Birmingham and Solihull Pathology Services

Musculoskeletal Laboratory

Laboratory Manual

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Personnel & Training Requirements:	• To be used by: • Service Users

CONTENTS

1. Introduction and Service Provided

The Department of Musculoskeletal Pathology, University Hospitals Birmingham NHSFT is located in premises at the University of Birmingham and is located in the Robert Aitken Building. The Department was established in June 1997 in response to demands for a more dedicated Histopathology Service than had previously been provided to the Royal Orthopaedic Hospital NHS Foundation Trust and in particular the Birmingham Orthopaedic Oncology Service.

The Birmingham Orthopaedic Oncology Service is one of the five national supra-regional bone tumour treatment centres and treats approximately 40% of the United Kingdom's primary malignant bone tumours. It is one of the largest bone tumour services in the world. As such, the pathological material is a rare and valuable resource of international interest.

The Department provides a diagnostic histology service including a frozen section service to The Royal Orthopaedic Hospital NHSFT. Within the histology service there are tinctorial, immunohistochemical & reverse-transcriptase polymerase chain reaction techniques applied by the staff to aid the diagnoses of the rare tumours seen at The Royal Orthopaedic Hospital NHS Foundation Trust. The sequencing of PCR products is carried out by The Functional Genomics, Proteomics and Metabolomics Facility, University of Birmingham. The Department supports other external laboratories and hospitals with specialist histopathology and opinions together with some external requests for more routine histopathology processing and reporting.

2. Quality Management

The Department of Musculoskeletal Pathology is subject to external accreditation by UKAS to ISO 15189:2012.

The Department of Musculoskeletal Pathology runs a comprehensive quality management system and participates in a number of relevant UK National Quality Assessment Schemes.

The Department is also recognised for training by the Royal College of Pathologists and has approval for the training of biomedical scientists by the Institute of Biomedical Sciences.

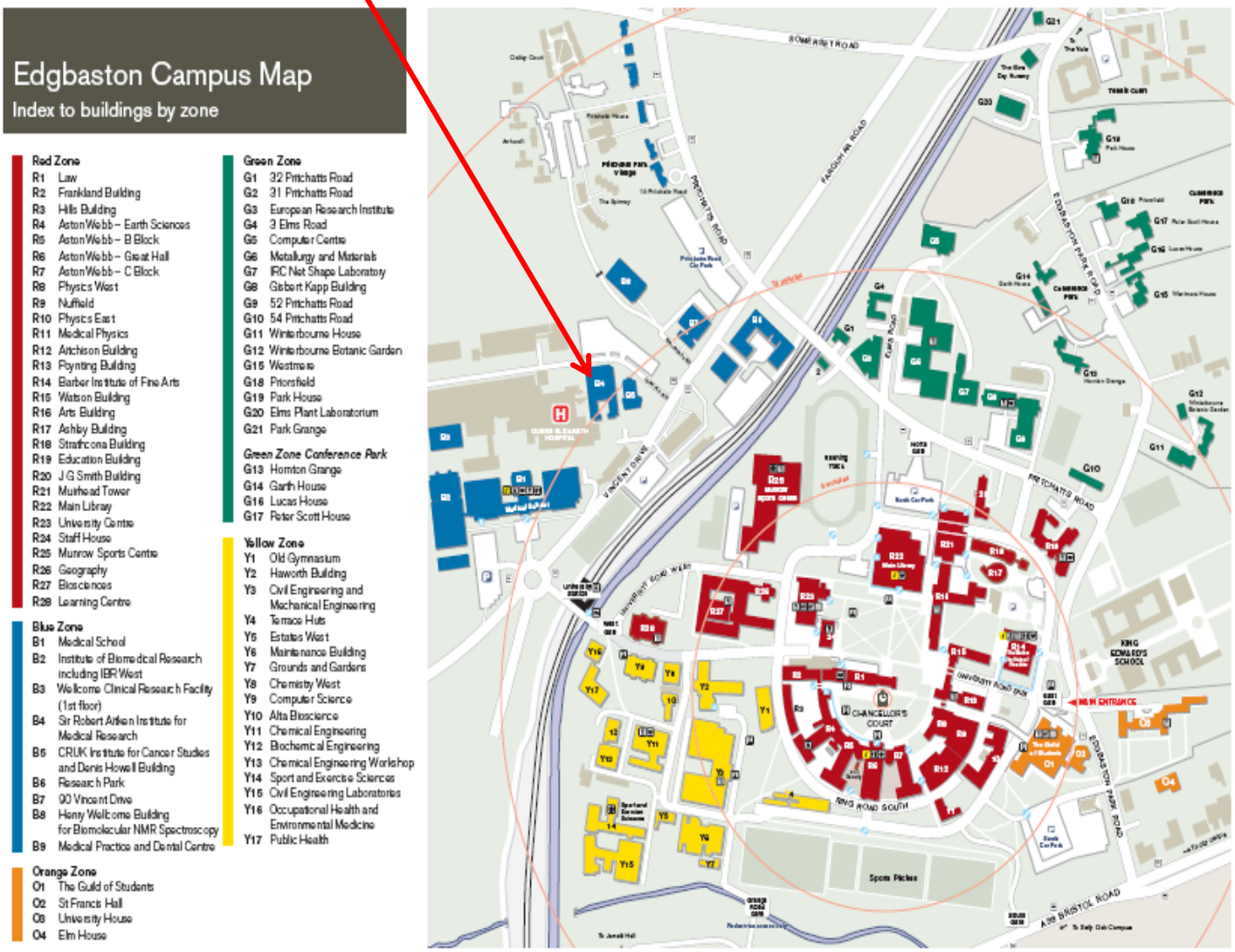
All work is carried out with due care for the health and safety of staff and with proper regard to the environment. The Department is licensed by the environment agency as a producer of clinical waste and the Department complies with all safety procedures including the Control of Substances Hazardous to Health.

