ROLE PROFILE

Job Title: NAFLD BioResource Project Manager
School/Department: School of Medicine, Nottingham Digestive Diseases Centre (NDDC)
Job Family and Level: Administrative, Professional, Managerial (APM) level 4
Contract Status: Fixed term for a period of 1 year.
Hours of Work: Hours of work are full-time (36.25 hours); however applications are also welcome from candidates wishing to work part-time (minimum 30 hours per week). Please specify in your application if you wish to work part-time and the number of preferred hours.
Location: Nottingham Digestive Diseases Centre, E floor, West Block
Reporting to: NDDC Operations Manager

Background:
The National Institute for Health Research (NIHR) BioResource in Common and Rare Diseases was established to further clinical research within the UK by providing a national resource for researchers, specifically volunteer (people with a rare disease or people with and without a health condition) recruitment by genotype and/or phenotype. The BioResource is coordinated from Cambridge and researchers can apply to the BioResource if they are interested in recalling volunteers from the panel.

The non-alcoholic fatty liver disease (NAFLD) BioResource is an integral part of the main NIHR BioResource. Levels of obesity have risen markedly in the UK over the past 20 years such that 28% of adults and 33% of year 11 children are now obese. This has led to a marked increase in the prevalence of non-alcoholic fatty liver disease (NAFLD) as a major metabolic complication of obesity. The NIHR funded NAFLD BioResource aims to be capable of identifying the key factors underlying susceptibility, progression and clinical outcomes which would assist effective risk stratification of patients.

Purpose of the New Role:
A highly motivated and enthusiastic individual is required to work within the NDDC team specifically for the NAFLD BioResource project. The NAFLD BioResource project is part of the NIHR Nottingham Biomedical Research Centre programme of work and is a collaboration between two other centres; Birmingham and Newcastle.
The post holder will be responsible for setting up new sites as identified, monitoring recruitment progress and reporting to the NAFLD Programme Manager in Birmingham. The post holder will be expected to work with internal and external stakeholders. The post holder will be required to play an integral role in the delivery of the NAFLD BioResource project objectives.

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<th>Main Responsibilities</th>
<th>% time per year</th>
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<tr>
<td>1. Research</td>
<td>20%</td>
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### Main Responsibilities

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- Working with the Principal Investigator (PI) and Lead Centre in Birmingham to develop trial documents and submit for local HRA approval (e.g. participant information sheet, informed consent form). Managing any amendments and ensuring accurate version control.
- Liaising with the Lead Centre and contributing to the Trial Steering Committee and Data Monitoring Committee, assisting the development and implementation of the trial database in the local vicinity and wider sites.
- Provide regular reports of study progress and recruitment from all allocated sites to the PI, Programme Manager and Lead Centre. These should be prepared to a high standard and completed in an accurate and timely manner.

2. **Project Management**

- Project management of the trial, working closely with PI and Lead Centre to ensure project milestones are met and the trial is delivered on time and within budget.
- Ensuring the trial is managed and conducted in compliance with the relevant SOPs, GCP guidelines and appropriate organisation policy and procedures.
- Liaise with the Programme Manager in Birmingham and Project Manager in Newcastle in the development, set up and management of new sites across the country.
- Contribute to the site selection process, identifying potential investigators and assist with assessing the feasibility of potential participating sites.
- Assist with SIVs and be the main point of contact for sites associated with the trial ensuring accurate record keeping and maintenance of site files.
- Liaise with the research team including the Research Nurses and Admin support to ensure all data is being collected and managed according to GCP guidelines.
- Developing and maintaining risk assessment for the duration of the project, ensuring risks are identified and minimised, and escalated to the appropriate member of the research team when necessary.
- Monitoring recruitment against targets to identify problems and their potential solutions, and work with sites to implement corrective actions if required.
- Developing and maintaining excellent communication with the PI, Programme Manager, R&I offices, Research Nurses, sponsors, funders and regulatory bodies.

### Knowledge, Skills, Qualifications & Experience

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<th>Essential</th>
<th>Desirable</th>
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<td><strong>Qualifications/Education</strong></td>
<td>Degree (or equivalent qualification) in a relevant subject OR Significant experience as a Clinical Trial Manager/Coordinator/Project Manager</td>
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Essential Desirable

Skills/Training
- Excellent presentation and communication skills both written and oral
- Self-motivated and able to motivate and influence others within a multi-disciplinary team from a range of professional backgrounds and levels of seniority
- Confident in prioritising and managing own workload and work with minimal supervision
- Ability to understand complex problems and challenges and apply knowledge to address them
- Excellent organisational skills with a flexible approach to working and the ability to multi-task
- Detailed understanding of statutory Clinical Trial regulations, GCP and research governance requirements
- Excellent computer skills, especially Microsoft Office software (Word, Excel, PowerPoint and Project)
- Excellent people management skills

Experience
- Experience of project management of clinical research with a track record of successfully completed trials
- Experience of preparing complex reports and trial related documentation
- Experience of working within a multi-disciplinary team, understanding the strengths and weaknesses of others to assist teamwork development

Other
- Able and willing to travel locally and nationally, for trial meetings or site visits as required
- Ability to work flexibly to meet the requirements of the role
- Willingness to adopt the Ethos and Principles of the School of Medicine to improve the student experience.
- Understanding of medical terminology

Additional Information

Background
The post holder will work as part of a team and will have responsibilities for the initiation, delivery, management and coordination of all research activities for the NAFLD BioResource project in compliance with all relevant regulations and SOPs for trials.

Working Environment
The post-holder will be based at the Nottingham Digestive Diseases Centre and will be part of a wider team liaising with the Biomedical Research Centre, GI & Liver Disorder Theme and others as appropriate. The Nottingham Digestive Diseases Centre is housed within the Queen’s Medical Centre, E-floor, West Block.

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Athena SWAN Silver Award