

Menzies Institute for Medical Research and Faculty of Health, University of Tasmania

Clinical Research Facility Users' Manual



Version 2

14/03/2017

This Manual, and all related attachments are available at
S:\\utas\\health\\Shared\\Resources\\MS1\\Clinic.

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1. About the Clinical Research Facility

The Clinical Research Facility at the University of Tasmania's Medical Science Precinct is a state-of-the-art, purpose-built facility for undertaking participant-based health research, as well as providing services to the public. The clinic is available for use by researchers from Menzies Institute for Medical Research (Menzies), the Faculty of Health (FoH) and other approved projects.

The Clinic is located on Level 3 of the Medical Science Precinct building. It is governed by the Clinical Research Facility Governance Committee, which reports to the Menzies/Faculty of Health Senior Management Teams. This Committee determines the rules and regulations governing Clinic use. These rules are enforced by the Clinic Coordinator.

This manual aims to inform Clinic users of how the facility is used and the rules under which it operates. While within the Clinic, all Clinic users must take reasonable care for their own health and safety, as well as the health and safety of others around them. They must comply with UTAS Work Health and Safety (WHS) protocols as outlined in this manual and located on the UTAS WHS website. Each Clinic user, including project investigators, staff, students and volunteers are expected to adhere to the rules contained in this manual, and ensure that they are adequately trained in the tasks they are to perform in this area.

For any enquiries relating to this manual, please contact the Clinical Research Facility Coordinator, Laura Quittenden 6226 4280 (Laura.Quittenden@utas.edu.au).

2. Contacts

For all *Clinic related matters*, including hazard reporting, maintenance, spills, safety, ordering, inductions or storage, please contact:

Clinic Reception	x4287
Clinic Coordinator Laura Quittenden	x4280/0457 350 451

In the event of a *serious or life threatening* situation, please contact:

Ambulance/Police/Fire Service:	0-000
MSP security	x4672 (can be called after hours)
UTAS security (outside working hours)	x7600

For *building faults and maintenance* issues requiring immediate attention, please contact Commercial Services & Development (CSD):

Jarrold Coad – Building Operations Manager	x7369/0409 435 783 (can be called after hours)
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For *First Aid Assistance*, please contact Designated First Aid Officers (or Security x4672):

Julie Harris	x2672	L2 Tech Office (Rm 226/teaching labs)
Geoff Phillips	x4818	L2 Tech Office (Rm 226/teaching labs)
Alina Heikkila	x1918	Level 3, SoM Admin, 303-14.
Jenny Smith	x8513/0417 111 964	L2 Tech Office (Rm 226/teaching labs)
Laura Quittenden	x4280	L3 MS1
Tim Albion	x7722	L4 MS2
Griffin Blizzard	x4688	L4 MS2 Menzies Administration
David Steele	x7147	L5 MS1 Technical Office
Sarah Kane	x4659	L5 MS1 Technical Office

In the case of a fire, the Fire Wardens for the Clinic are:

Roxanne Maher	x7713
Laura Quittenden	x4280
Kirby Donaldson	x4767

Other useful numbers include:

MSP Reception	x7700	IT Support	x1818
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3. Clinical Research Facility layout

Please see Attachment 1 for a map showing the full layout of the Level 3 MS1 Clinic space. There are three entrances into the restricted Clinic area. One is through the Clinic reception, one from the MS1 central stairs leading to the Clinic tea room, and one from the fire stair foyer connecting MS1 to MS2. Access can also be gained through the cardiology office space (302) and the level 3 Clinic office space (338). A proxy card is required at each of these entry points.

a. Reception

All visitors to the Clinic must first report to the Level 1 MSP reception, and then to the Level 3 Clinic reception area. The level 3 reception volunteers contact the employee who the participant has an appointment with. The employee then greets participants in this area. The reception area is not restricted access, and nor are the access toilets located to the right of the lift (when facing them).

b. Volunteers

The Clinic reception area is run by a small team of volunteers, who coordinate participants and general public coming into the facility. Volunteers also assist with the day-to-day restocking of consumables, linen, cleaning of the tea room, and general tidying and organising of the Clinic. If you would like to discuss any aspects of our volunteer program, including the potential to engage with volunteers in any of your research projects, contact the Administration Manager, Amanda Sartori, or the Administration Officer, Griffin Blizzard.

c. Telephones

Telephones are located in the Clinic tea room (337), nurses station (378A), reception (301), blood lab (329) or group room (319). There are phones that allow users to login in the Clinic office space (338A). All computers in the MSP have Skype for Business capability, and external calls can be made from computers after logging in with UTAS credentials.

d. General Clinic rooms

Clinic facilities include interview, procedure and examination rooms, with a variety of equipment such as adjustable beds, tables, chairs, computers or exercise equipment. Medical oxygen and air lines are available to many of these rooms. There is also a blood room, blood laboratory, drug room (for investigational product storage) and two compactus' (for storing confidential files).

e. Blood room

The blood room (327) is a custom-designed room for venepuncture. The room holds a number of phlebotomy chairs as well as equipment (trolleys, blood pressure machines and an Accuvein). Only trained phlebotomists are permitted to take bloods in this room. This room is a separate area with restricted proxy card access from the general Clinic area. For access to the room, please contact the Clinic Coordinator to organise a separate induction with the blood room manager.

f. Blood laboratory

The blood lab (329) is a custom-designed room for initial processing of samples taken from study participants/patients. The room contains two BioSafety cabinets for aliquoting substances, as well as a number of centrifuges for serum separation. Lab coats/gowns and gloves must be worn when carrying out tasks. Samples can then be transported to the -80 °C freezer or fridge (located in adjacent room 329a) for storage/before transport. There is also a packaging area with eskys, thermopacks and biohazard bags for transporting potentially biohazardous substances (329b). The blood lab is a separate area with restricted proxy card access from the general Clinic area. For access to the room, please contact the Clinic Coordinator to organise a separate induction.

g. Drug room

The drug room (328) is a separate area with restricted proxy card access from the general Clinic area. Within the drug room (328), a fridge and ambient wine cooler are provided to store investigational products depending on their temperature requirements. Both fridge (temperature 3-8°C) and wine cooler (16-21°C), as well as the shelving area (15-25°C) within that room are temperature monitored by the Clinic Coordinator. Temperature reports are circulated to drug room users at the beginning of each month. For more information regarding project requirements for drug room storage and/or temperature monitoring, please speak to the Clinic Coordinator. You will need to complete a short MyLO induction for access.

h. Compactus

There are two Compactus' located in MS1 Level 3. One Compactus (331) is located within the restricted Clinic area. This is for Clinic users mid-term storage of study data and confidential files. The other compactus is located in the foyer that connects MS1 to MS2 (333), and can be utilised by non-Clinic users. Each of these rooms is on individual proxy card access from the general Clinic area, and require approval before use. For access to either area, please contact the Clinic Coordinator to complete a short MyLO induction. If you require a key for the Compactus, the Clinic Coordinator also issues these. Racks for shelving can be obtained through Commercial Services & Development (CSD).

i. DEXA and MicroCT

The clinic contains a DEXA bone density scanner and a MicroCT (326 and 336). Both of these can only be operated by registered radiographers. If you wish to utilise these facilities, please contact the registered Radiographers who use the equipment. Contact the Clinic Coordinator for more information.

