Research and Development Laboratory User Manual GD044

Summary of Amendments

Version Number	Modification:
1.0	New document to cover all matters to do with handling of biological samples.

Key Points of this Document

Papworth Hospital has multiple laboratory areas on the Cambridge biomedical campus. This document outlines Good Clinical Laboratory Practice (GCLP) in all laboratory areas. These include the mini laboratory areas within Royal Papworth Hospital (RPH) outpatients, Clinical Research Facility (CRF) in the Victor Phillip Dahdaleh Heart & Lung Research Institute (VPD-HLRI), the Histopathology Lab on the first floor of the HLRI and specific laboratory areas within CUH Histopathology.

Papworth R&D has established a Laboratory User Group (LUG) to provide advice, oversight and a means for the wider R&D team to be involved in all matters to do with handling biological samples. This document ensures all staff working in laboratory areas work to the same high standards. It is an individual's responsibility to adhere to current legislation/ guidelines and local policies and procedures; these are referenced in the manual. This document applies to all staff irrespective of grade and position. It is the duty of R&D staff using laboratory areas and handling biological material to:

- read this manual before undertaking any work.
- ensure they have the appropriate training and competency for the work being undertaken.
- ensure they have read the protocol or laboratory manual for the work being undertaken.
- ensure they are aware of the COSHH guidance for any reagents / chemicals being used.
- keep the LUG informed of relevant updates and issues that require the Group's input.
- respond to, in a timely manner, requests for feedback/input from the LUG.
- support equipment servicing, such as keeping equipment status up to date and helping when engineers require access to equipment.

1 Purpose and Contents

To outline the Good Laboratory Practices (GLP) for the Papworth Hospital and HLRI laboratory areas used by R&D staff.

To explain guidelines and highlight associated SOPs and risk assessments on topics related to using laboratory areas.

2 Abbreviations

Abbreviation	
BSC	Biological Safety Cabinet
COSHH	Control of Substances Hazardous to Health
CRF	Clinical Research Facility
GCLP	Good clinical laboratory practice (GCLP)
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HTA	Human Tissue Authority
LUG	Laboratory User Group
R&D	Research and Development
RPH	Royal Papworth Hospital
UoC	University of Cambridge
VPD-HLRI	Victor Phillip Dahdaleh Heart & Lung Research Institute

3 Introduction

a. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki (ICH GCP Guideline).

b. Good Laboratory Practice (GLP) is intended to promote the quality and validity of test data. It is a managerial concept covering the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported (OECD GLP Guideline).

c. Good Clinical Laboratory Practice (GCLP) applies those principles established under GLP for data generation used in regulatory submissions relevant to the analysis of samples from a clinical trial. At the same time, it ensures that the objectives of the GCP principles are carried out. This ensures the and integrity of data generated by analytical laboratories.

d. This document outlines safe laboratory practices to ensure that quality standards are maintained from receipt of samples to final dispatch of samples after processing and to ensure safe working practices for staff undertaking research activity concerning the handling of human biological material.

e. Appropriate training will ensure that staff are able to utilise equipment properly and understand what is required to work safely within a laboratory area. Staff will be required to regularly review their training to ensure their practical skills are maintained.

f. General standard operating procedures are in place for use of equipment as well as regular maintenance schedules. Quality and safety of equipment is ensured by annual servicing. Staff are required to be up to date with reading of the relevant SOPs.

g. Papworth's Tissue Bank and MesobanK have additional specific SOPs for their procedures.

h. All chemicals / reagents being used within the laboratory space need to have COSHH assessment carried out, which must be uploaded into IQM and be acknowledged by staff using the chemical.

i. All laboratory documentation such as sample storage logs and training records should be audited to comply with Human Tissue Authority regulations and conditions of a study's research ethical approval.

j. Each research study will have a study specific protocol to give specifications on processing, storing and transporting samples.

k. Work carried out in the HLRI laboratories must be conducted in accordance with the Medicine Safety Manual Part 1 and Part 2.

l. Staff also working in the HLRI-CRF should read the CRF User Guidelines GD032 and the HLRI CRF Operations Manual (GD040).

