Biological Specimen Coordinator

Candidate Information

The Institute of Cancer Research

About our organisation

We are one of the world's most influential cancer research institutes with an outstanding record of achievement dating back more than 100 years. We are world leaders in identifying cancer genes, discovering cancer drugs and developing precision radiotherapy. Together with our hospital partner The Royal Marsden, we are rated in the top four centres for cancer research and treatment worldwide.

As well as being a world-class institute, we are a college of the University of London. We came top in the league table of university research quality compiled from the Research Excellence Framework (REF 2014).

We have charitable status and rely on support from partner organisations, charities, donors and the general public.

We have more than 1000 staff and postgraduate students across three sites – in Chelsea and Sutton.

Drug Development Unit

The Drug Development, within the Institute of Cancer Research and the Royal Marsden, is one of the leading Phase-1 Clinical Trials Unit in the world. The Unit, led by Professor Johann de Bono, comprises of Clinicians, Research Nurses, Scientists and administrative support staff.

The main aim of the Unit is to fast track the development of anti-cancer drugs, designed and synthesised in ICR or developed by CRUK or developed by industry collaborators, to maximise their potential towards the care of cancer patients. The Unit operates as a conduit, between laboratory research and clinical research that is fundamental to the modern drug development process.

Our mission is to make the discoveries that defeat cancer.

Biological Specimen Coordinator
Candidate Information

Our values

The ICR has a highly skilled and committed workforce, with a wide variety of roles, each requiring different skills. But whether you work as a researcher, or work as part of our corporate team, your work and behaviour is underpinned by these six values. They are what bring us together as one team - as 'One ICR'.

Pursuing excellence

We aspire to excellence in everything we do, and aim to be leaders in our field.

Acting with Integrity

We promote an open and honest environment that gives credit and acknowledges mistakes, so that our actions stand up to scrutiny.

Valuing all our people

We value the contribution of all our people, help them reach their full potential, and treat everyone with kindness and respect.

Working together

We collaborate with colleagues and partners to bring together different skills, resources and perspectives.

Leading innovation

We do things differently in ways that no one else has done before, and share the expertise and learning we gain.

Making a difference

We all play our part, doing a little bit more, a little bit better, to help improve the lives of people with cancer.

"Our values set out how each of us at the ICR, works together to meet our mission – to make the discoveries that defeat cancer. *They summarise our desired behaviours, attitudes and culture – how we value one another and how we take pride in the work we do, to deliver impact for people with cancer and their loved ones"*

Professor Kristian Helin
Chief Executive

Biological Specimen Coordinator
Candidate Information

Job description

Department / division:	Drug Development Unit / Clinical Studies
Pay grade / staff group:	Research Management 1
Hours / duration:	Full time (35 hours per week) Monday to Friday Fixed term contract for 1 year
Reports to:	Lead Study Manager
Accountable to:	Biomarker Lab Manager and Head of Operations
Main purpose of the job:	The post holder will be responsible for collecting, cataloguing and shipping clinical trial samples (Fresh and Archival tumour and blood specimens). The post holder will interact and coordinate with clinical trials' team in DDU, RM and translational research labs within the ICR and ensure trial samples are appropriately collected and sent for analysis. The post holder will be responsible for all administrative tasks associated with tissue management for clinical trials conducted in DDU. The post will be responsible for supporting the development, implementation maintaining tracking systems for all tissue samples coming through the unit and will ensure all procedures meet with Human Tissue Act (HTA) requirements and Good Clinical Practice UK Regulations for hosted commercial/academic studies as well as all tissue retrieved for central review from all participating centres in the UK and globally for studies running through the Drug Development.

Duties and responsibilities:

Biological Specimen Coordinator
Candidate Information

Key Duties

The Biological Specimen Coordinator will be required to liaise with internal and external contacts: these will include patients, researchers, clinical trial sponsors and academic organizations

- Working independently on a daily basis but as an integral part of an extremely busy research department and being responsible supervision and collection of patient samples for ongoing studies
- Obtaining informed consent from patients for non-interventional studies, where applicable
- Requesting and receiving archival tumour tissues from various centres;
- Attending clinical procedure areas in RM (Sutton and Chelsea) to collect fresh biopsy tissues
- Maintaining an adequate supply of kits and consumables on site for all clinical trials and inventory management
- Co-ordinating the shipment of tumour tissue samples to various centres, and completing the paperwork
- Management of all stored samples, management of the data associated with the collected material and other archival samples
- Addressing any queries associated with tissue collection and resolving the queries by coordinating with relevant staff groups.
- Communicating of study results to clinicians and other relevant members of staff (e.g. Trial Coordinators) in the Drug Development Unit and in meetings.
- Maintain Investigator Trial Files (ITF) and all documents related to the molecular characterisation study.
- Assist with data entry and data transcription activities for drug studies where appropriate.