j. Walking track

The hallway (377) is used as a 25 metre walking track for testing gait and exercise/walking capacity in various research projects. Please be aware that participants using the walking track have 'right of way'. When the area is in use, please avoid it. There are mirrors located on the walls near all entrances and doorways adjacent to the walking track. Please make use of these mirrors when entering the walking track.

k. Nurses station

The Clinic nurses station is demarked 378a. This area includes a telephone for emergency call outs, a computer for usage by Clinic users, an Automated External Defibrillator (AED), a glucometer, scales, a stadiometer, and a number of folders containing important information for Clinic users. These include WHS policies, Task Risk Assessments and Safe Work Procedures for all activities being carried out in the facility, as well as Safety Data Sheets (SDS) for all chemicals used in the Clinic (these are also available at S:\utas\health\Shared\Menzies\Clinic\General Clinic\Work Health & Safety (WHS)\Clinic Risk Assessments).

l. Toilets

There are female, male and access toilet facilities available for study participants and Clinic users in rooms 341, 342 and 343. The access toilet is within the reception area (not a restricted area). The male and female toilets are within the proxy card access only area, and may be used by participants or Clinic users. There is also a shower available for participants after exercise testing (room 324). This shower is not for general staff use. Staff should use the available showers in the facilities provided on Level 1 of the MSP.



m. Tea Room

There is a tea room available for Clinic participant use before or after procedures conducted in the Clinic, or while waiting for an employee. The tea room (337) has tea and coffee making facilities and a fridge and microwave. Projects may use the fridge to store food if supplying catering for participants. Clinic users may also utilise this area, though participants have priority.

n. Gym

The gym is located in room 332, and is a separate restricted swipe card area. It contains a number of exercise machines as well as weights and fit balls, and is maintained by CSD. A separate MyLO gym induction is required for access to this room. While priority access to this room is provided to researchers to undertake studies, the room can be utilised by all staff members, PhD students and volunteers for private use. Please contact the Clinic Coordinator or gym manager, Martin Schultz (Martin.Schultz@utas.edu.au) for an induction.

4. Rules for gaining access to the Clinic

The Clinic is an area restricted by proxy card access. All users (including staff, students and volunteers) need to go through induction procedures overseen by the Clinical Research Facility Governance Committee and enforced by the Clinic Coordinator, before access is gained. Within the facility, further restricted areas need a secondary clearance by the Clinic Coordinator/room manager. These areas are the two Compactuses, drug room, gym, blood room and blood lab. Further inductions or instructions apply to these areas and access will not be granted without certain conditions being met. There is an annual access review by the Clinic Coordinator for all areas, to ensure that only those requiring access to any area in the Clinic have access. Similarly, every three years, there is a review of inductions within the facility. Attached (Attachment 2) is a checklist for gaining access to the Clinic for new users/projects.

a. Protocol for new project internal approval

New projects must go through an internal approval process, as set out by the Clinical Research Facility Governance Committee. This includes consultation with the Clinic Coordinator, preparation of a project summary (Attachment 3) for all new projects, and inductions of all staff related to the project. All users must also prepare or review Task Risk Assessments and Safe Work Procedure forms for all activities to be undertaken in the Clinic. These documents ensure that the Clinic is maintained in a safe and effective manner, ensure that there is sufficient space and resources to accommodate the project/use of the facility.

Before any project can use the facility/make room bookings, the project summary and any new Task Risk Assessment/Safe Work Procedure documents must be forwarded to the Clinic Coordinator and the Chair of the Clinical Research Facility Governance Committee for review. Once approved, the Principal Researcher, or Research Coordinator will receive a confirmation email advising approval. The MSP reception will be notified to allow booking of rooms for the project.

b. Induction process for access

As a requirement of entry to the Clinic space, as mandated by the Clinical Governance Committee under the direction of UTAS WHS guidelines, all people with access to the area must be properly and consistently inducted. The exception is when the person is entering under the direct and continuing supervision of an inducted person and is authorised to be in the Clinic (e.g. contractors, service technicians, monitors, visitors invited to view the facility, etc.). This is to ensure a safe environment and workplace by making certain that everyone is aware of the policies and procedures that govern the workspace. There are a few steps in the induction process.

Firstly, all users must complete a MyLO induction module (to gain access to this, contact the Clinic Coordinator). Thereafter, the new user must complete a clinic orientation with the Clinic Coordinator, completing the attached form (Attachment 4). After these two steps are complete, the new user must review/create Task Risk Assessment and Safe Work Procedure documents for all intended tasks before they are undertaken. Managers/supervisors must also formally confirm that each person under their supervision requires access and that they are responsible for the person being adequately trained and competent to undertake tasks before they commence doing so in the Clinic. After this confirmation, the Clinic Coordinator will notify MSP Security to provide swipe card access.

The Clinic Coordinator (at the point of approving access), also notifies ITS to allow access to the Clinic folder on the S drive, where important Clinic-related WHS Policies, Task Risk Assessments, Safe Work Procedures and chemical SDS are located (S:\utas\health\Shared\Menzies\Clinic\General Clinic\).

Out of hours access is available for Clinic users with proxy card permissions. Users must enter via the MSP main entrance and sign in with MSP Security.

c. Task Risk Assessment and Safe Work Procedure documentation

Task Risk Assessments and Safe Work Procedure documents are to be filled in for all activities undertaken in the Clinic, for compliance with the *Work Health and Safety Regulations 2012*, and the *UTAS Minimum Standard – Work Health and Safety Project and Task Risk Management*. Task Risk Assessments identify risks associated to specific workplace tasks or equipment, and must be completed before the commencement of any new use of equipment or task, or where a task differs considerably since last the work was performed. These documents must be completed by a person who has knowledge/experience relevant to the task being carried out (templates in Attachments 5 and 6), and need to be updated every three years. Before undertaking any task, the documents must be approved by the Chair of the Clinical Research Facility Governance Committee. This forms part of the internal Clinic approval process, and is essential for compliance with UTAS WHS Policies. Current up to date TRA/SWPs for all Clinic tasks can be found in the Clinic folder on the S drive:

S:\utas\health\Shared\Menzies\Clinic\General Clinic\Work Health & Safety (WHS)\Clinic Risk Assessments.

As part of ongoing Clinic access, users will be asked intermittently to review and update TRA and SWPs by the Clinic Coordinator.

d. Good Clinical Practice

Good Clinical Practice (as standardised in the ICH-GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting trials that involve the participation of human subjects. It ensures that the rights, integrity and confidentiality of trial subjects are protected, as well as assurance that the data and results are credible and accurate. The guideline was developed by international regulatory authorities (e.g. US, Europe and Japan) to harmonise the conduct/reporting/recording of clinical trials. The principles outlined in GCP are applicable to clinical investigations that may have an impact on the safety and well being of human subjects.

It is University of Tasmania policy that all Clinical Trial Investigators must complete GCP training and forward their GCP training certificate to the Research Integrity and Ethics Unit at ethics approval stage. The Principal Investigator is responsible to train all staff/students/volunteers that are involved in clinical trials.