4. Laboratory codes of practice

4.1. Work safely in a laboratory

a. All staff working within laboratory areas must comply with laboratory codes of practice and local SOPs to ensure safe working practices. Good laboratory etiquette ensures the safety of all staff. Any unsafe working practices must be reported to management.

b. Before embarking on any activity in the laboratory, staff should ensure they are competent in the tasks to be undertaken and are fully aware of how to handle any chemical/biological hazardous substances and how to deal with a spillage.

c. Staff are required to understand what the potential hazards are within the laboratory, to be aware of appropriate risk assessments and to adopt safe working practices.

- Staff need to read the COSHH assessments for the chemicals / reagents they are using in the laboratory and the appropriate risk assessment.
- If a COSHH assessment has not been completed, then the member of staff who is going to use the chemical needs to complete a COSHH – see Appendix 3 for the process.

d. Staff must dress appropriately when working in a laboratory environment

- Always tie back hair that is chin-length or longer.
- In line with Trust uniform policy dangling jewellery should not be worn in laboratory areas.
- Appropriate footwear that provides adequate support, with enclosed toes MUST be worn. For specific activities, e.g. handling liquid nitrogen, protective footwear may be necessary.

e. Suitable personal protective equipment must be worn when working in the laboratory.

- Always wear face shields or safety glasses if there a risk of splashing from working with hazardous materials and/or chemicals.
- When handling any toxic or hazardous agent, always use the appropriate protection. When handling dry ice/ liquid nitrogen always wear gloves designed for cold temperatures and use a personal oxygen monitor. These monitors are kept in the drawer associated with desk AD3 in the R&D area of the HRLI, with a sign out/sign in sheet that must be completed.
- In most laboratory areas a white lab coat should be worn. In laboratory areas prone to higher temperatures (within Papworth hospital mini lab and point of care room) a uniform with an apron may be worn as an alternative.
- Hands must be washed before leaving the laboratory area.
- Do not touch face whilst wearing gloves and remove gloves when leaving the lab. Do not touch doors/ door handles or walk around the hospital with gloves worn whilst handling samples.

- Blue lab coats should only be worn in Category 2 laboratories (CRF lab). They must stay in the laboratory area. White lab coats are for Category 1 laboratories. Only white lab coats can be used to walk around corridors. Lab coats must not be worn in office areas.

f. Do not chew gum, drink, eat or apply cosmetics while working in the lab.

g. If the laboratory area is in a clinical area (both mini lab and point of care testing room are located within Outpatients) please close the door to prevent being disturbed whilst processing samples.

h. Experiments/sample processing should not be left unattended. If you do have to leave the area, make sure all relevant equipment is safe and samples secure.

i. The last person to leave an area must make sure all doors are locked, and all ignition sources are turned off.

j. Unsafe conditions should be reported to the person responsible in the specific area: (see Appendix 2) and then line manager.

k. Always follow the proper procedures for disposing lab waste. For clinical waste follow DN375 Waste Management Policy. For disposal of chemicals follow advice given in individual COSHH form.

l. In the event of a chemical splashing into eye(s) or on skin, immediately flush the affected area(s) with running water and follow the instructions in the relevant COSHH form. If a splash with blood or body fluid refer to DN180 – 'Needlestick Sharp and Splash incidents involving blood or body fluids. First aid eye kit contains saline solution.

4.2 General housekeeping rules

Laboratories must follow general housekeeping rules and infection control policies of the relevant area they are located in.

a. Always keep the work area(s) tidy and clean.

b. Floor areas must be kept clear.

c. Equipment from sponsors must be stored in the R&D basement room of the hospital.

d. As per Trust moving and Handling Guidelines DN271, only lightweight items should be stored on top of cabinets; where possible the load should be made smaller, so it is lighter and easier to move.

e. The area around equipment that requires air flow or ventilation to prevent overheating should always be kept clear.

4.3 Laboratory Maintenance

a. Each laboratory area has cleaning/disinfection procedures for area and equipment. All users of laboratory areas and equipment must take part in regular cleaning rotas.

b. Laboratory sign-in sheets should be completed by users to indicate which equipment has been used and cleaned after use.

c. Maintaining laboratory stock specific to a study is the responsibility of R&D staff assigned to the study.

d. General laboratory supplies such as gloves/Clinell wipes/Pasteur pipettes should be stocked up by all users of the laboratory area. General supplies are stored in the R & D basement. Please inform the relevant contact to report supplies are running low so they can be reordered by R&D Administration.

e. 7.5L and 30.2L reusable bins are obtained through Skanska extension 639000 / helpdesk.papworth@skanska.co.uk. One of each size should be present in the mini-lab and POCT room. 7.5 L Biobin for use in hood and spare ones can be stored in the R&D basement room. All reusable sharps bins are yellow, but the lids denote their use. The lab uses yellow bins with a yellow lid and clear top.

