Royal Devon University Healthcare NHS Foundation Trust

JOB DESCRIPTION

JOB DETAILS	
Job Title	Lead EH&IBD Tissue Bank Officer
Reports to	Exeter IBD Group Manager
Band	6 – Subject to the formal conclusion of matching
Department/Directorate	NIHR Exeter Clinical Research Facility, Research & Development

JOB PURPOSE

The Lead EH&IBD Tissue Bank Officer will be responsible for co-ordinating and managing the delivery of studies associated with the portfolio of gastroenterology and hepatology Tissue Bank and assisting with the day to day management of the Royal Devon Tissue Bank. This will include oversight of the work undertaken by staff working on the EH&IBD portfolio under the remit of the Royal Devon Tissue Bank.

The post holder will provide specialist knowledge, skills and experience within clinical research and act as a resource to advise and support those involved in clinical research at all levels working under the auspices of the Royal Devon Tissue Bank. The post-holder will be able to autonomously plan, implement, organise and manage concurrent research projects. They will develop networks with Multidisciplinary Teams across the Trust and other appropriate local and national agencies. They will provide leadership and drive to manage the Research Tissue Bank EH&IBD study portfolio and deliver recruitment accrual in line with performance and monitoring objectives.

KEY RESULT AREAS/PRINCIPAL DUTIES AND RESPONSIBILITIES

- The post holder will be responsible for the implementation and monitoring of the clinical requirements associated with delivery the studies under the remit of the tissue bank.
- Will ensure that research/studies will be conducted in accordance with the UK Policy framework for health and social care research, Good Clinical Practice guidelines and UK GDPR principles to provide assurance that the rights, safety and well-being of research participants and their data are protected.
- To supervise, lead, inform and delegate staff as appropriate to the needs of the tissue bank by utilising management skills and resources effectively.
- Ensure that all studies are reviewed and approved by the Royal Devon Tissue Bank steering committee and Royal Devon R&D.
- All research procedures are conducted according to study protocols and adhere to the requirements of the Royal Devon Tissue Bank.
- Be accountable for the recruitment, data collection and care of research participants with a focus on providing a quality experience
- Be the main point of contact, and use their specialist knowledge to advise PI's /Clinicians
- Manage all aspects of delivering the studies/collections from developing protocols through to long term storage/archiving.
- Manage the sample management/records systems to ensure all processes and samples are auditable.
- Line manage junior staff members and provide training as necessary.

KEY WORKING RELATIONSHIPS

Areas of Responsibility: CRF, RDUH outpatients, gastroenterology and hepatology clinics, surgery.

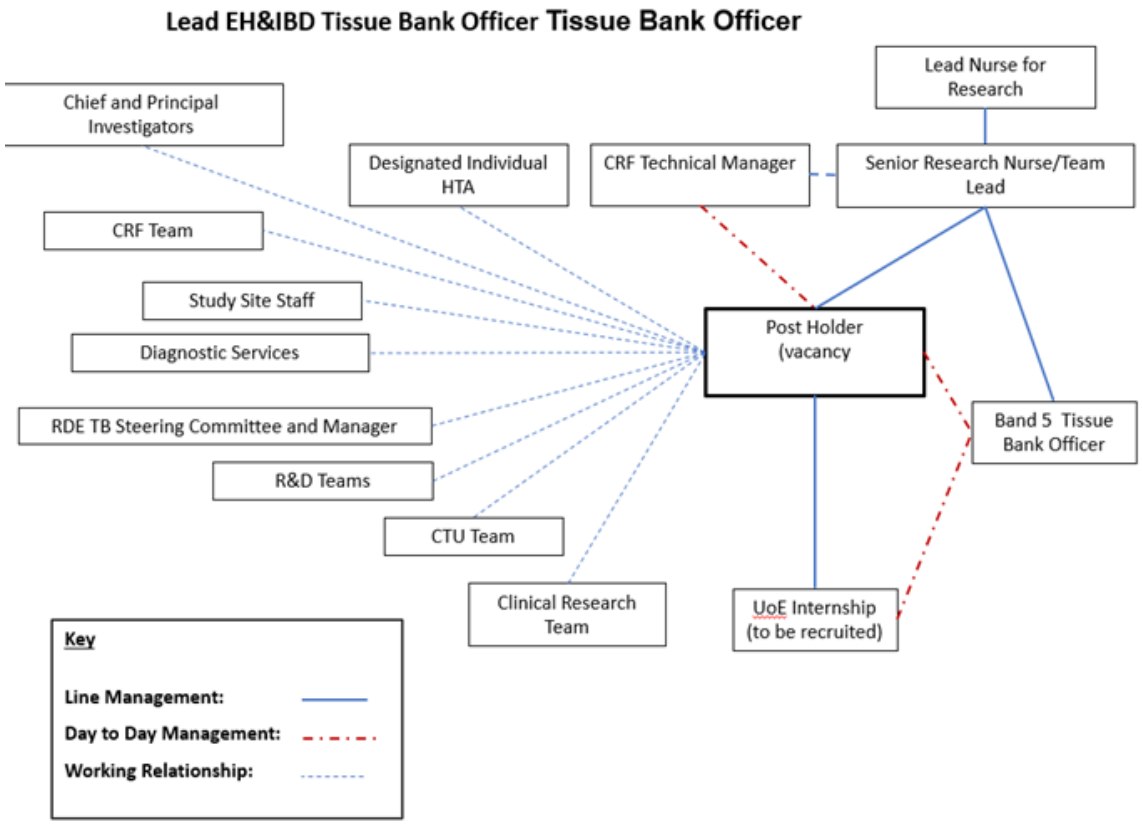
No. of Staff reporting to this role: TBA