The Department also has a broad based tissue research programme and is licensed by the Human Tissue Authority (HTA) to store tissue for research.

3. Key Information

3.1. Current Location of the Department

The Department is located on the **third floor** of the Robert Aitken Institute of Clinical Research, Vincent drive, University of Birmingham B15 2TT. This is **building B4** on the map below.



3.2. Opening Hours

Weekdays - A full laboratory service is available from 08:30 until 17:00 hours Monday to Friday. Staff will stay outside these hours if requested and if there is a genuine clinical requirement. Please telephone the Department to arrange this.

Saturdays, Sundays and Public Holidays - There is no service at weekends or on public holidays.

3.3. Out of Hours Service Policy

Owing to the nature of work carried out, an out of hours service is not normally required. Any specimens that miss the last scheduled collection by The Royal Orthopaedic Hospital (ROH) driver (4pm) should stay at the Hospital until the next morning (refer to Section 10 this document 'Specimen Collection and Transport to the Laboratory').

Large specimens should be kept in the ROH Theatre specimen refrigerator until the next morning, with the exception of Fridays, when staff may (by prior arrangement) wait to accept delivery of large resection specimens.

Amputations should ideally be received in the laboratory on Fridays or before a public holiday. If this is not possible then the theatre should telephone the laboratory **(415 8766 / 415 8767)** for advice.

All larger FRESH specimens that are awaiting despatch until the following morning / Monday should be stored in the Theatre fridge.

Smaller specimens i.e. biopsies, should be placed in fixative.

It is essential that specimens are not dispatched by any method other than the scheduled daily ROYAL ORTHOPAEDIC HOSPITAL service that runs until 4pm each day.

Specimens sent by any other method without prior arrangement with laboratory scientific staff may not arrive until after the Department is closed and therefore their safe receipt cannot be assured.

If a frozen section is required out of normal working hours, then the surgeon should telephone the Department to discuss this with a pathologist before attempting to send the specimen.

Other hospital sites may send specimens for routine histopathology processing and reporting by prior agreement. Typically this agreement will cover sample requirements and transport arrangements including a documented audit trail to ensure any issues over transport or identification are quickly identified and resolved.

4. Contact Information

The laboratory address is;

The Department of Musculoskeletal Pathology

University Hospitals Birmingham NHSFT

Robert Aitken Institute of Clinical Research,

University of Birmingham

Birmingham B15 2TT

- General Enquiries 0121 - 41**4 7641**
  (Requests for Reports)
- Laboratory Enquiries 0121 – 41**5 8766/8767**

5. Clinical Specimens Health and Safety

There are safety and security implications at all stages of the collection process and the storage and transport of clinical specimens.

All biological specimens should be treated as infectious and staff should take care to protect themselves and others even though the specimen might be contained within a specimen container.

6. Manual Handling

(Please see the Trust Manual Handling Policy)

Small biopsies may not be an issue; however a large number of specimens, particularly larger amputations are very heavy and care should be taken i.e. it may require two people to lift or move such specimen containers.

All staff are subject to the Manual Handling Operations Regulations (1992) and should attend regular manual handling training. Use the correct technique when lifting and use appropriate manual handling aids where appropriate/available.

