Quality Assurance Manager

Job Description

JOB PURPOSE:

To take a lead in ensuring that all clinical trial activity conducted through Warwick Clinical Trials Unit (CTU) meets the highest standards and complies with the relevant University and regulatory policies and procedures, working closely alongside the current Quality Assurance Manager within the Quality Assurance Team.

To support the Clinical Trials Unit Manager in the continued growth and development of Warwick CTU and its maintenance as a UKCRC Fully Registered CTU.

DUTIES AND RESPONSIBILITIES:

1. Act as the Warwick CTU's central focus for all matters pertaining to quality assurance. To design, implement and maintain a quality assurance system. Organise, conduct and oversee quality control activities within the CTU, Warwick Medical School and at investigator sites throughout the UK including feedback and action planning processes.

2. To take a lead role in ensuring that clinical trials adhere to robust Standard Operating Procedures (SOPs), Trust and University Policies, Good Clinical Practice and Information Governance requirements.

3. Contribute to the development, implementation, maintenance and improvement of clinical trial policies and procedures. Conduct the annual review of the Standard Operating Procedures seeking input from others as required.

4. Maintain an up to date understanding and working knowledge of relevant national and international legislation and regulations pertaining to the conduct of clinical trials and ensure new information is disseminated to staff as appropriate.

5. Responsible for pharmacovigilance systems at a national and international level, to ensure all safety reporting requirements are met. Act as trusted Deputy for the European Safety Reporting System (Eudravigilance).

6. To work closely with the Quality Assurance Team in the development and delivery of training for new members of staff within Warwick CTU. To assist checking WCTU staff training records are up to date and demonstrate competence / appropriate for their role. To support the recruitment of new staff as required.

7. Lead on the organisation and delivery of the CTU's course for Chief Investigators. Assist in the development and delivery of research governance training for staff within Warwick Medical School.

8. Provide clear, consistent and timely information and advice to researchers and other relevant colleagues through all phases of clinical trials. Assist in the review of new protocols to identify and assess risk and monitoring requirements and ensure adherence to regulations and Standard Operating Procedures.

9. Collate information / produce reports on trial unit activities as required including annual insurance declarations, MHRA GCP compliance reports, training activities.

10. Support the CTU Manager in maintaining UKCRC Full Registration status of the CTU, and promotion of the unit. Become a member of the national UKCRC QA group to share good practice.

11. Represent the CTU at external committees and other conference/external meetings, presenting externally and disseminating information to staff as necessary.

12. To develop and maintain the Research Governance pages of the CTU's web-site.

13. Be an active member of the CTU's Business Committee and advise on risks associated with new proposals. Support the development of new trial and research applications. Assist in the set up and running of clinical trials when required.

14. Oversight of the randomisation service to include staffing, cover and finances.

15. Responsible for organising archiving of CTU trial documentation both within the CTU building and off-site. Create and maintain an archive log and coordinate the storage, retrieval and destruction of documents.

16. Represent the CTU Manager as required.

This job description is an outline only and does not contain an exhaustive list of duties and you may be required to undertake additional responsibilities. It may be amended following discussion with you.

Person Specification

The Person Specification focuses on the knowledge, skills, experience and qualifications required to undertake the role effectively. This is measured by (a) Application Form, (b) Test/Exercise, (c) Interview, (d) Presentation.

Essential Criteria 1
Educated to degree level or equivalent (a)

Essential Criteria 2
Knowledge of ICH GCP and EU Clinical Trials Directive, Mental Capacity Act, Data Protection Act, Information Governance, Medical Devices Directive and Research Governance Framework for Health and Social Care (a) (c)

Essential Criteria 3
Experience of conducting audits to ensure compliance with relevant regulations (a) (c)

Essential Criteria 4
Previous experience of working in a clinical trials environment (a) (c)

Essential Criteria 5
Experience of the development and delivery of training (a) (c)

Essential Criteria 6
Excellent communication and relationship skills (a) (c)

Essential Criteria 7
Self-motivated with ability to motivate others (a) (c)

Essential Criteria 8
Planning and organisation skills (a) (c)

Essential Criteria 9
Ability to prioritise workload, use initiative and meet tight deadlines (a) (c)

