under the supervision or direction of qualified staff, to include measurement of blood pressure and height and weight. Further opportunity will be available to train to perform venepuncture/phlebotomy.
7. Following induction and a period of training, assist with ophthalmic photography/imaging, visual field assessment and measurement of visual acuity as required by study protocol under the supervision or direction of qualified staff. This may include techniques such as fundus photography, OCT, Heidelberg Spectralis imaging, Humphrey Perimetry and microperimetry.

8. Following induction and a period of training assist in completion and submission of accurate paper and electronic case report forms within the required time frames and assist with data queries.
   Extract, rename and upload ophthalmic images and electronic data to appropriate reading centres/trial coordinating centres.
9. Support the team in preparing documentation for monitoring visits, arranging suitable meeting rooms and act as a liaison when monitors are onsite
10. Follow research and clinical protocols and best working practices within the NICRF.
11. Have an understanding that all research must be conducted according to the EU Directive on Good Clinical Practice and Research Governance Guidelines and assist the team in upholding these. Where appropriate, develop knowledge of clinical research and ethics related to research and undergo training in aspects of clinical trials, including ICH-GCP, data collection and completion of Case Report Forms.

Planning and Organising:

1. Prioritise own workload along with the wider Ophthalmology/NICRF team and plan day-to-day activity to meet required deadlines and objectives.
2. Engage in forward planning to ensure continued smooth operation of clinical equipment and allocation of clinical accommodation.
3. Contribute to the planning of future research projects.

Resource Management Responsibilities:

1. Ensure research resources are used in an effective and efficient manner.
2. Responsible for overseeing and co-ordinating the maintenance and repair of all NICRF ophthalmic equipment.
3. Work with wider NICRF team to ensure sufficient stocks of equipment and supplies, following set ordering procedures.

Internal and External Relationships:

1. Daily contact with other staff engaged within the NICRF, University staff and NHS staff.
2. Participant contact in accordance with appropriate Clinical Practice/Participant Focused Care.
3. Liaise with contractors, suppliers and other visitors as required.
4. The post will be based primarily at the NICRF but may involve working in other clinics and outreach establishments across Northern Ireland.

ESSENTIAL CRITERIA:

1. Academic and/or vocational qualifications i.e. OND/ONC and/or NVQ level 3(or equivalent) in a health/science related discipline.
2. 2 years relevant work experience e.g. in a technical, laboratory, clinical health role.
3. Good IT skills to include working knowledge of applications such as Word and Excel.
4. Good organisational skills.
5. Understanding and awareness of Health and Safety regulations and procedures.
6. Good oral and written communication skills.
7. Good communication and interpersonal skills.
8. Ability to develop and demonstrate standard equipment and techniques.
9. Willingness to learn and undertake training relevant to the post.
10. Attention to detail.
11. Ability to work within established procedures but with minimal supervision.
12. Ability to plan own work schedule responding to new pressures and adjusting priorities.
13. Problem solving skills.
14. Willing and able to work outside normal working hours.
15. Willing and able to travel locally.
16. Appointment to this post is subject to the successful candidate's Enhanced Criminal Record Check.

DESIRABLE CRITERIA:

1. Hold a current GCP certificate.
2. Recent experience of clinical trials.
3. Experience working in an ophthalmology/optometry setting.
4. Experience operating medical imaging equipment.
5. Good understanding of relevant regulations and procedures.