7. Security of Specimens and Patient Data

The security of a collected specimen and its associated paperwork should be treated as a priority. Many specimens are unique and cannot be repeated, or if they can will require another clinical intervention. All clinical areas should have designated and secure areas for specimens prior to dispatch.

8. Histology Specimens – Documentation

All histology specimens must be accompanied by a properly completed histology form **AND** where specifically indicated a ‘consent for the use of tissue for research’ form.

Ensure that the request form is legible and completed as fully as possible.

The correct request form must be completed and accompany the specimen to the laboratory.

The consent form should be completed and signed by the patient (or representative, if appropriate) and the consenting clinician where samples are used in trials and research projects.

To avoid contamination forms should be separated from specimens using plastic wallets designed for that purpose.

Patient safety is paramount and the laboratory takes considerable precautions to ensure that the correct sample, belonging to the correct patient is analysed.

The normal (minimum) laboratory requirement is to have three points of positive identification, the **patient name** and two from the following list:

- Date of birth
- Hospital number
- NHS number

Please complete the request form as comprehensively as possible; include the source of the specimen (theatre or clinic number), the date and time the specimen was taken, the name of the requesting consultant and a destination for the report if this differs from the requesting consultant.

A brief clinical summary, including any treatment - e.g. radiotherapy or drugs should always be given.

The Department recognises that as it is off-site then rejecting a specimen may mean that the specimen may “go missing” therefore if the specimen is unlabelled or request form is incorrectly labelled then no work will commence on the specimen until the error is corrected. Laboratory staff will contact clinicians or theatre staff responsible for the procedure, to confirm and correct as necessary.

9. Clinical and Technical Advice (including unforeseen problems)

Clinical and technical advice can be obtained by telephoning the Department on the numbers in section 4 above.

10. Specimen Collection and Transport to the Laboratory

10.1. Specimens from Oncology Theatres

The majority of specimens for this laboratory come from operations carried out in oncology theatres. Specimens may be of three types:

A. Biopsies

B. Resection specimens

C. Amputations

10.2. Biopsies

Biopsies should be sent in two containers:

1. A dry container with a yellow lid so that the specimen may be sampled for DNA/RNA studies that may be required for diagnosis on some occasions and subsequently may contribute to the tumour tissue bank where appropriate.
2. A container with a white or orange lid containing 10% neutral buffered formalin for routine histology.
3. The containers should have an appropriate patient identification label attached to the outside.

Biopsy pots should be obtained from the Department (Tel: 0121 414 7641 / 7644)

10.3. Resection Specimens

Resection specimens should be sent dry and if small enough should be placed in a dry plastic pot. An appropriate patient identification label should be attached to the outside of the container.

If the specimen is too large then the specimen should be wrapped or placed in a plastic bag and then further wrapped in theatre paper and then sealed. Appropriate patient identification labels should be attached to the outside. In each case the specimen should be then placed in a sealed plastic bag.

10.4. Amputation Specimens

Amputation specimens should be wrapped in the same way as a large resection specimen and placed in a yellow ‘Griff bin’’, correctly and clearly identified with patient identification labels.

All specimens should be accompanied by an appropriately completed histology request form which has been signed by a member of the theatre team and (where indicated within ROH) a copy of a fully completed patient consent form for the Use of Tissue for Research and Teaching **(See SOP - GN 12)**. The histology request form and the consent for the Use of tissue for Research and Teaching should be placed in the plastic sleeve of a specimen transport bag. **The specimen in its container and the histology request form and patient consent forms should not be allowed to come into contact with each other.**

IF THE SPECIMEN CONTAINS METAL/IMPLANTS or there is a suspicion that the specimen could BE INFECTIOUS E.G. HIV, TB or HEPATITIS B this should be clearly indicated on the form.

Specimens should be placed in the ROH fridge in theatres reception to await collection by The Royal Orthopaedic Hospital driver. The driver will collect the

specimen/s from ROH Theatre Reception. The driver will place the specimens in a suitable transport box. Amputation specimens should be carried in the “Griff Bin”

The driver should take the box (or Griff Bin), place it securely in his vehicle and drive straight to the Laboratory.

The Department is not open after 5pm and so specimens sent by any means other than The Royal Orthopaedic Hospital driver **cannot** be delivered to the correct place.

10.5. Specimens from Other Theatres and Outpatients Department

These specimens should be placed in white or orange-lidded plastic specimen pots containing formal saline and labelled on the outside with a patient identification label. Specimens which are too large for the small formalin pots provided should be placed in the larger dry pots. It is not necessary to add formalin to these pots. The specimen should be accompanied by a histology request form and patient consent form for the Use of Tissue for Research and left at theatre reception for collection and transport to the laboratory along with the Oncology specimens.