As part of the Project Summary preparation for clinic access, Investigators will need to assure the Clinic Coordinator that both themselves and all staff/students/volunteers who will be involved in clinical trials in the Clinic have undergone GCP training. Please contact the Clinic Coordinator for more information.

e. Induction process for access to blood lab and blood room

There is a separate induction process for proxy card access to the blood lab and blood room. The induction to the blood room and lab involves a walk through the joint area and the completion of MyLO induction modules associated with them. Please adhere to Safe Work Procedures in these areas at all times. Contact the Clinic Coordinator for further information. As a requirement of entry to these areas, users must provide the Clinic Coordinator with evidence of their immunity to Hepatitis B. Please note that children are not permitted in the blood room unless under direct constant supervision, and children are not permitted in the blood lab at all.

5. General rules

a. General rules in the Clinic

The following standard procedures apply in the restricted Clinic area:

- All proxy card access doors must be kept closed (do not prop doors open).
- Infection control procedures must be adhered to.
- Equipment must not be used without permission and adequate training.

b. Infection control

Everyone with access to the Clinic area must complete the Hand Hygiene Australia short theory module on hand washing. Hands should be rubbed with Debug solution before and after contact with participants (regardless of whether gloves are worn or not) and after a procedure or body fluid exposure risk. Alcohol based hand rub (Debug) is less time consuming and is more effective than washing hands with soap and water. Hand washing with Avagard is only necessary if hands are visibly soiled.

It is important that surfaces and surroundings are kept clean and spills of biohazardous substances are cleaned up as soon as possible. The blood room (327) and lab (329) are the areas most likely to be affected by this, but any area where samples are collected should also be considered as at risk areas. The use of Isowipes, 70% Ethanol, and Viraclean is encouraged.

c. Common use items and ordering guideline

There are a number of common use items that the Clinic Coordinator orders for Clinic use, located in the supplies room 335. These items include gloves, hand hygiene items, tissues, band aids, blue liners, etc. Each group is responsible for their own study specific equipment calibration, ordering and finance (e.g. needles, syringes, tubes, freezer boxes, etc.).

For ordering of project-based consumables outside of the scope of the common use items, please use the ordering template located at S:\utas\health\Shared\Resources\MS1\Orders Folder. Please forward the completed form to MSP purchasing (msp.purchasing@utas.edu.au). There is a document within this folder with preferred suppliers, as well as catalogues from some of these suppliers.

d. Cost recovery

Cost recovery for the Clinic operates for all projects using the Clinic area. Costs covered by this include common use items, and calibrations of general-use equipment (scales, stadiometers, blood pressure devices, centrifuges, etc.). Costs are recovered based on the size of the projects, designated as small, medium or large. A small project is, on average, up to 2 hours average use per week; a medium project is, on average, between 2-10 hours Clinic usage a week; and a large project is, on average, 10 or more hours Clinic usage a week. This is based on reports generated from the booking system as well as from initial project summary documents, and is charged once per year.

6. Equipment

a. General equipment

The Clinic has available a number of general equipment items that are maintained and calibrated by the Clinic Coordinator for use by Clinic users. These include blood pressure devices, scales, stadiometers, centrifuges, dynamometers and thermometers, as well as an Accuvein in the blood room. There is also an ice machine located in the support lab room 329a. The Clinic Coordinator has an equipment manifest which can be used if project would like to borrow equipment from other groups.

b. Project equipment storage

For all other equipment necessary for projects, the study must purchase or borrow their own equipment and organise any servicing and calibration. There are storage areas available for both small and large equipment items within the restricted Clinic area, which can be discussed on internal application for Clinic use, through the project summary. Items are to be stored in these designated storage areas, not left in rooms unless authorised by the Clinic Coordinator. The Clinic Coordinator keeps track of available storage spaces. If equipment is left in the Clinic after the project is completed (and not removed after a period of six months), the Clinic Coordinator will consider it general Clinic equipment. Please see the Clinic Coordinator for more information.

c. -80°C Freezer

There is a -80°C Thermo Scientific freezer located in the support lab room 329a. It is managed and serviced by CSD. This freezer is for short-term storage only. Samples that need to be kept for longer than three months should be re-located to either the basement freezers or those on Level 5. Please speak to the Laboratory Manager (David Steele) for relocation of samples to these freezers.

In order to maintain the temperature within the freezers, please ensure that the door is not open for more than 30 seconds. The temperature is logged by the freezer software, and if it increases above -75°C, an alarm sounds to the Facilities Manager (Mark Burgess) as well as MSP security.

All samples need to be labelled clearly with the study name. This is to prevent loss of samples if a box is accidentally dropped during an emergency move (i.e. if temperature drops or the freezer breaks down). All sample boxes should be labelled with the study name, research group, contact person and phone number. The study details and contact person also need to be documented on the freezer plan located on the front of the freezer to enable removal of specimens if there is a breakdown. All specimens should be placed on racks in boxes to maximise the efficiency and maintain the temperature of the freezer.



d. Fridge

There is a fridge located in the support lab room 329a for Clinic users. This fridge is for short-term sample storage only, and space is limited. If you need to keep samples cold for long term, please speak to the Laboratory Manager (David Steele) for their relocation.

7. Room bookings

Rooms in the Clinic must be booked prior to use. Room bookings can be made through MSP level 1 reception (MSP.Reception@utas.edu.au or x7700) or by a nominated person within each study (as part of the internal approval process). Rooms may not be booked by groups that have not undergone the internal approval process, or without approval through the Clinic Coordinator.

8. Parking

There is limited free parking available for Clinic participants. Spaces 1 – 11 below the MSP are reserved for Clinic participants (off Liverpool street). The participants must report to MSP Level 1 reception on arrival to report the parking bay number they have used, along with their name, phone and registration numbers to avoid a fine. There are also several access parking spaces in the same area that are available for participants.

9. Emergency procedures

a. Duress alarms*

Duress alarms are located throughout the Clinic facility in a number of rooms. They are white oblong devices either on walls or on/under desks. To use a duress alarm put your finger in the hole, and push up. Duress alarms are present to alert both MSP security (automatically on activation) and immediate Clinic users (via an audible alarm and light) the need for assistance due to a personal threat or medical emergency. The alarm will continue until it is reset by security. Duress alarms located under desks are discreet: they will notify security but not produce an audible alarm.

*If you accidentally dislodge the alarm cable from the wall socket, you will hear the audible alarm sound: please reinsert the cable into the wall socket and the alarm will cease.

b. Evacuation plans

In the event of an evacuation (fire, threat, etc.), you will be given instructions via the public announcement speakers. Fire wardens (listed in Section 2) will direct you through the buildings. There are two emergency exits from the Clinic area: the main central stairwell near Clinic reception, and the fire stairs before the fire doors leading from MS1 to MS2.

In the event of an evacuation, please move quickly and carefully from the Clinic rooms to these stairwells as per Attachment 7. Do not run. Please be aware of the position of the exits to the Clinic from all work areas. Please see Attachment 7 for the assembly point after an evacuation. Please do not use the lifts.

If you are the first person to find a fire or smoke, call the fire service (0 000) and then notify security (7600), as well as the Clinic fire wardens (listed in Section 2).

There is a wheelchair located in the access toilets (room 343 in reception area) for use by people with limited mobility or people who are disabled/injured. Please position such people in the wheelchair against the wall at the top of the central MS1 stairwell (3011) or the fire stair landing (375), level 3 (to not block stair access), and notify the fire warden. The fire fighters will assist with their evacuation from that point.

c. First Aid

In the event of a first aid emergency, please call 000, then contact the closest Designated First Aid officer (listed in Section 2) to attend, or activate a duress alarm (located in each Clinic room). This will alert MSP security of the need for assistance, and they will attend immediately.