2

f. Clinical waste bins and biobins must only be filled to the maximum capacity line. Do not over fill the clinical waste bin. Full clinical waste bins must be put in the clinic waste area for recycling. Biobins once properly closed to be disposed of in the yellow clinical waste bag/bin.

g. NB: Staff working in the HLRI-CRF will use sharps bins provided by the University for use in the CRF.

4.4 Chemical Safety

In general

a. Every chemical should be treated as though it were dangerous.

b. Do not allow any solvent to come into contact with skin.

c. All chemicals should always be clearly labelled with the name of the substance, the concentration, the date it was opened and should have relevant safety information e.g. a hazard symbol.

d. Refer to COSHH form of the individual chemical. This will indicate potential hazards, and specific instructions required to deal with the spillage and disposal of the chemical.

e. Chemicals should never be mixed in sink drains. This includes dry ice.

f. For handling small amounts of liquid nitrogen, particularly for snap freezing human samples, a chemical fume hood is recommended, unless local SOPs specify the work to be undertaken using biological safety cabinet (BSC):

- Precautions are PPE: wear cryogenic gloves, face shield, and lab coat.
- Ventilation: ensure the fume hood or BSC is functioning properly.
- Handling: use containers and tools designed for cryogenic temperatures.

In HLRI-CRF and HLRI laboratory

Refer to local guidelines/SOPs on usage of hazardous biological or chemical substances in those areas.

In RPH

The laboratory areas within the hospital have limited ventilation, and there is no facility to dispose of chemicals. Therefore, only small volumes (up to 50ml) of alcohol or formalin should be used in these areas without an additional assessment being completed. Alternative tissue fixatives or larger volumes of chemicals must have a separate risk assessment to determine if it is safe to use in the outpatient mini-lab or the POCT room. Most tissue media are non-hazardous but refer to COSHH form if antibiotics have been added.

4.5 Dry ice handling - Datix Risk Registry Number 2204

a. Staff must be signed off as competent before handling dry ice. Access to dry ice in HLRI will require prior agreement and only be allowed after the HLRI training is completed (contact Ian Horan, please see below).

b. When handling dry ice in small laboratory areas limit the amount of time the dry ice container is opened. Make sure the door is open. Use the provided monitor, or if not available use the R&D monitors which are stored in the AD3 drawer R&D office, with a sign in/out sheet.

c. Do not leave the spare dry ice (even if enclosed in a container) overnight in point of care/ mini lab. Take any spare dry ice to HRLI Goods In so the HLRI can reuse the dry ice. Additional capacity for dry ice to be temporarily stored for disposal is available in the HLRI-CRF on agreement with the CRF team.

4.6 Chemical or Biological spills

a. For biological spills Clinell wipes/Tristel or Haz tab/granules can be used - see Processing Biological Samples SOP124 for more details. For chemical spills follow the relevant COSHH instructions.

b. Deal with all spills immediately. Once the initial spillage is resolved then the necessary parties can be informed (see later sections).

c. For large spills, the laboratory may need to be closed while the spillage is cleaned up. Inform the other users of the laboratory of the situation. Seek assistance from Estates if in Papworth Outpatient laboratory areas and follow local guidelines if working in HLRI or HLRI-CRF areas.

d. If a staff member comes into contact with any hazardous biological material or chemical Occupational Health Department should be contacted and line manager informed.

4.7 Electrical safety

a. Make sure all equipment is PAT tested annually.

b. Electrical equipment that can be switched off should be switched off at the end of the day.

c. All laboratory equipment should be serviced regularly.

4.8 Biological hazards

a. This is the exposure to fresh human samples with an infection risk, such as samples from the respiratory tract (sputum/ lavage/ mouth rinse).

b. In research the collection of highly infectious samples is avoided, however remember samples are from patients and may not been screened for all potentially infectious agents.

c. Handling of fresh unscreened human samples should be at Biological Containment Level 2 (CL2) or higher (can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.)

d. Where possible use a biological safety cabinet when handling human samples. Samples can be processed on the bench if the risk to samples/staff member has been assessed and correctly documented. Always wear goggles or face visor and gloves.

e. In the mini-lab in outpatients. This room does not have air exchange so the biological safety cabinet should be used for **all** sample handling and processing.

f. In the POCT in outpatients. This room does have air exchange so samples can be processed on the bench following an assessment of the risk of the sample being processed on the bench and the wearing of PPE as in section 4.4. Allow samples to sit for 15 min after centrifugation before opening blood tube and aliquoting to reduce the risk of aerosol. If the study protocol does not allow for this, then the post centrifugation processing should be done using the biological cabinet in the mini-lab.