Specimens should NOT normally require delivery to Department outside the driver’s normal delivery schedule. Should a specimen require delivery to the Department outside this schedule, theatre staff should phone the department PRIOR TO DESPATCH to discuss the urgency and, if necessary, alternative delivery arrangements. The Department is not open after 5pm and so specimens sent by any means other than the Royal Orthopaedic Hospital driver cannot be delivered to the correct place. All specimens that are being kept overnight before despatch, should be stored in the ROH Theatre fridge.

10.6. Specimens from CT clinic (See appendix (iv))

These specimens should be placed in white or orange-lidded plastic specimen pots containing neutral buffered formalin and labelled on the outside with a patient identification label. The specimen should be placed in a plastic specimen bag accompanied by a histology request form and completed consent form and left at theatre reception for collection and transport to the laboratory. It is the responsibility of Theatre staff to ensure the safe transit of the specimens to the Laboratory

A list of the specimens taken from each clinic should be included with the specimens to the Department. It is then the responsibility of the laboratory staff to check the specimens received against each list and to contact the relevant area if the specimens are not received.

10.7. Amputations not for histological diagnosis

All amputation specimens not requiring histological diagnosis should be sent to the Department in the same way as those requiring histological diagnosis i.e. in a Griff-Bin. The limb **must** be labelled with the patient’s registration details and must be accompanied by a completed histology request form indicating that the limb is for disposal only. On receipt the limb will be booked in onto the departmental database

and will be macroscopically examined and a report will be issued. Four weeks after reporting the limb will be sent for incineration.

11. Requests for Frozen Sections

When a frozen section is required the laboratory should be contacted on **0121 414 7641**. Please give 24 hours' notice wherever possible.

The case should be discussed with a Consultant Pathologist who will require the following information:

1. Patient's name
2. consultant
3. site of specimen (including provisional diagnosis)
4. date and time of procedure
5. theatre being used (including phone number)
6. any possible infection risk

If a frozen section is required outside normal working hours (9.00am – 5.00pm Monday – Friday) the Consultant Pathologist on call should be contacted.

As soon as the patient reaches theatre the appropriate transport should be arranged (usually the normal Royal Orthopaedic Hospital driver will make themselves available, if sufficient notice is given, otherwise the on-call drivers should be contacted via the porters).

The specimen should be transferred to a dry container and dispatched to the laboratory fully labelled and with a completed and signed request form stating that a frozen section is required and a contact number to which the report can be telephoned. Ideally the laboratory should be contacted at this point to say that the specimen is on its way. A fully completed and signed patient consent form should be included

The specimen should reach the laboratory within 30 minutes of being removed.

A verbal report will be telephoned to the theatre as soon as possible – usually within 30-60 minutes of receipt of the specimen.

A written confirmatory report will follow a few days later after the specimen has been through normal laboratory procedure.

Any further specimens from the same patient, which do not require a frozen section, should be handled in the normal way. They will require a separate request form.

12. Procedure for Release of Tissue for Ritual Burial

12.1. Preamble

This procedure should be followed in the event of a patient's request for the release of human tissue to be taken for the purpose of ritual burial. The Trust wishes to protect the public, so far as is reasonably practicable, from any hazards which may be present in human tissue and will not release such tissue unless reasonably satisfied that it is for ritual burial.

12.2. Procedure for Requesting the Release of Tissue

Tissue will only be released to an undertaker on behalf of a patient and cannot be collected by the patient or relative in person.

The patient must complete the form "Request and Authorisation for Release of Human Tissue". A photocopy of the completed form should be retained in the patient notes and the original forwarded to the Department of Musculoskeletal Pathology.

The Department of Musculoskeletal Pathology will liaise with the undertaker acting on behalf of the patient to arrange a date for release of the tissue.

12.3. Procedure for the Release of Tissue

Following receipt of the "Request and Authorisation." form and liaison with the undertakers, the tissue will be related as soon as possible after the department has completed necessary tests and release preparations.

The tissue will be well fixed and the fixative removed by through washing prior to dispatch.

The tissue will be wrapped and sealed so that its nature is obscured. It will be placed in a sealed container

Tissue will be released on the agreed date/time to the authorised undertaker. The undertaker upon the release of the tissue must sign the form "Removal of Specified Human Tissue".

Upon the release of the tissue, the undertaker is responsible for the safe handling and burial of the tissue.

The Trust cannot guarantee that specimens are non-infectious and non-toxic.

13. Procedure for the Return of Metal Implants

It is the policy of the department to discourage the return of implants to patients.