There are two first aid cabinets located in the Clinic: One in the office space (340), and one to the right of the central stairwell door near the tea room. Designated First Aid officers are also listed next to these cabinets.

An Automatic External Defibrillator (AED) is located at the nurses' station in the Clinic to be used in the event of a cardiac arrest. The AED is wired to the security system and whenever the door to its case is opened, security will be notified, attend the site and call 0 000. The AED is fully automated and will give clear voice instructions to the operator.

d. Fire extinguishers

There is a fire blanket on the wall in the tea room along with a fire extinguisher. Another fire extinguisher is located in the Clinic toilet hallway. Fire hoses and hydrants are located in the area adjacent to the lifts in reception, and the area where MS1 meets MS2 (Level 3). A fire phone is also located in this area.

10. Waste disposal

a. Sharps

Sharps are materials capable of causing cuts or injury, such as glassware and needles. Please dispose of all sharps into designated sharps containers (in most Clinic rooms). Always move the sharps container to your work place to dispose of such items, do not walk around carrying sharps. If a sharps container is full, please secure lid, and deposit into the biohazard waste bin (located in the dirty utility area, 329b, opposite -80°C freezer) for specialist disposal. Do not push sharps down into containers, or put fingers into the sharps containers. New sharps containers are located in the supplies room (335).

b. Biohazard waste

Biohazard waste bins (located in the blood lab, dirty utility area 329b) are for the disposal of equipment contaminated by biological substances. Materials to be deposited into the biohazard waste bins include pipettes, tubes, tips, cloths, contaminated gloves, or paper towels used to clean up biological spills. All Users are responsible for changing the biohazard waste bags, which are to be deposited into the large biohazard waste bin (located in the dirty utility area, 329b, opposite -80°C freezer) for specialist disposal. New yellow biohazard bags are located in this same area, in the cupboards.

c. General purpose bins

General purpose bins are present for the disposal of non-contaminated waste such as hand washing paper towel, and gloves that have not been contaminated with blood or bodily fluids.

d. Chemicals

Please read the SDS for appropriate disposal procedures for each chemical. This should be included in the chemical Risk Assessments located in folders in the blood lab and nurses station. SDS for chemicals used in the Clinic are also listed in the S drive (S:\\utas\\health\\Shared\\Menzie's\\Clinic\\General Clinic\\Work Health & Safety (WHS)\\SDS).



11. Cleaning

The Clinic general area is cleaned each day by external cleaners, as organised through UTAS Commercial Services & Development (CSD). If there are any problems with the cleaning of the general area, please contact the Clinic Coordinator.

a. General Clinic areas

General cleaning of work areas should be undertaken by the person using them. Please keep the Clinic rooms neat and tidy, pack away all Clinic items after use, and take personal/project specific items with you. Please ensure that participants take all belongings with them. There is a Clinic-only wet and dry vacuum cleaner, as well as a general use mop and bucket and dustpan and broom located in the dirty utility room (329b). The instructions for use of the vacuum are located on the wall above it.

b. Blood room and blood lab

The blood room and lab (rooms 327 and 329) floors are cleaned, along with general bins emptied by the cleaners. However, lab benches and blood chairs must be wiped down by the Clinic user after use. It is the responsibility of all users to appropriately clean (with 70% ethanol) kidney dishes, tourniquets and squeeze balls after use, along with lab benches and blood room chairs and trolleys. BioSafety cabinets must be cleaned before and after use with 70% ethanol.

All biohazardous waste must go into the biohazard bins located in these areas. All sharps must be placed into the sharps containers. Both sharps containers and biohazard waste bags must be placed in the biohazard waste bin in the dirty utility area (329b, opposite -80°C freezer) for specialist disposal once full. Replacement biohazard waste bags are located in the cupboard in the dirty utility room. Replacement sharps containers are located in the supplies room (335). It is the responsibility of all Clinic users to dispose of these items in this way. The Clinic Coordinator will empty the biohazard waste bin once full: if you notice that it is full, please notify the Clinic Coordinator. There is a blood room/lab specific mop in the dirty utility area.

c. Blood spills

Any blood spills must be dealt with immediately. For spills inside a BioSafety cabinet, keep the BioSafety cabinet on, remove gloves and disinfect hands (Avagard/Debug), and replace with new gloves. Mop up the spill with paper towel and dispose of these in the biohazard bin, and spray the area with Viraclean. Leave this on for ten minutes. Wipe hands thoroughly with 70% (w/w) ethanol or Debug. Turn off the cabinet and engage the UV light (with UV screen protection in place). Consult with your supervisor or Clinic Coordinator on further action.

For spills outside a BioSafety cabinet, notify nearby personnel, contain the spill using a spill kit and/or absorbent towels. Dispose of these in the biohazard bins. Cover with Viraclean, and leave for ten minutes. Remove any contaminated clothing, disinfect hands, and other exposed body areas with Debug. Notify your supervisor and Clinic Coordinator.

For spills within the centrifuge, keep lid closed for 30 minutes to allow aerosols to settle, and notify nearby personnel. Remove tubes and excess spill with paper towels, and soak/clean rotor using Viraclean.

d. Linen

It is the responsibility of all Clinic users to change linen after use. Please remove linen/towels from all beds/pillows and place in the green linen bags in the storage cupboard (320). Once these bags are filled to the white line, please change the bag, tie up the full one, and place to the right of the

cupboard. Linen bags for dirty linen are located in the blood room, and in the linen cupboard 320. Dirty linen is collected by Blue Line Laundry (organised through CSD), who wash and return linen each week. The clean linen is returned to the cupboard by the volunteers.

12. Chemical safety

When handling hazardous chemicals, please follow all safety protocols as outlined in the Safety Data Sheets (SDS: In folders located at the Nurses station and in the blood lab), including the use of Personal Protective Equipment (PPE) and how to clean up individual spills. Please read and understand the chemical Risk Assessment (in folders located at the nurses' station and in the blood lab) before using any chemical within the Clinic. If you are unsure about handling chemical substances, please consult your supervisor or the Clinic Coordinator (Laura Quittenden). Please be aware of the flammability of the chemicals you are using, and do not expose them to heat or flame.

In the case of a chemical spill, spill kits are located in the blood lab, under the sink. Please notify the Clinic Coordinator in the case of a chemical spill. All spills must be cleaned up immediately after they occur to avoid slipping hazards. Always wear PPE before cleaning chemical spills.

All chemicals used in the Clinic are listed in a chemical manifest using ChemWatch. For access to this list, please ask the Clinic Coordinator. All chemical SDS and Risk Assessments are available on the S drive: S:\\utas\\health\\Shared\\Menzies\\Clinic\\General Clinic\\Work Health & Safety (WHS)\\.

13. Biological safety

Always assume that biological substances (such as blood, urine, saliva) are infectious and handle accordingly. Please only open containers containing such substances in the blood lab BioSafety cabinets (for aliquoting, adding of preservative, etc.). Never mouth pipette biological substances. Never eat or drink in the blood lab. Please follow all induction protocols in the Clinic pertaining to hand hygiene and PPE to avoid contact with biological substances, such as with needle stick injuries.

Any major spills must be reported immediately to the Clinic Coordinator. Action must be immediately taken to clean up any biological substances.