Essential Criteria 10
Ability to maintain confidentiality and deal sensitively and effectively with staff (a) (c)

Essential Criteria 11
Good working knowledge of Microsoft Office 2010 and some familiarity with web page design and maintenance (a) (c)

Essential Criteria 12
Line management experience (a) (c)

Essential Criteria 13

Meticulous attention to detail (a) (c)

Desirable Criteria 1
Experience of writing and maintaining the core SOPs required by a Medical School (a) (c)

Desirable Criteria 2
Experience of providing oversight and management of clinical trial monitoring activities (a) (c)

Desirable Criteria 3
Participation in UKCRC networks (a) (c)

Senior Project Manager

Job Description

Job purpose

To provide exceptional project management across a portfolio of clinical trials in a variety of therapeutic areas to ensure that projects are delivered on time, within budget and in accordance with the protocol and relevant regulations.

Duties and responsibilities

1. To oversee the preparation of a portfolio of project plans and the setup of new clinical trials so they are ready to start on time with a sufficient number of experienced sites identified to enable recruitment targets to be achieved.

2. To monitor progress of both new and on-going trials within the portfolio against project milestones and to assist the Clinical Trial Coordinators in formulating and implementing strategies to improve progress and remedy recruitment difficulties as necessary.

3. To review staff resources for a portfolio of trials to make sure resource is being used in the most efficient way.

4. To actively participate in Trial Management Group meetings to identify problems and then work with the trial teams to resolve them.

5. To develop and implement systems for effective trial management and share best practice, identify ways to streamline trial procedures, increase efficiency and reduce costs without compromising quality.

6. To assist in the recruitment and training of trial team staff, mentor Trial Coordinators and Administrators and provide day to day management and supervision thereafter.

7. To review project budgets with the Chief Investigators and Trial Coordinators to ensure resources are being spent and used appropriately.

8. To collate information / produce reports on trial activities as required by funding, regulatory and other agencies.

9. To support the development of new trial and research applications, in particular work with Chief Investigators to formulate a realistic recruitment plan.

10. To contribute to the design, conduct, publication and presentation of the research and play a pivotal role in the preparation and timely completion of final report to the funding bodies.

11. To keep up to date with research literature and developments in relevant disease areas, regulatory guidance, and trial management.

12. To provide bespoke support to individual trials as required.

13. To undertake trial related duties as required, either at the coordinating centre or at participating sites.

Person Specification

The Person Specification focuses on the knowledge, skills, experience and qualifications required to undertake the role effectively. This is measured by (a) Application Form, (b) Test/Exercise, (c) Interview, (d) Presentation.

Essential Criteria 1

good honours degree (2:1 or above) or equivalent (a)

Essential Criteria 2
Knowledge of ICH GCP and EU Clinical Trials Directive, Mental Capacity Act, General Data Protection Regulation, Information Governance, Medical Devices Directive and Research Governance Framework for Health and Social Care (a) (c)

Essential Criteria 3
Project management qualification or equivalent experience (a) (c)

Essential Criteria 4
Extensive experience in setting up and managing clinical trials (either drug, non-drug or complex interventions as required by the nature of the portfolio) (a) (c)

Essential Criteria 5
Extensive experience of liaison with the NHS and clinicians (a) (c)

Essential Criteria 6
Previous knowledge and experience of selecting and setting up clinical trial sites and working with them to recruit to target (a) (c)

Essential Criteria 7
Previous knowledge and experience of preparing applications for regulatory and ethical review (a) (c)

Essential Criteria 8
Experience of supervising and mentoring staff, with the ability to maintain confidentiality and deal sensitively and effectively with staff at all times. (a) (c)

Essential Criteria 9
Good working knowledge of MS Office applications (including Excel and Access) (a) (c)

Essential Criteria 10
Excellent team working skills (a) (c)

Essential Criteria 11
Excellent written and oral communication skills (a) (c) (d)

Essential Criteria 12
Self-motivated with the ability to motivate others (a) (c)

Essential Criteria 13
Ability to work in a proactive and reactive environment (a) (c)

Desirable Criteria 1
MSc or PhD or equivalent (a)

Further Particulars
Warwick Medical School

Deputy Head of Operations

Job Description

Job purpose

To manage the operational activity within WCTU and implement strategies for continuous improvement, working closely with the senior management team to ensure the successful and efficient delivery of the clinical trials portfolio to the highest standards of quality and compliance.