Specimen Coordination

- Collect, collate and maintain appropriately completed informed consent forms from patients for non-interventional studies
- Ensure the timely and efficient collection of tissues and biological fluid samples, by coordinating with clinical and lab teams
- Attend biopsy procedures to facilitate the collection of biological samples from the Royal Marsden Hospital sites in Sutton and/or Chelsea
- Retrieve and return tissues for trial participants from external hospitals / Biobank facilities
- Log in samples as they arrive on Progeny and distribute them to research groups, laboratories, commercial and academic sponsors.
- Ensure consumable are available for samples to be packed, labelled and handled appropriately

Biological Specimen Coordinator
Candidate Information

- Ensure the dispatch and retrieval of samples ambient or frozen (using dry ice) as requested via external courier services;
- Retrieve samples nationally and internationally and coordinate the receipt of these samples in a timely fashion to meet research study time points for central, interim and final analysis, as well as treatment decisions and diagnostic purposes.
- Liaise with the laboratory teams to receive all the results from molecular analysis and file these documents appropriately.
- Liaise with clinical trial study teams and lab teams to ensure all trial specific tissue management documents are maintained and laboratory scientists are supported in carrying out administrative tasks.
- Ensure up to date inventory for tissue processing kits, liaise with Study Managers to maintain re-supply of kits.
- Liaise with lab teams and study managers for timely completion of trial specific paper work and support he shipment of these samples.
- Attend SIVs and maintain record of trial documents for research labs.
- Maintain and accurate list of trials and trial status for research labs; support submission of regular reports for GCP teams.
- Communicate study results to clinicians and other relevant members of staff (e.g. Trial Coordinators) in the Drug Development Unit.
- To aid in the development, maintenance and review of working documents (e.g. Laboratory Manuals) following protocol amendments
- Attend various weekly team meetings with the Study Management Team and Site Initiation Visits on behalf of the CB Histopathology Group and disseminate relevant information to the CB teams
- Maintain all study documentation and ITFs.

Biological Specimen Coordinator
Candidate Information

Service Maintenance and Improvement

- The post holder will work with Study Managers and Lead Study Managers to support development/implementation of new practices and also support changes to improve the service.
- The Drug Development Unit has an expanding translational research programme including a large number of ICR/RM sponsored multicentre trials. The post holder will be central in coordinating study specific and unit processes/procedures to ensure all samples are retrieved, tracked, stored and managed appropriately for central review carried out within the RM/ICR.
- The post holder will work with Lead Study Manager for identifying areas for improvement and implementation of improved methods/process for the team to adhere to.
- The post holder will prepare, participate and support internal and/or external regulatory audits and statutory inspections

Communication

Communication is instrumental to the effective collection, storage and use of samples.

- Be responsible for ensuring the correct consent procedure is followed for assigned studies and ensure compliance is met. Post holder is responsible to work with study teams and ensure corrective and preventative actions are put in place, in a timely manner.
- Retrieve appropriate clinical data relating to collected samples.
- Liaise with outpatient and theatre personnel in order to ensure an efficient and effective sample collection service.
- Communicate with staff in the Histopathology Cancer Biomarkers and Molecular Pathology Laboratories of the RM and the ICR.
- Ensure efficient and effective links with other sites to facilitate the transporting of samples to and from and between the RM/ICR.
- Contact referral centres and liaise with staff based at other clinical centres from where tissue is retrieved and returned to request or return archival material.
- Liaise with staff in the Drug Development including clinicians (consultants, research fellows and registrars), research nurses, trial coordinators, data managers, GCP compliance manager and other Biological Specimens Coordinators.

Biological Specimen Coordinator
Candidate Information

Governance Responsibilities

Accurate information needs to be collected to demonstrate the movement of each sample through different departments/laboratories within the RMH/ICR as well as movement in and out of the RM/ICR with outside organizations.

- Implement and maintain study specific sample tracking databases in order to continually track and identify samples from retrieval into the RM/ICR, from department to department until dispatch off site.
- Use databases to allocate unique identifiers and storage locations of samples.
- Enter clinical data onto a secure database and maintain accurate compliance to study protocols
- Retrieve anonymised clinical data to accompany samples when removed from storage.
- Assist with the preparation of reports detailing sample collection, storage and use.
- Comply with ICR/RM Information Governance policies
- Undertake GCP, Human Tissue Act and IATA Training and maintain compliance to these regulatory standards
- Observe and comply with the ICR & RM policies and procedures for Health and Safety ensuring the environment in which you and your staff work is safe, clean and tidy.
- Comply with standard infection control precautions to prevent or minimise the spread of micro-organisms and communicable diseases to patients, staff and surrounding community.
- Observe and continually promote equal opportunities in compliance with the Trust's policies on Equality and Diversity and Dignity at Work.
- Ensure the benefits to patients are maximised through careful, economical and appropriate use of NHS resources including equipment, property, money, time, etc.