Please abide by the hand hygiene protocols as outlined in safety inductions: there are hand disinfection facilities in each of the Clinic rooms, including Debug hand hygiene solution and hand wash stations.

The Class II BioSafety cabinets in the blood lab provide complete protection from aerosol exposure, while also preventing release into the environment of aerosols. These are the only are in the Clinic where potentially biohazardous samples may be opened/aliquoted.

14. Electrical safety

The University has an 'Electrical Safety in the Workplace Policy' which is available on the UTAS WHS website. Electricity is dangerous and should be treated with respect. Be on the lookout for any exposed wires, damaged insulation of equipment or extension leads, wet conditions in an area where equipment is being used, or fire. Do not use double adaptors or power boards within the Clinic. Do not attempt to rewire plugs or sockets. Please report any faults or any problems with electrical equipment to the Clinic Coordinator who will organise repair/installation. There is a testing and tagging procedure in place to check the electrical safety of all equipment that is present in the MSP. Do not use any equipment that does not have an 'in date' tag. If you see equipment that has an 'out of date' tag, please notify the Clinic Coordinator.

Within the Clinic, the procedure rooms are Body Protected Electrical Areas – meaning any procedure being conducted using an electrical medical device needs to be done in those rooms. The mini-theatre is a Cardiac Protected Electrical Area, and in this room only, cardiac-related electrical procedures (involving electrical currents applied to the heart) can be conducted.

15. Reporting of Hazards, Accidents and Incidents

A hazard is anything in the workplace that has the potential to harm people. If you are the first person to recognise a potential Hazard in the Clinic area, please do what you can to contain, control or minimise the hazard, alert other people to the hazard and contact the Clinic Coordinator. An accident/incident is any unplanned event resulting in, or having a potential for injury, ill health, damage or other loss.

All hazards, accidents or incidents need to be documented via the UTAS WHS website. The Clinic Coordinator inspects the Clinic area on a bimonthly basis for any faults/Hazards, which are reported through the UTAS WHS website or CSD for non-hazard work requests. As such, if you notice a hazard, the Clinic Coordinator can assist with reporting it. This is also relevant to 'near misses', which are safety hazards that have been identified that could potentially lead to incidents in the future. Incidents, hazards and near misses must be reported as soon as reasonably practicable. For further information, please contact the Clinic Coordinator, or Health and Safety Representative for MSP.

16. Abbreviations

CSD	Commercial Services & Development
MS1	Medical Science Precinct Building 1
MS2	Medical Science Precinct Building 2
MSP	Medical Science Precinct
PC2	Physical Containment Level 2
PPE	Personal Protective Equipment
SDS	Safety Data Sheet
SWP	Safe Work Procedure
TRA	Task Risk Assessment
UTAS	University of Tasmania
WHS	Work Health and Safety



Attachment 1 - Clinical Research Facility layout (MS1 Level 3)



Attachment 2 - Checklist for Clinical Research Facility usage

The following checklist (along with the Clinical Research Facility Users' Manual) is designed to help streamline the process of internal approval for new studies wanting to use the Clinic.

- ☐ Contact the Clinical Research Facility Coordinator with your intention of conducting a trial/study within the Clinic.
- ☐ Complete the Project Summary document (after ethics approval has been gained) and return to the Clinical Research Facility Coordinator and Chair of the Clinical Research Facility Governance Committee.
- ☐ Review Task Risk Assessments and Safe Work Procedure documentation for all tasks to be carried out in the Facility, and complete new documentation for any new tasks not covered in the common procedures. Return these to the Clinical Research Facility Coordinator.
- ☐ Ensure that all staff/students/volunteers are appropriately trained before using the Facility for these tasks.
- ☐ Ensure that all staff/students/volunteers are appropriately trained in Good Clinical Practice before initiating Clinical Trials.
- ☐ Arrange a time for all staff/students/volunteers to be inducted into the Facility with the Clinical Research Facility Coordinator. Ask the Clinic Coordinator for access to the inductions on MyLO.
- ☐ Arrange a time for all staff/students/volunteers to also be inducted into the blood room and blood lab if necessary.
- ☐ Ensure that you have access to the Clinic Folder (S drive), and familiarize yourself with the relevant WHS documents therein.

Resources at: S:\\utas\\health\\Shared\\Resources\\MS1\\Clinic.

Attachment 3 - New Clinic user project summary and approval document

PROJECT SUMMARY AND APPROVAL DOCUMENT

Part A: Project Summary

1. Full project name and any related acronyms:
2. Brief project overview/summary:
3. Name of Faculty/School/Institute 'responsible' for project:
4. Principal/Chief Investigator details (name, title, organisation, phone number, email address):
5. List of research team members (staff/volunteers/students) who will be using the clinic and their respective roles in the project (i.e. research nurse/officer, volunteer, external monitor), their phone numbers and email addresses:
6. Staff member that will need to make clinic room bookings and their contact details:
7. A list of project related activities/procedures that will be undertaken in the clinic (for the provision of task risk assessments and safe work procedures. *NB: if procedures listed are not 'common tasks' in the clinic, these documents will need to be prepared*).
8. Timeframe for which the study will require clinic use:

e.g. There will be 2 phases, with n=x in each phase. The first phase will run for 1 month, and the second for 5 months with 2 months in between.
9. Number of participants and the expected participant visit pattern:

e.g. Each participant will have 4 visits to the clinic involving a baseline visit, another at three months another at six months and another at 12 months.
10. Details about which clinic facilities are required: will you/who of your group will require access to the blood room/lab, freezer, drug room, compactus?
11. The room requirements, including the type and number of rooms, and the participant throughput:

e.g. Two procedure rooms for two full days a week, with 12 participants per room per day, every week for 12 months.
12. List of major project equipment (if any) that the project is expecting to house on site including related size and safety information:
13. List of any study specific small equipment/consumables that are expected to be stored in the clinic and any related safety requirements:
14. If this is a clinical trial, please specify the type and amount of investigational product/device that you will need to bring in and store in the clinic.

Part B: Principal/Chief Investigator Declaration

The principal/chief investigator is ultimately responsible for the conduct of their research team members, and the integrity of the research conducted in the clinic.

As such, please confirm the following:

I confirm that all research team members are required to undertake a clinic induction prior to being given access to the clinic, with further inductions for restricted rooms therein.	Y/N
I confirm that ethics approval has been gained for this project.	Y/N
I understand that all clinic users must abide by the rules and regulations governing the clinical research facility (as described in their inductions), including mandatory safety rules, along with policies and guidelines issued by UTAS and Menzies Institute for Medical Research.	Y/N
I confirm that the usage of the clinic for this project will be cost recovered annually to recoup direct research costs.	Y/N
I understand that I am responsible for ensuring that the research team members are appropriately trained and competent to undertake project activities in a safe manner.	Y/N
<i>If this is a clinical trial:</i>	
I confirm that I have completed Good Clinical Practice training current in the last three years.	Y/N
I confirm that all staff/students/volunteers involved in the trial have been appropriately trained in Good Clinical Practice (please contact the Clinic Coordinator for more information/if you need to source such training).	Y/N

Principal/Chief Investigator

Name:

Signature:

Date /..... /.....