The post holder is required to deal effectively with staff of all levels throughout the Trust as and when they encounter on a day to day basis. In addition the post holder will deal with the wider healthcare community, external organisations and the public. This will include verbal, written and electronic media.

Of particular importance are working relationships with:

Internal to the Trust	External to the Trust
• Principal Investigators/research teams • NIHR CRF Senior Management • NIHR CRF Team members • Trust Multidisciplinary team (Gastroenterology and Hepatology) • Clinical Histopathologists • RDUH Research and Development Team • Designated Individual (HTA) for the site • Diagnostic Services	• Research Ethics Committees • Study Funders • Commercial partners • Study Sponsors • University of Exeter

ORGANISATIONAL CHART



FREEDOM TO ACT

- The post holder will be expected to have enough experience to work autonomously.
- Provide effective advice to study teams on study related matters including data queries, organisation of source documents and site files, monitoring procedures and schedules.
- Monitoring and reporting recruitment of participants into the study, identifying barriers and implementing strategies to improve recruitment.
- Provide guidance to colleagues experiencing problems with recruitment.
- Take lead role in developing, implementing and maintaining digital systems to ensure that the above key responsibilities and research needs are met.

- Play a role in the monitoring, development and implementation of CRF and study- specific Standard Operating Procedures to ensure that they are fit for purpose and accurately detail procedures for study processes.
- Resolve clinical, logistical and operational problems pertaining to the delivery of studies in own portfolio.
- Act as an expert resource and provide complex advice regarding study set up, recruitment planning and study delivery.

COMMUNICATION/RELATIONSHIP SKILLS

- Providing complex and sensitive information on research studies and the justification for collecting samples and tissue. Offering assurance, high knowledge around the scientific techniques. Motivating and persuading patients and staff to participate in research and overcome barriers to understanding. Will need to be tactful and use language to actively encourage and give patients confidence to participate in the research.
- Providing training on the research protocols, these can sometimes be complex and contentious, e.g. additional biopsies, genetic information.
- Presenting complex information to staff, general public and panel members around the work and outcomes of the tissue bank studies.
- Ensure that when communicating with patients and staff that language/information is transparent and clear.
- Some parts of the research will involve invasive techniques and will need to show empathy and sensitivity when receiving information from patients.
- Proactively seek feedback from participants and their families during their research involvement on the standard of information and care that they have received including participating in the clinical trials patient feedback survey.

ANALYTICAL/JUDGEMENTAL SKILLS

- Assist Clinicians with tissue bank applications, utilising their expertise, to ensure that these applications fulfil the remit of the tissue bank ethics
- Clinical knowledge within a relevant sphere of practice is required to enable screening against specified complex inclusion/exclusion criteria for participant recruitment.
- Provide guidance and clinical expertise on the study protocol and other essential documentation through the development of specialist, in-depth knowledge of experimental medicine studies and clinical trials.
- Ensure study data is complete, accurate and up to date for analysis according to agreed deadlines.
- Work with the lead clinician and senior research team lead to develop and review complex clinical trial protocols and to develop a balanced portfolio of studies for each speciality that the post holder works across.
- Assist and/or lead in regular monitoring of participant recruitment, review or participant recruitment figures and managing problems with participant recruitment.
- Identify relevant material as defined by the Human Tissue Act and escalate queries as required to the Human Tissue Authority Designated Individual for site.
- Review and assess study protocols, consider all potential research in terms of capacity and capability and viable recruitment period.
- Identify and work with the Senior Manager/s to resolve resource implications in delivering and facilitating clinical research.
- Assess and evaluate the progress of on-going clinical research for which the post holder has responsibility, maintaining accurate records of the status of studies and providing regular updates to the department on the status of the studies. This will involve ensuring that CRF Manager® and EDGE (Local Patient Management System) are updated with key trial data and validated efficiently.