Duties and responsibilities

Operational

1. Manage the senior project managers (SPMs), and their teams to ensure WCTU clinical trials are carried out on time, within budget and in accordance with good clinical practice, the study protocol and adhering to all relevant regulatory requirements and standards.

2. Support the development of trial proposals, providing operational and financial expertise to ensure that there is sufficient budget to successfully delivery the trials to the highest standard of quality and compliance.

3. Develop WCTU's operational framework, taking responsibility for driving efficiency across WCTU's clinical research portfolio.

4. Chair the WCTU Operations Committee, contributing as a senior member of WCTU's management team to oversee CTU wide issues that relate to trial operations such as scheduling, recruitment and resource management.

5. Provide support for ongoing UKCRC registration, ensuring that WCTU continues to operate to the highest standards and meets the criteria for UKCRC full CTU registration status.

6. Develop, implement and manage a policy for inclusion of patient representatives.

Finance

7. Provide monitoring and oversight of trial budgets. Undertake regular review of WCTU research grant income to identify whether staff contracts can be extended and research delivery maintained.

Personnel

8. Lead, manage, motivate and engage the Senior Project Managers and Divisional Support Officer, taking full responsibility for line management.

9. Effective deployment of human resources, including temporary staff, taking into account budgetary allocation and allowance, to ensure continuity, efficiency, and appropriate support of activity.

General

10. Provide data and summary reports on request to support WCTU trials.

11. Deputize for and support the Head of Operations with other operational activity as appropriate and in accordance with the role.

12. Other duties may be required in consultation with the Head of Operations.

Person Specification

The Person Specification focuses on the knowledge, skills, experience and qualifications required to undertake the role effectively. This is measured by (a) Application Form, (b) Test/Exercise, (c) Interview, (d) Presentation.

Essential Criteria 1
Educated to degree level in a relevant discipline or equivalent experience. (a)

Essential Criteria 2
Extensive experience of managing multicentre clinical trials (including drug trials). (a), (c)

Essential Criteria 3
Experience in the development of operational procedures and processes. (a), (c)

Essential Criteria 4
An extensive staff management track record. (a), (c)

Essential Criteria 5
Committee management experience. (a), (c)

Essential Criteria 6
Established senior project management skills, including the ability to produce high quality outputs to tight deadlines. (a), (c)

Essential Criteria 7
Substantial knowledge and understanding of current developments in clinical trial research and a clear understanding of the policies, regulations and standards to which clinical research must comply. (a), (c), (d)

Essential Criteria 8
Knowledge of UK legislation underpinning recruitment and employment of staff. (a), (c)

Essential Criteria 9
Ability to analyse complex research protocols for operational delivery, governance, cost and risk implications. (a), (c)

Essential Criteria 10
Excellent oral and written communication skills. (a), (c), (d)

Essential Criteria 11
Ability to interpret financial information, monitor budgets and create comprehensive reports. (a), (c)

Essential Criteria 12
Extensive team management skills, including strong leadership, ability to motivate, leading by example with drive and enthusiasm. (a), (c)

Essential Criteria 13
Self-motivated with ability to motivate others. (a), (c)

Essential Criteria 14
Excellent interpersonal skills, including the ability to build relationships with key stakeholders, respect confidentiality and deal with staff in a professional, sensitive and effective manner. (a), (c), (d)

Essential Criteria 15
Good knowledge of IT applications including word processing, spreadsheets, databases, email and internet applications. (a), (c)

Desirable Criteria 1
Project management or clinical research qualification. (a), (c)

Desirable Criteria 2
Experience of making applications to HSCIC, NHS Digital. (a), (c)

Desirable Criteria 3
Research contract negotiation and management experience. (a), (c)

Further Particulars
For further information about the department, please visit the departmental website

For further information about the University of Warwick, please read our University Further Particulars.

Diversity and Inclusion
The University of Warwick provides an inclusive working and learning environment, recognising and respecting every individual's differences. We welcome applications from individuals who identify with any of the protected characteristics defined by the Equality Act 2010.

