# Purpose

This varied and challenging post will involve among other tasks, preparation of ethics and R and D submissions, dissemination of information about studies, upkeep of diagnostic and research databases and assistance with recruitment into and conduct of clinical trials and natural history studies. The postholder will be responsible for the collation and management of regulatory documentation to ensure the team is conducting research in accordance with UK regulations and local guidance. The postholder will also assist the team in all aspects of clinical research organisation including audits, registries, biobanks and databases.

# Main Duties and Responsibilities

1. Prepare and track submissions for ethical and other relevant approvals including Site Specific Assessments.
2. Assist with costings for clinical trials (and subsequent amendments) and facilitate negotiation with the funder representative.
3. Ensure proactive communication with sponsors and funders, advising on study status, particularly with regard to regulatory documentation
4. Ensure close communication with Clinical Research Facility, Research and Development and Clinical Trial Unit and all other relevant parties throughout the lifetime of a study
5. Prepare submissions of protocol amendments for local R&D and ethics approval
6. Organise and coordinate feasibility meetings
7. Ensure relevant internal parties and the Muscular Dystrophy UK are advised of new studies and their progress through to active status through timely communication
8. Preparation for, and facilitation of, audits and/or inspections
9. Ensure archival of essential documents in accordance with local policy
10. Maintain and update the project database to ensure swift reporting of data and status on studies
11. Develop and register patient information leaflets and clinical guidelines according to local policy
12. Organise, attend, and document meetings or training events relevant to the start-up, conduct or closure of trials
13. Provide guidance and support for Principal Investigators, sharing knowledge of best practice and current legislation/guidance
14. Use initiative and judgement in day to day management of workload and problem solving

# Assist in the collection of natural history data to inform future trials

1. Participate in short term audit and research projects with other members of the team
2. Assist in the maintenance and development of diagnostic and follow up databases including patient assessment according to prescribed protocols.
3. In conjunction with the multidisciplinary team facilitate the production of good quality research.
4. Take responsibility for continuous improvement of research administrative processes and target achievement, in line with changing regulations and faculty strategy
5. Take responsibility for identifying own learning needs, including identifying appropriate courses to ensure up to date knowledge in the regulations governing clinical research and research data
6. Liaise with other specialties, including but not limited to cardiology, anaesthetics, and respiratory care and orthopaedics for the generation of follow up data and maintenance of appropriate registries
7. Oversite of regulatory issues relating to visitors and research staff
8. Undertake other reasonable duties or responsibilities as requested.
9. Be aware of and take responsibility for working in accordance with applicable regulations and guidance including:
   * International Conference on Harmonisation (ICH) Guidelines on Good Clinical Practice.
   * UK Regulations on Clinical Trials (and pending implementation of GCP Directive).
   * Data Protection Act 1998.
   * Research Governance Framework for Health and Social Care.
   * Trust and University policies

# Dimensions

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| **Staff** | The postholder may supervise staff. |
| **Financial** | No budgetary control but a level of responsibility for the costing process of trials and assisting with grant costings |
| **Research** | Facilitator & support role, as opposed to owner of any research projects, taking on Principal Investigator responsibilities to ensure regulatory & research governance compliance within the CRF. Responsible for multidisciplinary projects at various stages of development and conduct. Some independent input into study design with respect to outcome measures will develop as post progresses |
| **Teaching** | None |
| **Customer** | Joint Research Office  Commercial & non-commercial sponsors and funders (e.g. representatives of Pharmaceutical companies, Department of Health, Medical Research Council, NHS Trusts or Universities)  Chief Investigators, Principal Investigators and research teams  Clinical Research Facility (CRF) staff (including business, clinical and administrative)  Interaction with CRN and NIHR groupings |
| **Administrative** | Attendance at project/internal meetings as required providing real-time project summaries. Provision of reports/information as required. Maintenance of databases |
| **Other** | Responsibility to attend essential training and ensure up to date knowledge of Clinical Trials, and associated, regulations/guidance. Application of this knowledge to all projects and to the continuous improvement of internal processes. For example: contract negotiation; R&D approval; project registration; & management of essential documentation.  Support will be provided from the neuromuscular team particularly in relation to the clinical aspects of trials. |

# Planning and Organising

# Excellent time management and organisational skills are essential to carry out the duties of this post, for example effective workload and project planning. Ability to work autonomously in the planning and organisation of several trials at different stages of development. Ability to set, communicate and meet deadlines.

# Decision Making

# The post holder may be a first point of contact and as such is expected to prioritise and make decisions regarding the urgency/importance of actions and requests from both internal and external customers.

# Internal and External Relationships

Deal effectively with a wide range of individuals including:

* + Administrative, nursing, medical, academic and other support staff
  + Scientific staff
  + Administrative and senior members of organisations sponsoring and/or funding and/or co-ordinating the conduct of clinical trials including pharmaceutical and biotechnology.

# Other Relevant Information This is a responsible role that requires the postholder to have a broad range of skills, to be flexible, reliable, organised and efficient.

# Person Specification

### Knowledge (inc. qualifications)

*Essential*

* 1st degree in relevant subject or professional qualification
* Knowledge of clinical research regulatory requirements in the UK
* Knowledge of local and national research governance and management processes

*Desirable*

* Higher degree in a relevant discipline
* Knowledge of clinical research regulatory requirements in Europe / USA

### Skills (professional, technical, managerial, practical)

*Essential*

* Capacity for original thought
* Excellent oral communication and writing skills
* Team-working skills
* Excellent Information technology and computing skills
* High level of personal organisation

### Experience and Achievements (paid or unpaid)

*Essential*

* Previous experience of working within a clinical research team environment
* Experience of preparing ethics and R&D submissions
* Experience of coordinating commercial and academic lead clinical research
* Experience of costing clinical research

*Desirable*

* Research experience, assessment and clinical trials
* Experience in neuromuscular or other chronic conditions
* Experience of working with local clinical research support services

**Other**

*Essential*

* Willingness to undertake work outside of normal working hours