PLANNING/ORGANISATIONAL SKILLS

- Responsible for the operational delivery of the Royal Devon EH&IBD Tissue Bank Research Portfolio.
- Manage research performance within the relevant specialty in relation to team activities and study timelines.

- Collaborate with other Trusts and organisations within the region to improve research delivery.
- Keep up to date with research management issues through liaison with other Research Specialists /Team leaders/University researchers and link with national networks.
- Work with the HTA Designated Individual for the site and ensure tissue bank samples are stored under conditions that comply with the Human Tissue Act.
- Balance the needs and demands of clinical and managerial pressure and deadlines.
- Monitor and plan in advance the research workload within the team and manage team performance. Ensure that study complexity and intensity is considered when delegating roles within the team.
- Ensure all studies are operating according to UK GDPR principles.
- Lead in maintaining effective communication within the research team and between the multidisciplinary clinical team.
- Promote a just and learning culture in reporting incidents and where appropriate support local investigation of incidents.

PATIENT/CLIENT CARE

- Take a leading role in the clinical care of research participants within sphere of competence and provide relevant health promotion and education.
- Use relevant clinical knowledge to screen and identify patients for clinical research using inclusion and exclusion criteria and utilising NHS records, screening clinics, visiting wards and outpatients and using Trust IT systems and databases.
- Act as a specialist resource and role model for all aspects of Research Clinical Practice in order to optimise patient care and clinical practice this may include carrying out physical assessments, conducting sample retrieval and processing, providing or coordinating interventions and treatments, clinical monitoring.
- Undertake all mandatory training and ensure that the clinical workforce is up to date with mandatory training.
- Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- Demonstrate professional development and an in-depth knowledge of current clinical and research practice.
- Provide on-going specialised advice and information to patients/research participants and their carers/families with regard to their participation in clinical research in order to facilitate effective informed consent.
- Where appropriate receive and document written informed consent from research subjects, for their participation in research studies and support other members of the team with best practice.
- Be responsible for the safe and accurate collection of research data through clinical procedures where appropriately trained to do so, such as venepuncture, biopsy, history taking, standard observations (height, weight, BP, RR, HR, SpO2, temperature) and other assessments such as ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the study protocol
- Centrifuge, process, store, track and ship samples in line with study protocol requirements.
- Ensure accurate patient/research participant documentation including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes in a timely manner.
- Refer to other specialists as required in order to provide optimal care of the participant, if required.
- Monitor clinical standards within the research team and escalate any persistent
- issues to the clinical team.
  Work within the relevant professional code of conduct, demonstrating accountability for own actions and awareness of own limitations.
- Provide cover for other Research Practitioners as required, within sphere of competency.
- Proactively seek feedback from participants and their families during their research involvement on the standard of information and care that they have received including participating in the clinical trials patient feedback survey.
- Coordinate and run study visits including off site whilst adhering to the lone worker policy.

POLICY/SERVICE DEVELOPMENT

- Contribute to the development and implementation of clinical and research, policies, procedures and SOPs.
- To act in accordance with local policies and procedures laid down by the Royal Devon University Healthcare NHS Foundation Trust.
- Undertake training as required for the post, at the discretion of line manager and management team.
- Responsible for maintaining a professional profile.
- Responsible for maintaining a training log.
- Maintain a suitable work environment when working remotely. Escalate any challenges with remote working to line manager in a timely manner.
- Appraise research findings that inform and influence practice, policy and service provision and demonstrate the ability to make research judgments based on this appraisal.

FINANCIAL/PHYSICAL RESOURCES

- Have an awareness of the income stream relevant to clinical research and work within local and Trust wide financial and budgetary guidelines.
- Ensure accurate costings for clinical research activity during study set up. Utilise planning tools such as the intensity toolkit.
- Identify resource implications for individual studies and the portfolio of studies within the specialty.
- Ensure participant expenses/payments are made in a timely manner and according to the study's budget
- Ensure research equipment is maintained in an effective working and good clinical order.
- Work with the Nurse Manager/s and research team to ensure accurate costing for clinical research and appropriate negotiation of required financial support to deliver clinical research.