THE UNIVERSITY OF WARWICK

WCTU Head of Operations
JOB DESCRIPTION

JOB PURPOSE:

To lead the day to day operations of the Warwick Clinical Trials Unit (WCTU)

To manage the framework for operating clinical trials in Warwick Medical School (WMS).

To develop and manage the business model for a self-financing Clinical Trials Unit.

To implement and manage the strategic business plan for WCTU.To be responsible for all aspects of Research Governance and Information Governance within the Clinical Trials Unit, and to provide advice and assistance across Warwick Medical School on regulatory approval for clinical trials of investigational medicinal products and other interventions.

To develop contacts with partner organisations and support Chief Investigators in setting up and running clinical trials that deliver on time, within budget and in accordance with the protocol and relevant regulations.

To implement strategies for continuous quality improvement.

DUTIES AND RESPONSIBILITIES:

1. To lead the day to day operations of the Warwick Clinical Trials Unit (WCTU).

2. To develop a sustainable business plan for the WCTU.

3. To implement and manage the strategic business plan for WCTU. To provide regular reporting and analysis of financial and academic progress to the CTU Directors and Senior Management Team. To participate in strategic developments to improve the performance and ensure sustainability and growth of WCTU.

4. Responsibility for the management of the Clinical Trials Unit including all financial, HR, accommodation and other operational matters.

5. Contributing as a senior member of the Medical School's administrative team to School wide issues and initiatives, this will include attendance at the senior administrative team meetings.

6. To supervise the WCTU Quality Assurance Manager to ensure that Standard Operating Procedures are maintained and updated, staff are trained in a timely and appropriate manner, arrangements are put and kept in place to adhere to GCP and the Research Governance Framework, safety reporting procedures are in place at all times, data is filed according to the data protection act and audits are conducted on selected research within WCTU and the Medical School. WCTU has a legal requirement to comply with the EU Clinical Trials Directive for certain trials. The CTU Manager will work closely with the Quality Assurance Manager to ensure work is conducted to the appropriate standards and that the Unit is prepared for any inspections by the regulatory authorities.

7. To implement and manage Information Governance procedures within the CTU, to include developing and approving the Information Governance Plan, the Service Level Security Plan and

equivalent policies. Responsibility for leading on the management and reporting of information incidents involving WMS CTU members of staff.

8. To ensure that WCTU continues to operate to the highest standards so the UKCRC full registration status is maintained. To be responsible for submissions for on-going registration.

9. Where appropriate to be involved in or lead the submission of funding applications to support the activity of WCTU and WCTU estates

10. Providing advice, training and mentoring to Chief Investigators/teams of investigators/ project teams in clinical trials, research governance, regulatory approval and project management.

11. Provide high level project management input, supervising senior project managers, clinical trial coordinators and recruitment teams to ensure clinical trials are carried out on time, within budget and in accordance with GCP, the protocol and adhering to all regulatory requirements.

12. Co-ordinate applications for funding with Chief Investigators, and ensure that the arrangements and resources and funding proposed will allow the collection of high quality, accurate data and that the systems proposed are those required to allow appropriate data analysis and data protection. Review new grant proposals and protocols for governance, cost and risk implications.

13. Develop, implement and manage a policy for inclusion of consumer representatives.

14. Responsible for the recruitment, retention, training, appraisal and supervision of all administrative staff within WCTU.

15. Overall responsibility for management of trial budgets, department budgets and maintenance of accounts. Undertake regular review of WCTU grant income to identify whether employee's contracts can be extended and staff maintained.

16. Committee servicing, support for monitoring visits, audits and inspections.

17. Oversee the management of the WCTU randomisation service.

18. Oversee the work scheduling of the programming and trial administration teams.

19. Marketing and appropriate promotion of the Clinical Trials Unit, including web-advisory resource and web-site.

20. Instigate and adhere to arrangements for the sponsor, other stakeholder organisations and the CTU to be alerted if significant developments occur as studies progress (e.g. safety, recruitment, personnel issues).