General

- To communicate effectively with other members of the team and the centre.
- To attend routine Study Manager Meetings regularly, including chairing the meeting and minute taking on a rota basis.
- To provide a troubleshooting/problem solving approach to ensure specimen coordination issues are resolved effectively.
- To play a full and supportive role in contributing to and maintaining a cohesive study site coordination function within the unit, contributing to best practice within the team.
- To represent and promote the DDU at external meetings/conferences and present information as required.

Biological Specimen Coordinator
Candidate Information

- To develop extensive knowledge of, and comply at all times with the EU and UK Legislation for clinical trial conduct, RM Trust Level SOPs and local DDU procedures.
- To assist with the preparation of research papers as requested, and/or the collection of data required for publication/presentation of materials.
- To work in a flexible manner and be organised to ensure timely completion of objectives by the agreed deadlines.
- Prepared to perform other duties as required, which are consistent with the grade of the post.
- To adhere to the regulatory rules and safety regulations of the Institute of Cancer Research and Royal Marsden NHS Foundation Trust.

Confidentiality

All information concerning patients and staff must be held in the strictest confidence and may not be divulged to any unauthorised person at any time, unless to do so is in the best interest of the individual. In this instance a Senior Team Member would appropriately advise the post holder.

Computer data should only be accessed if this has been authorised and is necessary as part of your work.

The post holder must abide by the requirements of the Data Protection Act at all times.

Post holder may undertake any other work in line with the pay grade and as required for the team

This job description is a reflection of the present position and is subject to review and alteration in detail and emphasis in the light of future changes or development.

Biological Specimen Coordinator

Candidate Information

Person specification

Education and Knowledge

BSc or equivalent degree in Biomedical Science	Essential

Experience

Experience with range of laboratory molecularly biology techniques	Desirable
Knowledge of FFPE samples and circulating plasma DNA	Desirable
Experience handling clinical samples	Desirable
Experience with a Laboratory Information Management System (LIMS) for e.g. Progeny	Desirable
Experience of working in a clinical trial centre	Desirable
Contact with patients suffering from terminal disease	Desirable

Skills

Practical skills in molecular biology techniques	Desirable
Computing skills	Essential
Knowledge of genomic databases	Desirable
Demonstrable skills for proficient evaluation, as well as documentation and presentation of research and clinical data	Essential
Ability to work independently and as part of a team	Essential
Ability to organise and prioritise work to meet deadline	Essential
Excellent problem solving skills with the ability to troubleshoot in specialist area	Essential
Enthusiasm to work in an interdisciplinary environment towards the goal of developing improved cancer therapies	Essential

Biological Specimen Coordinator
Candidate Information

Person specification

General

Interest in early phase drug development processes and cancer research	Essential
Excellent interpersonal skills to engender successful working relationships and communication with colleagues and trial collaborators	Essential
Excellent organisational skills and time management skills, able to meet competing deadlines	Essential
Effective oral and written communication skills, with the ability to communicate complex information to a range of audiences	Essential
The desire to develop his/her skills further for the benefit of the Drug Development Unit and Cancer Biomarkers teams	Essential
Able to work flexible hours in order to facilitate the collection of biological samples from the Royal Marsden Hospital sites in Sutton and Chelsea	Essential

Biological Specimen Coordinator
Candidate Information

Benefits

We offer a fantastic working environment, great opportunities for career development and the chance to make a real difference to defeat cancer. We aim to recruit and develop the best – the most outstanding scientists and clinicians, and the most talented professional and administrative staff.

The annual leave entitlement for full time employees is 28 days per annum on joining. This will increase by a further day after 2 years' and 5 years' service.

Staff membership to the Universities Superannuation Scheme (USS) is available. The USS is a defined benefit scheme and provides a highly competitive pension scheme with robust benefits. The rate of contributions is determined by USS and details of the costs and benefits of this scheme can be found on their website. If staff are transferring from the NHS, they can opt to remain members of the NHS Pension Scheme.

We offer a range of family friendly benefits such as flexible working, a parents' group, and a maternity mentoring scheme. Other great benefits include interest free loans for discounted season tickets for travel and bicycle purchases, access to the NHS discounts website, a free and confidential Employee Assistance Programme which offers a range of well-being, financial and legal advice services, two staff restaurants, and access to a gym and sporting facilities at our Sutton site.

Further information

If you require further information, you may contact Lydia Turner by emailing ddu@icr.ac.uk .

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