HUMAN RESOURCES

- Lead the recruitment of new junior personnel and ensure that an appropriate and safe skill mix is maintained. Work with the Manager/s to promote retention of staff.
- Identify and resolve study performance issues, escalating on-going issues to the Manager/s where required.
- Act as line manager for junior members of the research staff as applicable
- Ensure all staff within sphere of responsibility have access to essential training and achieve 100% compliance.
- Be responsible for the deployment of HR policies including proactively managing sickness and performance in line with the Trust policy.
- Ensure the health, safety and security of the clinical research team within sphere of responsibility.
- Assist in the recruitment of Royal Devon Tissue Bank staff.
- Assist with the training and development of junior staff members to ensure retention of staff and workforce development where possible.
- Contribute to the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.

INFORMATION RESOURCES

- Work flexibly – hours and locations – to support the needs of your portfolio of studies.
- Manage own time to best effect across locations minimising the impact of cross- site, multi-location and remote working on service delivery.
- Arrange and carry out meetings using available IT resources – Skype, Zoom, MS teams etc. to support flexible, remote and cross-site working.

RESEARCH AND DEVELOPMENT

- Take a leading role in the delivery of clinical research and ensure a balanced portfolio of experimental medicine, academic and commercial studies utilizing the Research Tissue Bank.

- Ensure that the delivery of studies meet requirements with regards to the Department of Health's UK policy framework for Health and Social Care Research and the EU Clinical Trials Directive by implementing quality systems.
- Ensure that staff participate in Good Clinical Practice (GCP) training.
- Contribute to the Expression of Interest / Study Selection process for the ROYAL DEVON Tissue Bank.
- Attend biannual HTA site meetings and participate in required audit schedule (internal and external).
- Be responsible for promoting and overseeing the appropriate referral and recruitment of patients to clinical research studies. Work with investigators and support the clinical research team to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- Work with other departments within the Trust to ensure that research specific investigations and procedures are undertaken as required by the trial protocol, in order to establish eligibility and safety of patients within clinical research.
- Ensure clear, accurate and concise records are kept for research projects in accordance with all regulatory requirements including the Data Protection Act.
- Ensure that data is transcribed accurately where required and maintain the Trial Master Files for the EH &IBD portfolio in the Research Tissue Bank and affiliated studies.
- Respond to data queries generated by the study coordinating team within a timely manner.
- Ensure the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the clinical research to the trial co- coordinator/Principal Investigator (PI) and R&D office in line with the study protocol, local policies and regulatory requirements.
- Promote collaborative working with other clinical researchers within the CRN and NIHR structure.
- Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- Assist in study close down and the preparation of results of research for presentation as posters, abstracts, papers or scientific presentations.

PHYSICAL SKILLS

- The role requires substantial IT based administrative work with computer-based activities.
- Occasionally travel to other sites/locations when required.

PHYSICAL EFFORT

- Frequent requirement to exert moderate physical effort. This may include lifting dry ice, moving shipments and carrying large tissue samples, from surgery to histopathology. Research offices are not necessarily based where patients are seen or recruited and the research team members are required to work across all sites of the RDUH.

MENTAL EFFORT

- The post holder will be expected to manage all aspects of the EH&IBD,
- There is a frequent requirement for prolonged concentration
- To ensure the delivery the studies and collections to a high standard as required by the HTA and regulators.
- Be aware of risks in the work environment and their potential impact on own work and that of others.

EMOTIONAL EFFORT

- The post will be consenting patients who have agreed to participate /donate samples, there will be occasional exposure to distressing or emotional circumstances

WORKING CONDITIONS

- The post holder will be collecting blood and other biological samples, as well as biopsies. The samples will need to be processed according to the protocols.

OTHER RESPONSIBILITIES

Take part in regular performance appraisal.

Undertake any training required in order to maintain competency including mandatory training, e.g. Manual Handling

Contribute to and work within a safe working environment

You are expected to comply with Trust Infection Control Policies and conduct him/herself at all times in such a manner as to minimise the risk of healthcare associated infection

As an employee of the Trust, it is a contractual duty that you abide by any relevant code of professional conduct and/or practice applicable to you. A breach of this requirement may result in action being taken against you (in accordance with the Trust's disciplinary policy) up to and including dismissal.