PERSON SPECIFICATION

POST TITLE: **WCTU Head of Operations**

DEPARTMENT: **Warwick Medical School, Clinical Trials Unit**

The Person Specification focuses on the knowledge, skills, experience and qualifications required to undertake the role effectively.

REQUIREMENTS The post holder must be able to demonstrate:	**ESSENTIAL (E) or DESIRABLE (D) REQUIREMENTS**	**MEASURED BY:** a) Application Form b) Test/Exercise c) Interview d) Presentation
Educated to degree level in relevant discipline	E	a)
Established project management skills, including the ability to produce high quality work to tight deadlines	E	a), c)
Substantial knowledge and understanding of current developments in clinical research and a clear understanding of the policies and guidelines to which research must comply	E	a), c)
Quality assurance management experience	E	a), c)
Analytical skills: ability to analyse complex research protocols for governance, cost and risk implications	E	a), c)
Ability to develop policy and service development implementation	E	a), c)
Excellent oral and written communication skills	E	a), c)
Business planning experience and ability to interpret financial information and monitor budgets effectively	E	a), c)
Excellent staff management skills, including the ability to lead by example with drive and enthusiasm.	E	a), c)
Self-motivated with ability to motivate others	E	a), c)
Excellent interpersonal skills, including the ability to build relationships with key stakeholders, respect confidentiality and deal with staff in a professional, sensitive and effective manner	E	a), c)
Good knowledge of standard desktop IT applications including word processing, spreadsheets, databases, email and internet applications	E	a), c)
Post graduate qualification	D	a)
Project management or clinical research qualification	D	a)
Extensive experience of managing multicentre clinical trials including drug trials	D	a), c)
Committee servicing experience	D	c)


THE UNIVERSITY OF
WARWICK

Research Governance and Quality Assurance Manager (71324-105)

Vacancy Type/Job category
Management & Professional

Department
Research & Impact Services (R&IS)

Salary
Grade 7

Location
University of Warwick, Coventry

Vacancy Overview

Research & Impact Services is seeking a Research Governance and Quality Assurance Manager, to provide quality assurance and oversight to the University's research activity.

In this role you will support the Head of Research Governance (Deputy Director of Research & Impact Services), Senior Academics, and the University's Senior Management Team to achieve the necessary standards of research governance and ethics by developing and maintaining robust quality management and oversight systems and procedures.

Excellent communication skills will be essential to ensure awareness of and compliance with current legislation, national guidelines and policies.

Job Description

JOB PURPOSE:

To take a leading role in proactively developing and supporting quality assurance and oversight systems for research ethics and governance processes at the University of Warwick. In doing so, the post holder will help ensure that research at the University is conducted to the highest standards of research governance, in accordance with accepted principles of good ethical practice, current legislation and regulations, and national, international, and professional policies, guidelines, and standards relating to research governance.

DUTIES AND RESPONSIBILITIES:

Quality Assurance:

To develop and implement appropriate policies, systems, and procedures for the oversight and quality assurance of effective research governance in the University, to enable compliance with relevant UK and European Legislation and Regulations, Medicines & Healthcare products Regulatory Agency (MHRA), the Medicines for Human Use (Clinical Trials Regulations 2004 (SI 2004/1031), the Health Research Authority (HRA), and the Research Governance Framework for Health & Social Care 2005 (to be replaced in the future by the UK Policy Framework for Health and Social Care Research), International Conference on Harmonisation guidelines on Good Clinical Practice (ICH-GCP), and the highest standards of research ethics, and the responsibilities of research sponsors.

Monitoring of processes for Quality Assurance within the Clinical Trials Unit (CTU).

Ensuring the appropriate oversight of clinical research not managed by the CTU.

Establishing and maintaining a quality assurance database to aid identification of risk and compliance.

Overseeing the delivery of monitoring/audit programmes to agreed timelines ensuring appropriate corrective and preventative actions are put in place.

Providing input into the development, approval, and management of research governance and ethics Standard Operating Procedures (SOPs), establishing a programme for review of the portfolio of University SOPs and associated templates to ensure compliance with ethical, regulatory and

other frameworks relevant to the conduct of clinical trials, identifying and correcting gaps in processes.

Expertise and advice:

Lead on preparations for inspections by regulatory agencies and/or other audits working with the R&IS senior tem to prepare responses and evaluate corrective actions.