14. Procedure for Requests for Images or Slides from Patients

Any request from a patient for images or slides of their resection, should be discussed with their consultant. The patient then should put his request to the pathology manager in writing. The department will then consider each request on its merit and will endeavour to meet the patient's request.

15. Procedure for the Release of Blocks and Slides to a Referring Hospital

A referring hospital that wishes to review slides from a patient that they have been referred by The Royal Orthopaedic Hospital NHSF Trust must put their request in writing and send via email or post with details of the consultant histopathologist the material is to go to and a full address for the receiver.

16. Procedure for the Release of Blocks and Slides for Second Opinion from Patients

It is the policy of the department to assist a patient who wishes to have his/her case reviewed by another pathologist of their choice. The Department will require from the patient written authority from the patient to release sections, address and packaging instructions from the pathologist's laboratory. The Department may charge for post and packaging.

17. Issuing of Reports

All reports issued to the ROH by the Department are done so electronically. Clinicians and secretaries have limited access to the Pathology Database which will allow them to access authorised reports only.

Following analysis of workload trends and previous figures, the anticipated turnaround times for specimens received into the Department are, as follows:

80% of samples are reported, confirmed and authorised within 7 calendar days of procedure (as recommended by the Royal College of Pathologists).

90% of all other specimens are reported, confirmed and authorised within 10 calendar days of procedure (as recommended by the Royal College of Pathologists).

18. Formalin Spillage

A spillage kit for formalin is carried by the Driver and one is located in Theatre 2 (see appendix (viii) for procedure); if further advice is required, please telephone the Department.

19. Appendix I - Current Staffing List

Consultant Pathologists

Dr Shalini Chaudhri	Clinical Service Lead	0121 371 3347
Dr V P Sumathi	Consultant Pathologist	0121 414 **7641**
Professor C Fisher cyril.fisher@nhs.net	Consultant Pathologist	0121 414 **7643**