You must also take responsibility for your workplace health and wellbeing:

- When required, gain support from Occupational Health, Human Resources or other sources.
- Familiarise yourself with the health and wellbeing support available from policies and/or Occupational Health.
- Follow the Trust's health and wellbeing vision of healthy body, healthy mind, healthy you.
- Undertake a Display Screen Equipment assessment (DES) if appropriate to role.

APPLICABLE TO MANAGERS ONLY

Leading the team effectively and supporting their wellbeing by:

- Championing health and wellbeing.
- Encouraging and support staff engagement in delivery of the service.
- Encouraging staff to comment on development and delivery of the service.
- Ensuring during 1:1's / supervision with employees you always check how they are.

DISCLOSURE AND BARRING SERVICE CHECKS

This post has been identified as involving access to vulnerable adults and/or children and in line with Trust policy successful applicants will be required to undertake a Disclosure & Barring Service Disclosure Check.

GENERAL

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you.

Everyone within the Trust has a responsibility for, and is committed to, safeguarding and promoting the welfare of vulnerable adults, children and young people and for ensuring that they are protected from harm, ensuring that the Trusts Child Protection and Safeguarding Adult policies and procedures are promoted and adhered to by all members of staff.

PERSON SPECIFICATION

Job Title	Lead EH&IBD Tissue Bank Officer

Requirements	Essential	Desirable
QUALIFICATION/ SPECIAL TRAINING		
Relevant healthcare or biomedical sciences degree	✓	
Research training (e.g. GCP, degree module, informed consent)	✓	✓
Management or leadership qualification		✓
Completed MRC Research & Human Tissue e-learning course or equivalent		
KNOWLEDGE/SKILLS		
Knowledge of the UK Policy Framework for Health and social Care	✓	
Good working knowledge of Good Clinical Practice	✓	
Working knowledge of the Human tissue Act	✓	
In-depth knowledge of clinical research and research methods	✓	
In-depth knowledge of data collection & data entry for clinical research and data protection.	✓	
Pertinent clinical skills including venepuncture IT skills including ability to work with databases	✓	
Ability to organise and prioritise own workload and to work to tight deadlines	✓	
Ability to make independent decisions Critical appraisal skills	✓	
Good leadership skills and proven managerial ability.		✓
EXPERIENCE		
Experience of clinical research within the NHS setting Proven record of meeting participant recruitment targets	✓	
Line management experience within the NHS		✓
Experience of delivering commercial and academic research	✓	
Experience with EPIC electronic patient records	✓	
Experience with Redcap	✓	
Experience of working under the Human Tissue Act	✓	
PERSONAL ATTRIBUTES		
Ability to work autonomously	✓	
High level of interpersonal and communication skills Flexible and adaptable	✓	
Willingness to learn, instigate and develop efficient working systems	✓	
Ability to work cohesively as a member of a team	✓	
Willingness to undertake any necessary training & development to enhance work performance	✓	
Commitment to openness, honesty and integrity in undertaking the role	✓	
Willingness and ability to work across sites including the community	✓	
Hold a drivers license / willing to travel as required		✓
OTHER REQUIREMENTS		
The post holder must demonstrate a positive commitment to uphold diversity and equality policies approved by the Trust.		
Ability to travel to other locations as required.		

WORKING CONDITIONS/HAZARDS		FREQUENCY (Rare/ Occasional/ Moderate/ Frequent) R	O	M	F
Hazards/ Risks requiring Immunisation Screening					
Laboratory specimens	Y				X
Contact with patients	Y				
Exposure Prone Procedures	Y				X
Blood/body fluids	Y				X
Hazard/Risks requiring Respiratory Health Surveillance					
Solvents (e.g. toluene, xylene, white spirit, acetone, formaldehyde and ethyl acetate)	Y			X	
Respiratory sensitisers (e.g isocyanates)	N				
Chlorine based cleaning solutions (e.g. Chlorclean, Actichlor, Tristel)	Y		X		
Animals	N				
Cytotoxic drugs	Y	X			
Risks requiring Other Health Surveillance					
Radiation (>6mSv)	N				
Laser (Class 3R, 3B, 4)	N				
Dusty environment (>4mg/m3)	N				
Noise (over 80dBA)	N				
Hand held vibration tools (=>2.5 m/s2)	N				
Other General Hazards/ Risks					
VDU use (> 1 hour daily)	Y				X
Heavy manual handling (>10kg)	N				
Driving	Y		X		
Food handling	Y	X			
Night working	Y	X			
Electrical work	N				
Physical Effort	Y		X		
Mental Effort	Y				X
Emotional Effort	Y			X	
Working in isolation	Y	X			
Challenging behaviour	Y		X		