To keep abreast of new legislation, regulation, standards, and best practice relevant to research ethics and governance, ensuring these are brought to the attention of relevant stakeholders, and to contribute to the drafting of new policies, procedures, and guidelines arising from these.

Act as a point of contact and resource to trial personnel to ensure protocols are developed with due consideration to governance requirements, particularly with regard to safety reporting and oversight processes.

Act as a point of contact to R&IS practitioners regarding research ethics and governance for the planning and management of research projects undertaken at the University ensuring at application stage all appropriate governance costs and considerations and insurance cover are included.

To advise and support R&IS senior management on matters relating to research governance, including research ethics and research sponsorship, producing data, management information, and reports on research ethics and governance within the University, on request, for senior officers of the University.

University Research Ethics & Sponsorship Committees:

To develop and manage the research ethical review processes operated by the Committees.

To provide secretarial support to the Committees.

To advise and support the Chairs of Committees on issues relating to research ethics and governance, and research management.

To undertake and manage project work assigned by committee chairs, ensuring key milestones and objectives are identified and met, and appropriate follow-up action is taken.

Research Sponsorship:

To develop and manage the University of Warwick research sponsorship application and review processes.

To develop and maintain processes and systems to support the University in meeting its responsibilities as a research sponsor.

Liaison with representatives of NHS or other co-sponsors to be reassured that co-sponsor responsibilities are fulfilled.

Training:

To plan and deliver research ethics and governance training to academic and administrative staff, and students, across campus.

Miscellaneous:

To contribute to the design and content of informational intranet pages on research ethics and governance in liaison with relevant internal and external stakeholders.

To build and maintain effective working relationships with relevant internal and external stakeholders on matters relating to research ethics and governance, including, but not limited to, the University's Clinical Trials Unit, the University's research governance and ethics committees, University Hospitals of Coventry and Warwick (UHCW) and other Trusts, NHS Research Ethics Committees, and The NIHR Clinical Research Network: West Midlands.
To undertake and manage project work assigned by senior management in R&IS on matters relating to research ethics and governance, e.g. position statements, policy briefings, responses to public consultations, and initial enquiries into potential research misconduct.

PERSON SPECIFICATION:

The Person Specification focuses on the knowledge, skills, experience and qualifications required to undertake the role effectively. This is measured by (a) Application Form, (b) Test/Exercise, (c) Interview, (d) Presentation.

Essential Criteria 1
A good honours degree or equivalent (a)

Essential Criteria 2
Substantial experience working in research or quality assurance environment (a) (c)

Essential Criteria 3
Experience of successfully managing project work that has wide organisational impact (a), (c)

Essential Criteria 4
Experience of policy and procedure development (a), (c)

Essential Criteria 5
Experience delivering training in a variety of formats (web-based, group, individual) (a), (c)

Essential Criteria 6
Advanced organisational and planning skills, including ability to take the initiative and to work accurately and to tight deadlines under limited supervision (a), (c)

Essential Criteria 7
Understanding of of research ethics and governance and/or quality assurance frameworks and related legislation.

Essential Criteria 8
The ability to absorb, explain, and present complex and detailed guidelines, legal requirements, and regulations (a), (b), (c)

Essential Criteria 9
Ability to work in a team and manage workload effectively (a), (c)

Essential Criteria 10
Developed IT skills and the ability to use a broad range of computerised systems and data sources to support improved communications, information and data dissemination, and project management relating to research ethics and governance and/or quality assurance (a), (c)

Desirable Criteria 1
Higher qualification (or equivalent)

Desirable Criteria 2
Experience of preparing for and responding to regulatory and/or quality inspections (a), (c)

Desirable Criteria 3
Familiarity with funding bids and associated procedures (a), (c)

Recruitment of Ex-Offenders Policy
As an organisation using the (DBS) Disclosure and Barring Service to assess applicants' suitability for positions of trust, the University of Warwick complies with the DBS Code of Practice and undertakes not to discriminate unfairly against any subject of a Disclosure on the basis of a conviction or other information revealed. More information is available on the University's Vacancy pages and applicants may request a copy of the DBS Code of Practice.