4.9 Transporting samples around the Cambridge Biomedical Campus

a. Detail on transporting samples on dry ice to be found in S:Shared>R&D>Pathology>H&S related documents.

b. Samples must be packed so they are protected during transport.

- Samples that are liquid or contain liquid must be placed within a clear sample bag, which is then placed into the packaging containing absorbent material in case of a spillage during transfer.
- The outer container must be appropriate for the sample container. The lid must be secure in case of trip or accident and wherever possible use a medical transport bag.

c. Frozen samples can be transported using dry ice or ice packs in a sample transport carrier or a Styrofoam box. Ice packs are stored in the R&D freezer on Level 1 of RPH to transfer frozen samples.

- Do not travel in the lift at the same time as samples of dry ice.
- Avoid walking samples through patient areas of the hospital. In Papworth from Outpatients use the ambulance bay / modular building to meet couriers. Code for gate available from the team leaders.

d. There are various options for dealing with frozen samples arriving/leaving Papworth. For example:

- Samples can be packed and transported around the site on ice packs to enable the use of lifts. In this instance frozen samples are handed to the courier at the ambulance bay/modular build who packs them onto the waiting dry ice.

- Courier will deliver dry ice to the modular build, and this is taken to the mini-lab for packing, which is returned to the modular build for pick up by the courier.

4.10 Receiving consumables/equipment from suppliers

All couriers dropping off or picking up equipment must go to Goods Inwards in the hospital or reception/Goods In at HLRI. Papworth Good Inwards will then put anything they receive into the R&D basement storage. HLRI Goods In will call/email the relevant team informing them of a delivery for collection. Couriers can be met at Goods Inwards if preferable.

5. Laboratory Training

5.1 Induction

Initial training will be given to all new R&D staff members (see Laboratory Programme for Research and Development Staff). Inductions will consist of the Laboratory Knowledge Course, and/or completion of the online Practical Laboratory Skills training from the NIHR (must have completed GCP training before completed the course). Trainers are identified within each team to support new staff members.

5.2 Mentoring

New staff members will be mentored in laboratory skills that are appropriate for the clinical trials/ research studies they have been assigned to. The trainer / trainee completes the mentoring section of the laboratory induction for R&D Staff. This section includes the skills the trainer has demonstrated, and afterwards the skills the trainee has demonstrated. Both trainer/ and trainee sign to state the record is correct.

5.3 Practical skills assessment

- Staff members will have a practical assessment of laboratory skills required for their specific job role. This may include competency assessment of equipment such as centrifuge, pipettes or biological safety cabinets, or assessment of a process such as handling dry ice.

- Once a Staff member is fully signed off for all relevant competencies the Laboratory Induction From can be signed off.

- **Staff members that are competent can help train and sign off other members of staff.**

5.4 Maintaining Laboratory skills

a. Annual skills review

- During staff member's annual appraisal, practical skills should be reviewed, and further training will be given if required. A self-assessment skills review can be completed, and any areas staff require guidance/further training should be discussed with their manager and arrangements made with a competent member of staff to give further training.
- Staff will be required to refresh topics relevant to their job role every 2 years. Staff members are required to keep individual records of all training to show level of competence.

b. Study specific training

- When a study in initially set up staff members will be given specific training for study by sponsor, site file will include specific training details of the study.

6. Laboratory Health and Safety

6.1 Health and Safety inspections

These should be conducted every six months, following local standard procedures. Inspection reports to be saved down in S: R&D> Pathology folder and a copy sent to Incidents and Risks email address: papworth.incidentsandrisks@nhs.net

6.2 COSHH

Each Laboratory area RPH, CRF, HLRI will have their own H&S folder. A RPH COSHH assessment must be completed for all chemicals used and saved in. S: R&D>Pathology>H&S related documents.