Part C: Project Internal Approval

Approval considerations / recommendations	
Appropriate approvals have been gained	Y/N
Principal/Chief Investigator has provided necessary assurances	Y/N
Necessary information provided	Y/N
Estimated clinic user charge	
Clinic capacity considerations	Y/N
Clinic Coordinator recommendation: Approval	Y/N
<p>Dr. Laura Quittenden (signature) Date / /</p> <p><i>Clinical Research Facility Coordinator</i></p>	

Formal Approval	
Project approved as per recommendation	Y/N
Additional matters are to be addressed:	
<p>Prof Bruce Taylor (signature) Date / /</p> <p><i>Chair: Clinical Research Facility Governance Committee</i></p>	



Attachment 4 - Clinical Research Facility orientation form.

CLINICAL RESEARCH FACILITY ORIENTATION

Personal Details:

Please fill out your personal and project details below.

First Name	Last Name	Email Address	The full name of Project/s and acronym	Principal Researcher's name

Role in Project:

.....

Date of Clinic Orientation session: / /

Access requirements and MyLO Inductions:

All users can access the Clinic's general areas rooms and general areas. Other areas are restricted to those who specifically need to utilise those areas. Please tick areas you require access to. Please also tick that you have completed the MyLO Induction Modules for these areas

I require access to:					
General Clinic area	Blood room/Lab (327/329)	Drug Room (328)	Compactus inside clinic (331)	Compactus outside clinic (333)	Gymnasium (332)
(Office use only) I have completed my MyLO inductions for:					

*PLEASE NOTE EVIDENCE OF HEP B IMMUNISATION IS REQUIRED FOR LAB/BLOOD ROOM ACCESS

(Office use only) My Supervisor/Manager has formally approved need for access to:					
Do you need access to the Hot Desk room?					Y / N
Do you need access to the Clinic Booking system?					Y / N



What tasks and procedures will be undertaken in the Clinic area?

Please list every task/procedure (below) that the person will undertake in the Clinic. You will be sent task risk assessments for these tasks if they are common in the Clinic. If they are not common, you will need to create a task risk assessment and safe work procedure document for the task.

**Common task risk assessments are available on the S drive.*

	<i>Procedures/Tasks</i>	Confirm that the person has been provided with the Risk Assessment for this task (initial each below)	Supervisor/manager confirmed responsibility for person being adequately trained and competent to undertake the tasks before they commence doing so in the Clinical Research Facility
1			
2			
3			
4			
5			
6			

Inductee to complete:

I confirm that:

- I understand that I must only undertake the tasks listed in this form;
- My supervisor must provide me with training in all nominated tasks and assess my competence to undertake the tasks; and
- I will not undertake the tasks until competent to do so.

Signature: **Date:** /..... /.....

Clinic Coordinator to complete:

Clinic Coordinator (or delegate) name:

Signature: **Date:** /..... /.....

<i>Office Use Only:</i>			
Supervisor contacted	Y / N	Date:	Security Notified?

Attachment 5 - Template for Task Risk Assessment.

STEP 1.										
Project / Task Name:					Work Area:				Org Unit	
Project / Task Description:									File ID	

STEP 2.		STEP 3.	STEP 4.	STEP 5.	STEP 6.	STEP 7.	STEP 8.			STEP 12.
Ref No.	SPECIFIC TASK / ACTIVITY STEPS	IDENTIFY POTENTIAL HAZARDS	RISK RANKING			RISK CONTROL MEASURES <ul style="list-style-type: none"> Hierarchy of Control – Elimination, Substitution, Isolation, Engineering, Administration, Personal Protection. Additional information can be attached. 	RESIDUAL RISK			Actioner / Initials
			Consequence	Likelihood	Risk Rating		Consequence	Likelihood	Residual Risk	
				STEP 9.		Highest Remaining Residual Risk				

STEP 10.				
Risk assessment prepared by:	Risk assessment trained person =		Date:	/ / 20__



	Other participant names =			
Consultation conducted with:			SWP to be developed?	Yes / No

Residual Risk	APPROVAL REQUIRED TO PROCEED	Approval Signature	Approval Date:
Extreme (E)	Approval must be obtained from a member of the UTAS Senior Management Team such as a Dean before work starts*		
High (H)	Approval must be obtained from the Budget Centre Head/RO before work starts*		
Moderate (M)	Work can commence when a Budget Centre Head/RO or a nominated delegate e.g. Senior Lecturer/Researcher, or University Manager Level person has approved this risk assessment, & all identified control measures are in place.		
Low (L)	Work can commence when an approved University Staff member has approved this risk assessment, & all identified control measures are in place.		
	Organisational Unit Head (or nominated delegate) must approve Risk Assessment if it is used to develop a SWP.		

* Discretion for the Organisational Head/Officer to approve Extreme / High risk work to proceed only applies where there is a risk to production loss/plant. This discretion does not apply to work if the Ext/High residual risk relates to the potential for personal injury or environment risk.

Step 11.

If the Project/Task does not involve any permits and sign-off sheets, or participants are not registered in the Fieldteq database, then all participants must sign on (and sign off when complete if relevant) before they are permitted to be involved in the Project/Task.

By signing below, participants acknowledge they have read and understand the risk assessment and agree to comply with all steps and control measures:

NAME	SIGN ON	DATE	SIGN OFF	DATE	NAME	SIGN ON	DATE	SIGN OFF	DATE

RISK CALCULATOR (Risk Rating = Consequences x Likelihood)

LIKELIHOOD	CONSEQUENCE				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)