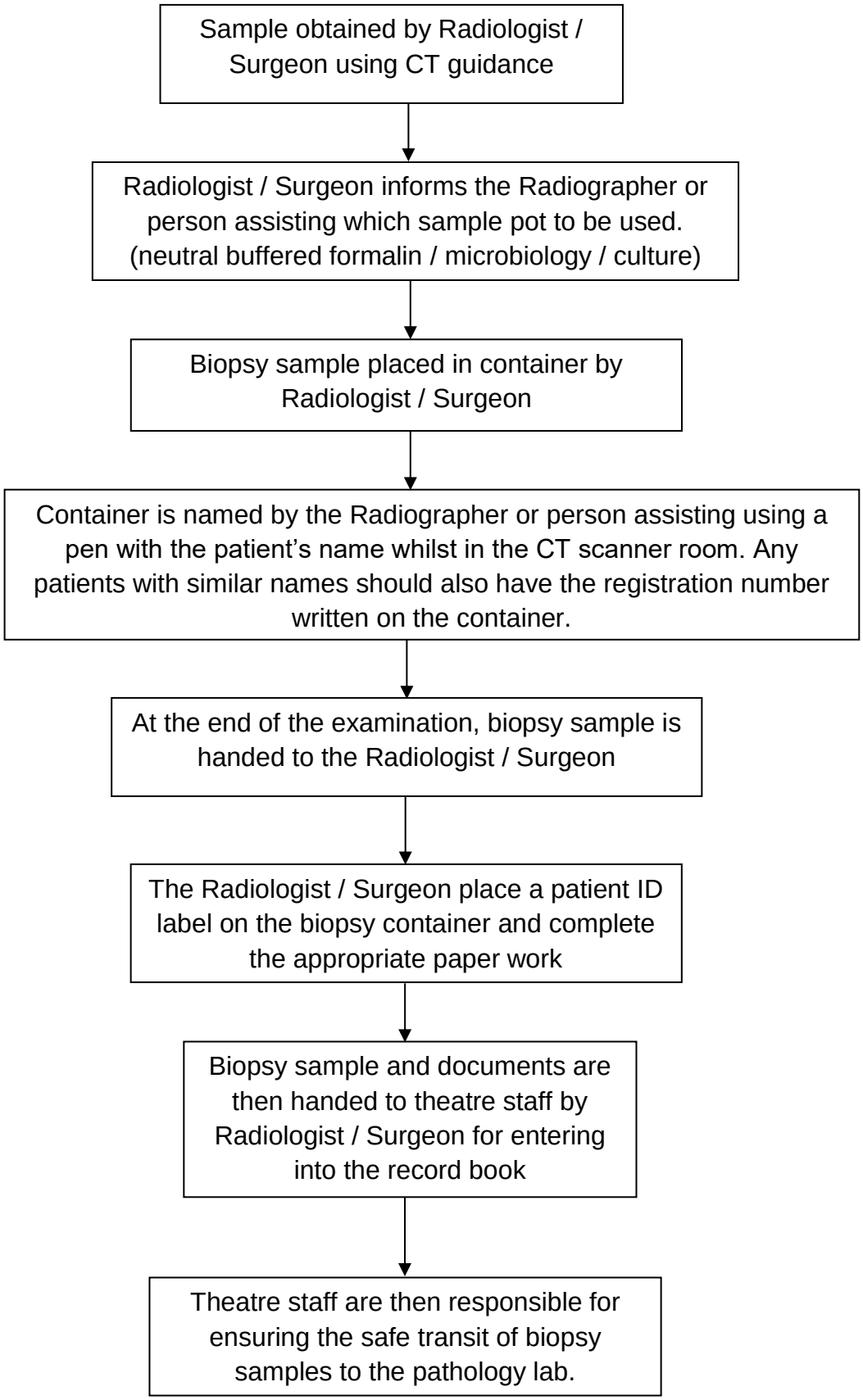
Laboratory Staff

Martin Collard	Head Biomedical Scientist	0121-371-3343
Satveer Kaur	8a Operational Manager	0121- 414 **7642**
Kulvinder Gill	Biomedical Scientist *(Specimen Reception Enquires)*	0121- 415 **8766**
Karen Joynes	Biomedical Scientist *(Research Enquiries)*	0121- 415 **8767**
Angela Niblett	Senior Biomedical Scientist *(Molecular Enquiries)*	0121- 414 **7790**