6.3 Risk assessment

a. All laboratory equipment has a risk assessment to indicate to the user what safety precautions need to be taken when using the specific piece of equipment/process.

b. Royal Papworth's COSHH assessment template incorporates a risk assessment. Certain risks also have a separate risk assessment, or one completed on Datix. Copies of documentation regarding all these different assessments must be saved in the central location R&D>Pathology>H&S related documents.

c. During the set-up of a new study a COSHH form and/or risk assessments must be completed for any new chemicals not already in use following the process outlined in Appendix 3.

6.4 Reporting health and safety issues

a. First speak with other members of a team who are experienced and have also been signed off as competent.

b. Any safety issues should be dealt with in a timely manner and a Datix completed about the event.

c. Any near miss incidents should also be reported for investigation by the person who identified the near miss, and if necessary, a Datix completed.

d. Inform the Laboratory User Group of any safety issues. If appropriate results of any discussions will be fed back at the monthly BUZZ meeting, to make all staff members aware.

e. If equipment is broken/ unsafe to use put a sign on it and report to the most relevant person (see table for contact details Appendix 2).

f. Emergency protocol - If a staff member is unwell within the hospital laboratory area, then then they should go to the clinical area near the laboratory for help. For example, users of the mini lab/ point of care room should speak with a member of staff within Outpatients.

g. If the laboratory needs to be temporarily closed due to a major incident, please inform R&D Operational Manager and arrange for an all-user R&D email to be sent notifying the department of the temporary closure.

h. Appendix 2 is a table that contains useful contact details.

i. Staff should be aware of the Outpatient operational policy/manual https://staff.royalpapworth.nhs.uk/download.cfm?doc=docm93jijm4n3408.pdf&ver=4061

6.5 Equipment decontamination

a. Laboratory equipment must be decontaminated before servicing or repair. Follow DN418: Medical Devices – Decontamination of Medical Electrical Equipment prior to Maintenance or Repair. A Trust Declaration of Equipment Contamination Status Form DN418 must be completed.

b. The service company may also require you to sign their own decontamination declaration. Each individual SOP for equipment will describe how to clean the equipment.

c. Obtain freshly made Tristel solution for decontamination purposes from the relevant clinical area.

7 Quality Control

7.1 Maintaining accurate records - Sample record sheet

a. Use a sample record sheet to document processing of samples. This may be provided by a study sponsor and example of information required follows:

- Patient identification- normally the patient's study number/ initials/ year of birth
- Time samples were taken
- Time samples were processed
- Time samples were frozen
- Sample location
- Sample volumes once processed

b. If samples are stored in the -80 freezer an electronic sample log should be completed as soon as possible, See Freezer Management SOP029 for more information.

7.2. Equipment records

a. Not all fridges are electronically monitored. If samples/media/ fixatives are stored in these then the temperatures of these must be recorded during the weekday to make sure the temperature stays within the allowable range using Manual Temperature Monitoring form TPL049.

b. Laboratory cleaning log: when processing samples please record which equipment you have used, and that you have cleaned it after use.

c. Biological safety cabinet (BSC) requires a weekly and monthly clean. Please initial and date when you have completed cleaning. See Biological safety cabinet SOP095 for more details.

d. Fridge temperature, freezer scrapping logs and cleaning records should be scanned once completed and stored in S: Shared> R&D > Pathology>Equipment>Freezers

8. Appendices

Appendix 1 – Relevant RPH Guidelines, SOPs and polices.

RPH R&D SOP No	SOP Name	Location
SOP 029	Freezer management	Intranet
SOP 049	GCP Training for Research Staff	Intranet
SOP 050	Handling of Protocol Non-Compliance	Intranet
SOP 060	Version Control of Study Documents	Intranet
SOP 063	Research and Development: Internal Good Clinical Practice (GCP) Audit	Intranet
SOP095	Laboratory Biological Safety Cabinet	Intranet
SOP096	Centrifuges	Intranet
SOP097	Sample Transport	Intranet
SOP098	Pipetting	Intranet
SOP124	Biological Sample Handling	Intranet
ID 2204	Handling Dry Ice	Datix
ID 2212	Transporting Dry Ice	Datix
ID 2214	Handling liquid nitrogen	Datix
ID2203	Transporting liquid nitrogen	Datix
ID 2437	Freezing of biological samples	Datix
ID 2436	Using centrifuges	Datix
ID2604	Exposure to Formalin	Datix
ID2412	Incorrect Disposal of Laboratory Waste	Datix
ID2400	Labelling Samples for research/Tissue Bank	Datix
GD040	HLRI-CRF Operations Manual	S:shared>R&D>HLRICRF>HLRI
GD032	User Guidelines for HLRI-CRF	Intranet
GD043	Management of freezer alerts and emergency transfers	Intranet
RAC/RD/ TBR/001	Blood Collection	Datix
RAC/RD/ TBR/007	Transport of Relevant Material	Datix
RAC/RD/ TBR/004	Fresh samples collection	Datix