Almost Certain (5)	M (11)	H (13)	E (20)	E (23)	E (25)
Likely (4)	M (7)	H (12)	H (17)	E (21)	E (24)
Possible (3)	L (4)	M (8)	H (16)	E (18)	E (22)
Unlikely (2)	L (2)	L (5)	M (9)	H (15)	E (19)
Rare (1)	L (1)	L (3)	M (6)	M (10)	H (14)
STEP	QUICK GUIDE OF WHAT TO DO	MORE DETAILED INFORMATION ON EACH PROJECT/TASK RISK ASSESSMENT STEP			
1.	Complete a description of the <u>Project / Task</u>	<ul style="list-style-type: none"> At the top of the risk assessment record the task name, a brief description of the task, and the relevant work area and section. Keep as simple as possible, but with enough information to identify the task. If the Risk Assessment is being used to develop a Safe Work Procedure (SWP), the risk assessment task name should correspond with the title of the SWP. 			
2.	Detail specific <u>task steps</u>	<ul style="list-style-type: none"> In the first column "Ref No." write the step no. starting from 1. up until however many steps/tasks there are in the task. If applicable, these should align with any associated SWP to enable cross referencing. List each of the specific tasks, activities and/or steps associated with the project that will be undertaken. 			
3.	<u>Identify potential Hazards</u> for each Task/Activity in Step 2. <ul style="list-style-type: none"> Use <i>WHS Hazard Prompt Sheet</i> (Appendix 2) for help. 	<ul style="list-style-type: none"> In the column next to listed tasks/activities, identify all potential hazards relevant to each item. Record each hazard on a separate line. A common mistake is to refer to a hazard as the actual harm or the health effect it caused rather than the hazard. E.g. If the task was hosing down an area, the hazard is the wet floor not the potential harm caused e.g. fall / cut knee. If no hazards are found for a task/step or the risk has been addressed in a previous hazard, the task still needs to be listed to show it has been considered, and to keep the steps/tasks in line with any associated SWP. 			
4.	Evaluate the possible <u>Consequence</u> of the Hazard <ul style="list-style-type: none"> Use Risk Calculator above 	<ul style="list-style-type: none"> Simply put if someone was exposed to the hazard, what would be the reasonable consequence? It is not always the "worst" case scenario; e.g. if you fell 1m off a ladder you could be killed as an extreme (e.g. land on your head), but the most likely consequence would be you might sprain your wrist or break a leg. Therefore the consequence is more likely to be moderate rather than catastrophic. 			
5.	Evaluate the <u>Likelihood</u> of that Consequence <ul style="list-style-type: none"> Use Risk Calculator above 	<ul style="list-style-type: none"> Ask yourself will it ever happen; if so what factors are needed for it to happen, and how often would those factors be around. Then ask yourself what you think the reasonable frequency would be, before determining the Likelihood. 			
6.	Determine <u>Risk Ratings</u> of hazards <ul style="list-style-type: none"> Use Risk Calculator above 	<ul style="list-style-type: none"> Determine each hazard's risk rating by intersecting the "Consequence" and "Likelihood" levels on the Risk Calculator table. For more detailed information on determining risk levels, refer to the Risk Matrix (appendix in Risk Management Policy CORP 13.1). 			
7.	Identify <u>Controls</u> to reduce hazard risk	<ul style="list-style-type: none"> Control measures need to reduce hazard risk ratings to an acceptable level if the current risk level is unacceptable; aim for a low risk. Apply the Hierarchy of Control when determining control measures (refer to Minimum Standard: Risk Management Project/Task – 1.3). 			
8.	Evaluate the <u>Residual Risk</u> (risk rating with controls in place)	<ul style="list-style-type: none"> After control measures have been identified, you need to reassess each hazards risk rating to determine what the remaining risk would be with the controls in place from Step 7 (follow the principles in Steps 4 & 5 above). The aim is to achieve a Low Risk; if not achieved review controls again and/or ask for help. 			
9.	Determine <u>highest remaining residual risk</u>	<ul style="list-style-type: none"> If the highest residual risk on the risk assessment is a Low Risk, or a Moderate Risk the task/project can commence once all control measures are in place and the risk assessment has been reviewed and approved. If a High or Extreme risk still remains, then the task/project must not commence and further review must be undertaken involving the Budget Centre Head/RO or a member of the UTAS Senior Management Team such as a Dean (an Elected Safety Representative should also be involved). <p><i>Exemption: In exceptional circumstances, if the "Ext" or "High" risk rating does not apply to personal injury or environmental damage (e.g. potential for property damage only), and the Budget Centre Head/RO in consultation with the WHS Unit believe it is an acceptable risk for</i></p>			



		<i>the University, the task may be approved. This does not apply for Personal injury or Environmental risks; a "M" (Moderate) risk is the highest ranking allowable.</i>
10.	<u>Approval / SWP development</u>	<ul style="list-style-type: none"> Once the risk assessment is complete, all participants should record their name at the bottom of the sheet, document any consultation that was had (e.g. tabled at WHS Committee) and the Budget Centre Head / RO or delegate should sign off the task for approval. Specify if a safe work procedure (SWP) is required to be developed (e.g. for routine / regular tasks). If yes, this should be done in accordance with the Minimum Standard - Safe Work Procedure Development.
11.	<u>Sign on / off</u>	<ul style="list-style-type: none"> All persons involved in a project/task must acknowledge they have read and understood a risk assessment and agree to comply with all steps and control measures.
12.	Document <u>Actioners</u>	<ul style="list-style-type: none"> Reference the initials of the person responsible for ensuring a particular control is implemented before progressing with the task/project.



Attachment 6 - Template for Safe Work Procedure.

Safe Work Procedure (SWP) Template

Overview of the Task

- Scope
- Authorisation
- Hazards
- Personal Protective Equipment (PPE)
- Emergency Response/First Aid Requirements

Undertaking the Task

- Step-by-step Procedure (including 'Preparation/Precautions')

Document Control

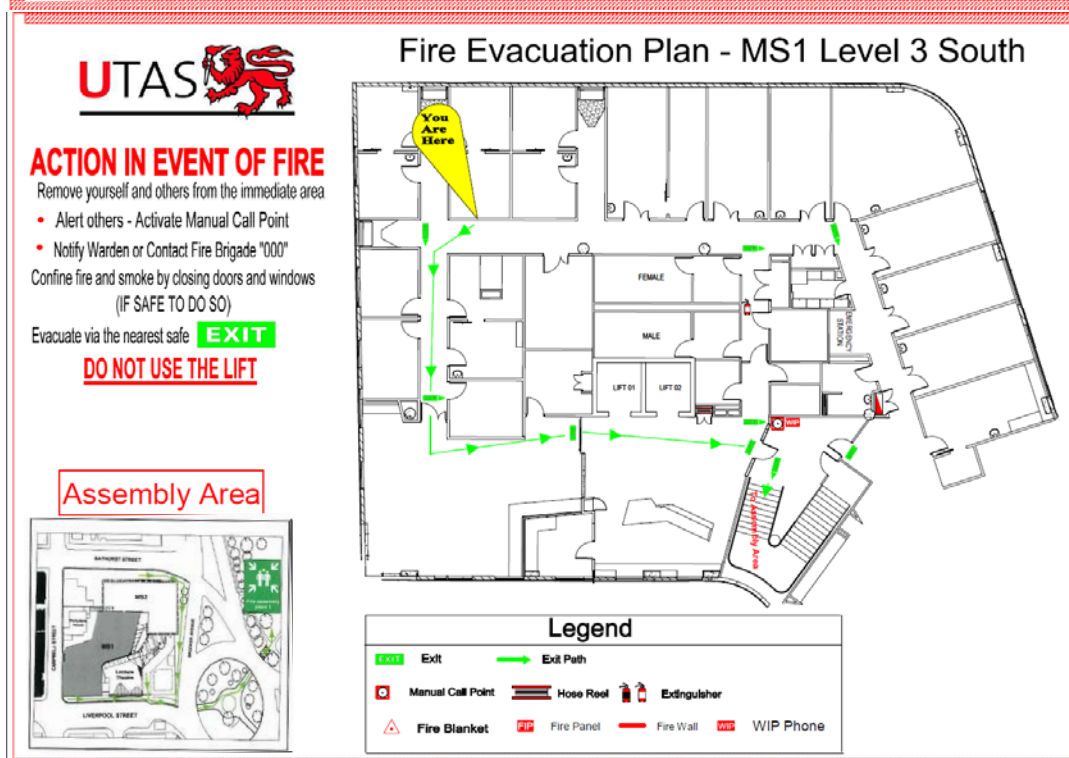
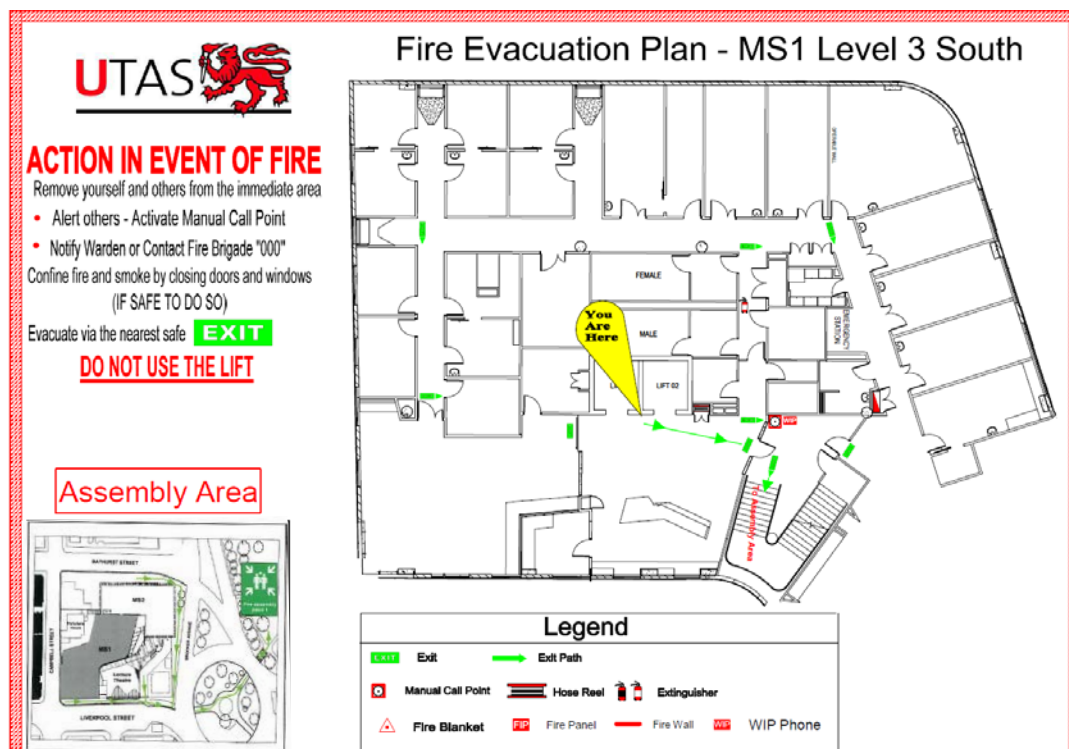
- Attachments/References
- Approval
- Distribution
- Revision History