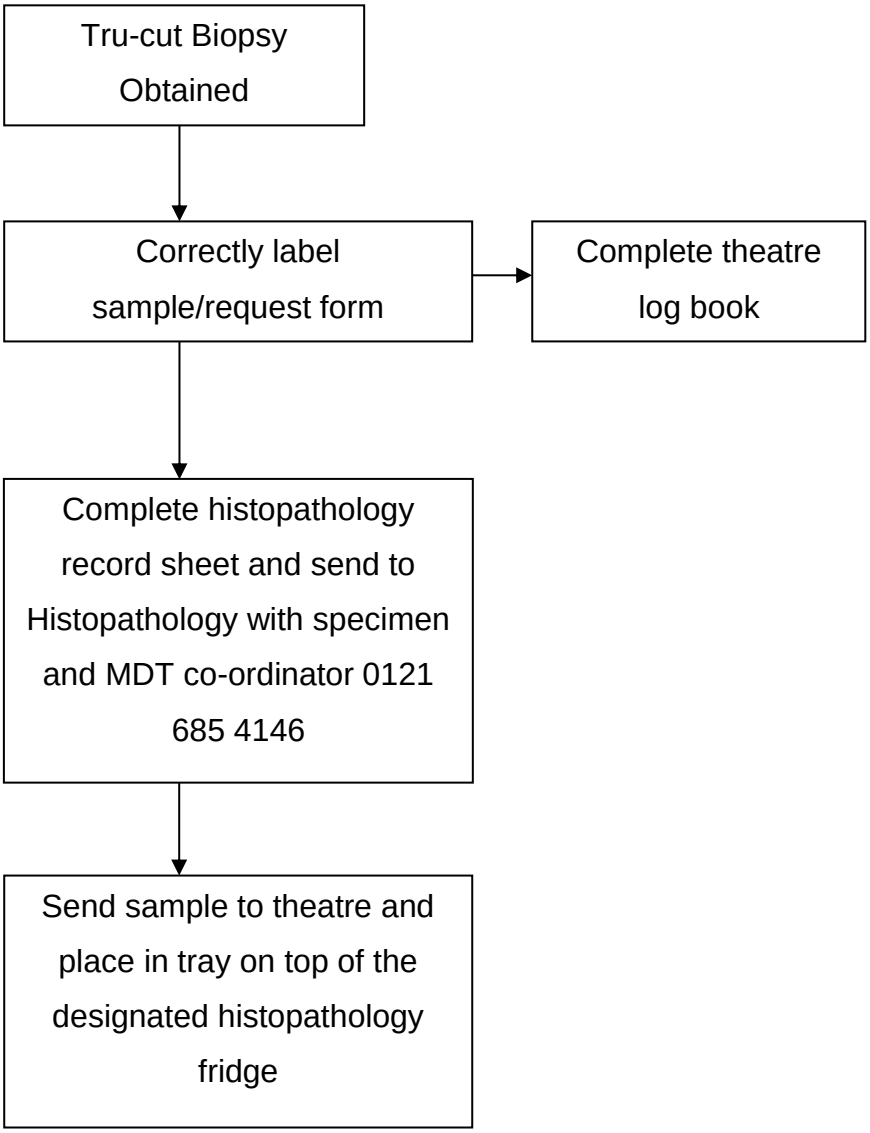
Clerical Staff

Departmental Secretaries	0121 – 414 **7641**

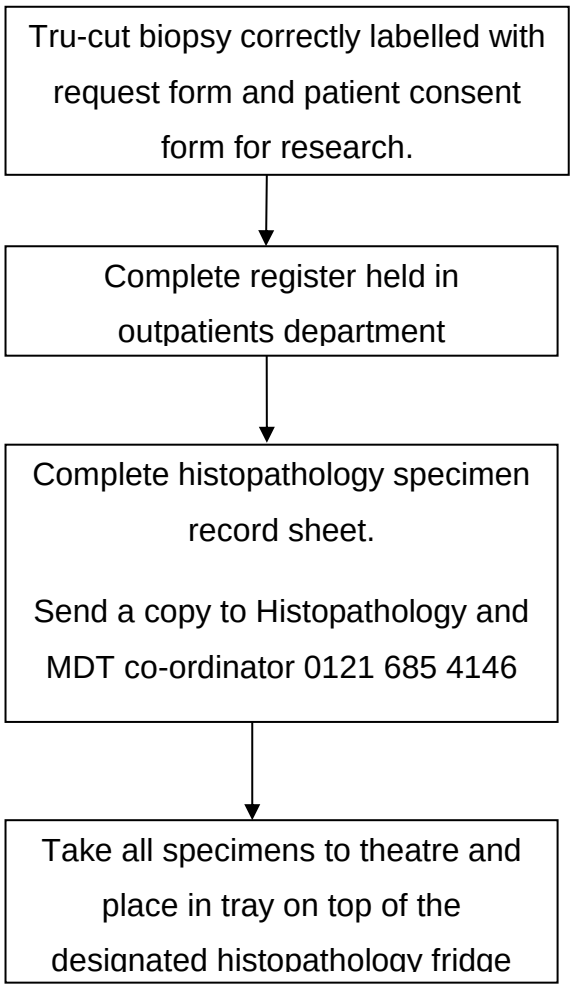
20. Appendix II - Procedure for naming CT guided biopsy samples



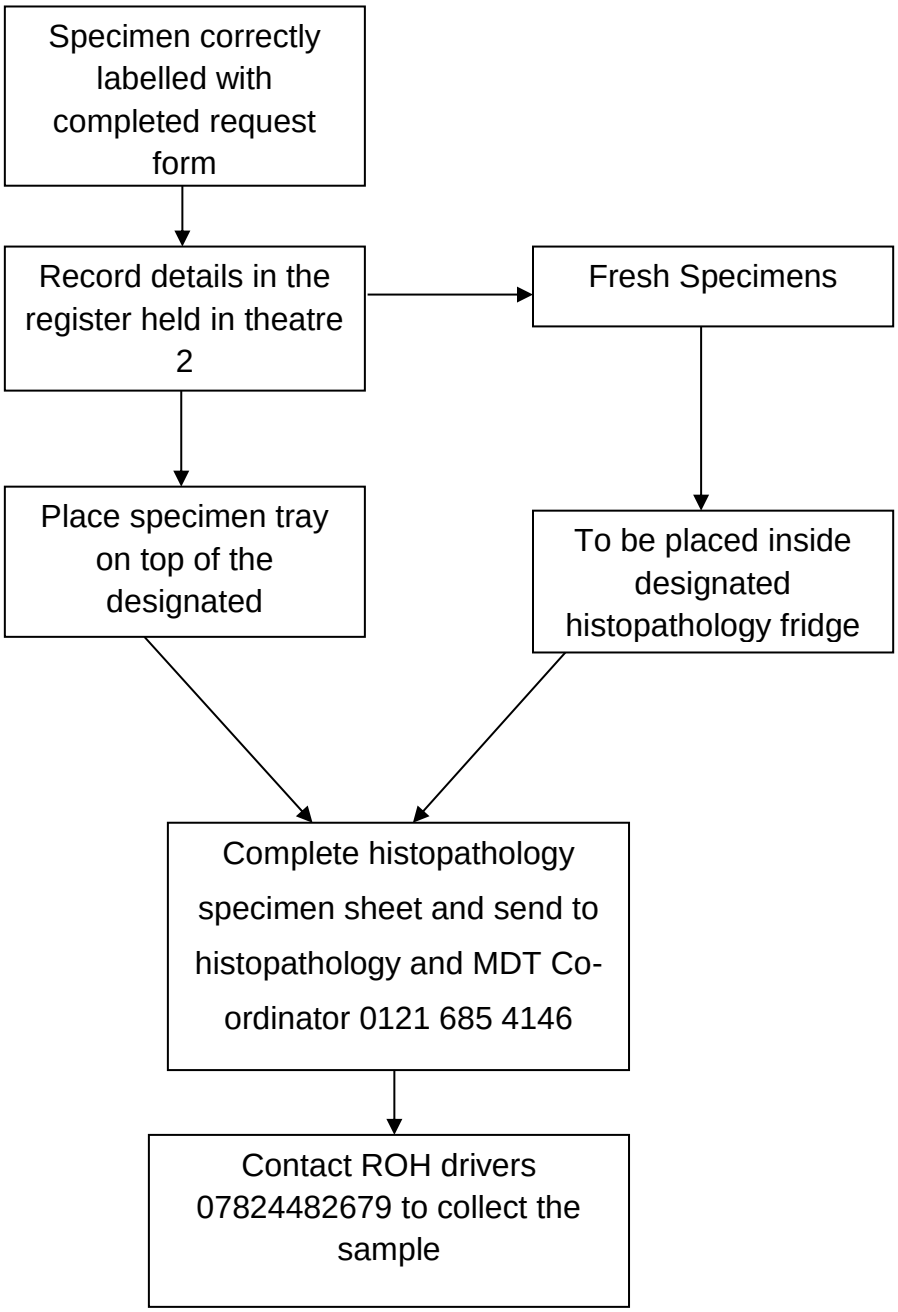
21. Appendix III - Procedure for Samples Obtained on Ward 12 / CT Biopsies and Ultrasound Biopsies Performed In X-Ray