Policy Number	Document Name
DN737 and 015	Infection Control
DN257	Dress Code & Uniform Policy
DN115	COSHH
DN289	Health and Safety

DN361	Tissue Bank
DN483	First Aid at Work
DN046	Lone Worker
DN150	H&S Inspection
DN375	Waste Management
DN418	Medical Devices – Decontamination of Medical Electrical Equipment prior to Maintenance or Repair - Procedure
DN292	Medical Gases

Appendix 2: Contact details for dealing with laboratory related issues:

	Contact name /Source of information	Contact details
Estates	Helpdesk phone for urgent request, and non-urgent requests via email or online portal	Help desk (01223) 639000 Helpdesk.papworth@skanska.co.uk
Outpatient cleaners	Operational Policy – Royal Papworth Outpatient Department v7.6	
Nurse in charge of Outpatients	Rota for this	Ask at Outpatient Reception
Infection Control	https://staff.royalpapworth.nhs.uk/ infection-control-ipc-contacts	papworth.infectioncontrolpractitioner@nhs.net
H&S/Risk	Dinusha De Silva	(01223) 639846
Skanska	helpdesk.papworth@skanska.co.uk	extension 639000
Occupational Health – e.g. needlestick injury	https://staff.royalpapworth.nhs.uk/occupational-health	(01223) 216767 – needlestick/sharps/splashes/ injuries
Contact for problem with safety cabinet	Primary contact Aline Demartino Secondary contact Julia Knight	aline.demartino@nhs.net R&D mobile: 07384242714 Julia.knight2@nhs.net (01223) 638075
Contact for problem with centrifuges	Tissue Bank team or Aline Demartino for hospital lab areas. Secondary contact Julia Knight For HLRI -CRF contact Federica Occhipinti Secondary contact Jenny Castedo	aline.demartino@nhs.net R&D mobile: 07384242714 Julia.knight2@nhs.net (01223) 638075 Federica.occhipinti@nhs.net (01223) 639220 jenny.castedo1@nhs.net
Contact for arranging repairs to RPH equipment	Primary Contact: Pathology Research Assistant (TBC) Secondary contact Stephanie Wilmott	**TBC** Stephanie.wilmott1@nhs.net
HLRI CRF contacts	Federica Occhipinti (Laboratory Coordinator) Jenny Castedo	Federica.occhipinti@nhs.net (01223) 639220 Jenny.castedo1@nhs.net
HLRI histology lab & facilities Co-ordinator	Ian Horan	Contact for reporting any concerns (01223) 768312 iph21@medschl.cam.ac.uk

Appendix 3: Guidelines for completing COSHH assessments

The COSHH Regulations (Guidance on the Control of Substances Hazardous to Health Regulations 2002) lay down the essential requirements and a sensible approach for the control of hazardous substances and protecting people exposed to them.

1. During study set up a sponsor should provide a COSHH assessment for any chemical that is trial specific, and that sponsor form can be used for the study in association with study-specific risk assessments.

2. If it is a chemical that will be used department wide (and not just study specific) then a general COSHH for the R&D department must be completed.

3. The RPH COSHH template also contains a section for risk assessing the use of the chemical at Papworth. If one has not been completed before, or the documentation supplied by a study sponsor is not deemed sufficiently detailed, then a new COSHH assessment should be completed. Completion of the COSHH should be undertaken by the member of staff using the chemical using the DN115 for guidance and the online COSHH tool:

   Getting started - COSHH e-tool

4. This assessment will need to be reviewed and validated by a second member of R&D staff. This is usually the line manager or a team leader. However, if they do not have suitable expertise to review a specific assessment then one of the following:
   - Stephanie Wilmott
   - Julia Knight
   - Victoria Stoneman
   - Dawne Amato
   - Marie (Chet) Malgapo
   - John Mammarapallil
   - Georgia Moule

5. Once the assessment is validated it should be uploaded into IQM and a paper copy should also be kept in the relevant laboratory location.