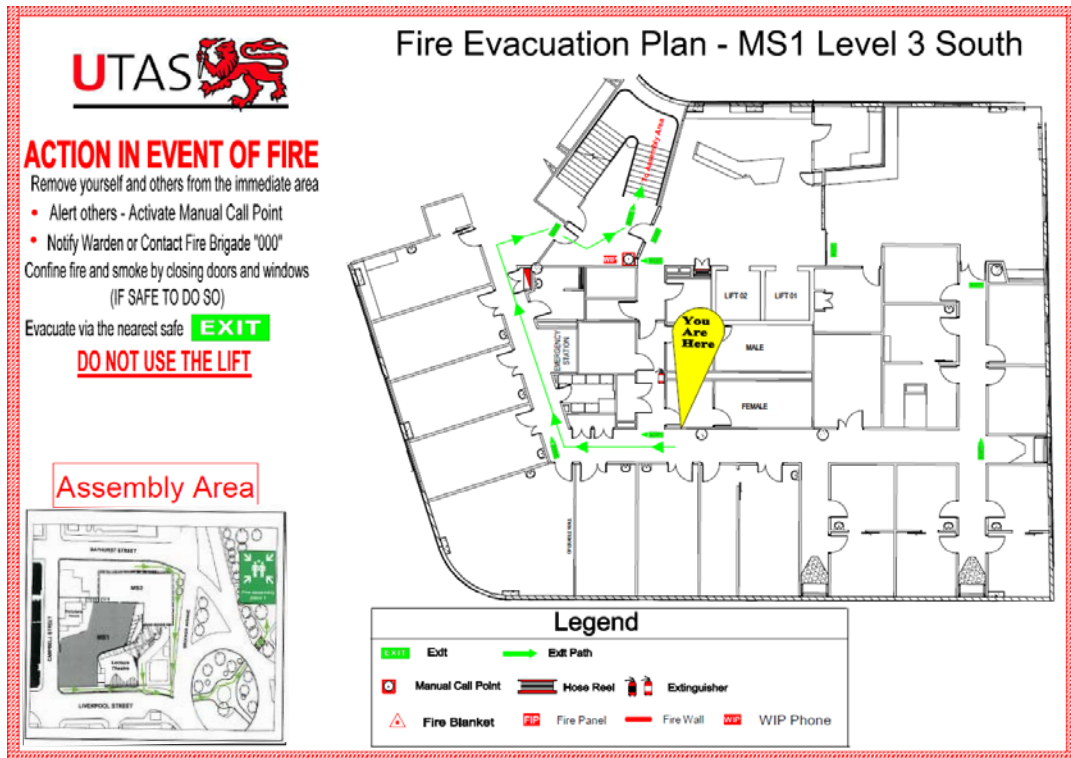
Safety End Note/Disclaimer



Attachment 7 - Clinical Research Facility fire evacuation plans

MS1 Level 3 South.





MS1 Level 3 North





Fire Evacuation Plan - MS1 Level 3 North

ACTION IN EVENT OF FIRE

Remove yourself and others from the immediate area

- Alert others - Activate Manual Call Point
- Notify Warden or Contact Fire Brigade "000"

Confine fire and smoke by closing doors and windows
(IF SAFE TO DO SO)

Evacuate via the nearest safe

EXIT

DO NOT USE THE LIFT

Assembly Area



Legend

EXIT	Exit	Exit Path
Manual Call Point	Hose Reel	Extinguisher
Fire Blanket	Fire Panel	Fire Wall
		WIP Phone



Fire Evacuation Plan - MS1 Level 3 North

ACTION IN EVENT OF FIRE

Remove yourself and others from the immediate area

- Alert others - Activate Manual Call Point
- Notify Warden or Contact Fire Brigade "000"

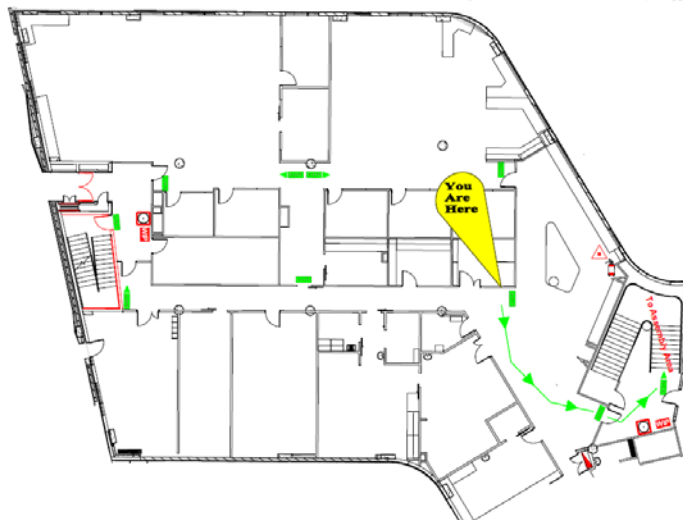
Confine fire and smoke by closing doors and windows
(IF SAFE TO DO SO)

Evacuate via the nearest safe

EXIT

DO NOT USE THE LIFT

Assembly Area



Legend

EXIT	Exit	Exit Path
Manual Call Point	Hose Reel	Extinguisher
Fire Blanket	Fire Panel	Fire Wall
		WIP Phone