22. Appendix IV - Procedure for Specimens Taken In Out-Patients for Transfer to Histopathology



23. Appendix V - Procedure for Storing and Transferring Specimens from Theatre to Histopathology



IT IS THE RESPONSIBILITY OF THE THEATRE CO-ORDINATOR AT THE END OF THE DAY TO ENSURE ALL SPECIMENS HAVE BEEN SENT AND TO ENSURE THE RECORD SHEET HAS BEEN FAXED TO HISTOPATHOLOGY AND THE MDT CO-ORDINATO

24. Appendix VI – Histology / Microbiology Specimens

Ward…… Theatre…… Clinic area……

Surgeon……... Date……

NAME	HISTO	MICRO	OPERATION PERFORMED	STAFF NAME (SIGN AND PRINT)

25. Appendix VII - Protocol for Formaldehyde Spills

COSHH Assessment No: 055, 262, Risk Assessment No: 152

Equipment:

PPE – gloves, laboratory coat, mask or respirator, aldehyde extraction equipment, safety signage and spillage kit.

Method:

1. Evacuate the area and if in the need of advice please immediately call through to the Laboratory.

2. Use the spillage kit and safety equipment provided

3. Contain the spill by applying F.C.G (formalin control granules) around the perimeter of the liquid. Continue to apply inward until all liquid is absorbed with F.C.G. Avoid splashing.

4. Carefully mix, add more F.C.G if necessary to absorb liquid.

5. Allow mixture to stand. Formaldehyde solutions 15% to 37% in concentration will solidify in 10 to 20 minutes. Solutions less than 15% require slightly longer because of the high percentage of water present and will polymerize the formaldehyde, but produce a slurry rather than a solid mass.

6. Dispose of polymerized product in accordance with local, state and federal regulations (contact Health and Safety advisor at ROH for details).

7. Wash spill area with cold water.

8. Use F.C.G only for formaldehyde spills. Do not use to treat acid, base or solvent spills. Before treating a spill, make sure that proper safety equipment such as a respirator, chemical splash goggles, gloves and protective clothing are worn.

Provide adequate ventilation. The polymerization reaction generates a small amount of heat – this is normal.

25.1. First Aid

Eye: Flush with large amounts of water for at least 15 minutes whilst holding eyelids open. Seek medical advice.

Skin: Wash with large amounts of soap and water, rinse. If irritation persists, seek medical advice.

Inhalation: Remove victim to fresh air, apply artificial respiration if necessary. Seek medical advice.

Ingestion: **Do not induce vomiting**. If victim is conscious, give large amounts of water. Seek medical advice.