# Standard Operating Procedure
# Research Governance

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| **Title:** | **Assessment of Risk to Personnel for the Handling of Human Tissue** | | |
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| | Name and Position | Signature | Date |
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Revision Log

| Previous Version number | Date of Review/Modification | Reason for Review/Modification | New Version Number |
|---|---|---|---|
| 005/002 | 02/01/2013 | Reformat because of integration to Research Governance | v1.0 |
| v 1.0 | 07/01/2015 | Periodic Review | v 2.0 |
| V 2.0 | 10/04/2017 | Review in response to Human Tissue Authority's Codes of Practice and Standards update. | V3.0 |
| V 3.0 | 17/05/2019 | Periodic review. Logo and name of Chair updated on cover page. Web links updated. | V4.0 |
| V 4.0 | 05/11/2021 | Periodic review. Web links updated. | V5.0 |

## 1. Purpose

This Standard Operating Procedure (SOP) describes the process by which a risk assessment is carried out, recorded and controlled in connection with the handling of relevant material as defined by the Human Tissue Act 2004 (HT Act).

## 2. Introduction

The HT Act came into force on the 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue. A risk assessment is defined as 'a systematic examination of the hazards associated with the work, an evaluation of the risks to health associated with the hazards and a judgement on the measures required to eliminate or control harmful exposure to the hazard[1]. It is essential that all risks identified during the course of a scheduled purpose are appropriately recorded and acted upon. If the process involves chemical or biological hazards then a COSHH assessment must be completed as appropriate.

Guidance is available from the University's Safety Services website:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/

## 3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are involved with the removal, storage, use of relevant material for scheduled purposes.

Note: Human tissue samples collected as part of a clinical trial of an investigative medicinal product (CTIMP) or samples acquired and stored in the Northern Ireland Biobank will have their own procedures and requirements and should not follow this SOP.

## 4. Responsibilities

### 4.1 Designated Individual

The Designated Individual (DI) is responsible for ensuring that appropriate risk assessment procedures are in place.

### 4.2 Person Designated

The Person Designated (PD) is responsible for providing advice and guidance on human tissue related risk assessment procedures in their area as required.

### 4.3 Chief Investigator or Custodian

The Chief Investigator (CI) or custodian of the material is responsible for ensuring that all activities carried out under their supervision have had appropriate risk assessment and that any risks identified during the assessment are dealt with via the implementation of appropriate control measures. The CI or custodian must ensure that any individuals undertaking activities involving human tissue are suitably trained to undertake the tasks.

[1] MRC Health and Safety Policy, Guidance Note 2

### 4.4 Researcher and Support Staff

The researcher and/or other support staff undertaking tasks involving human tissue must ensure that these tasks are carried out in accordance with the risk assessment and that appropriate control measures are applied as necessary.

## 5. Procedure

All applicable health and safety policies and procedures, including the University's Biological Safety Guidance and Chemical Safety Policy, must be adhered to when working with human tissue:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/.

Risk assessments must be completed for all research activities involving human tissue to minimise the risk of contamination and protect the health and safety of staff, students and visitors.

Risk assessment and the application of appropriate control measures should be approached through careful consideration of the following paragraphs.

### 5.1 Is the sample likely to contain prions?

If the tissue is of neuronal or lymphoid origin then there is a risk that it may contain Transmissible Spongiform Encephalopathy (TSE) agents (eg Creutzfeldt-Jakob disease, Gerstmann-Straussler-Scheinker syndrome, fatal familial insomnia, Kuru).

No work with tissues from patients with known or suspected TSE should be attempted without prior consultation with a University Biological Safety Officer[2], as this will require containment at Level 3 and special procedures for the disposal of tissue and contaminated equipment. Guidance on TSE risk management is available from the Advisory Committee on Dangerous Pathogens TSE Risk Management Subgroup (see http://www.dh.gov.uk/health/2012/11/acdp-guidance/).

### 5.2 Is the tissue sample likely to contain other infectious material?

Any material likely to contain infectious agents must be handled at the level of containment designated by the Advisory Committee on Dangerous Pathogens (ACDP). Categorisation of infectious organisms is into 4 levels and lists of organisms with details of the containment required are available from ACDP website:
(https://www.gov.uk/government/groups/advisory-committee-on-dangerous-pathogens ) and ACDP: The Approved List of Biological Agents (2004) (http://www.hse.gov.uk/pubns/misc208.pdf). Blood samples from sources other than the Blood Transfusion Service carry a risk of containing blood-borne viruses and should be handled under Level 2 containment as detailed in The Approved List of Biological Agents:
(http://www.hse.gov.uk/pubns/misc208.pdf).

If the tissue contains biological hazards then a COSHH assessment must be completed as appropriate. Guidance on working with biological agents is available from the University's Safety Service website:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/

[2] List of School Biological Safety Officers
(https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/HealthandSafetyPoliciesandGuidance/PoliciesandProceduresLibrary/BiologicalSafety/)

**5.3 If the tissue sample contains infectious agents what procedures are necessary to minimise risk?**

Attention should be paid not only to level of containment but also to procedures to reduce the creation of aerosols and to avoid work with "sharps". Personnel need to be experienced in good microbiological practice.

For further advice on risk assessments relating to biohazards contact a University Biological Safety Officer.

Guidance on working with biological agents is available from the University's Safety Service website:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/

**5.4 Is the tissue likely to contain a harmful (non-radioactive) drug or chemical, eg a cytotoxic agent, used to treat the person from whom the sample was derived?**

If the sample contains an exogenous chemical substance a COSHH assessment should be performed in the same way that other chemicals are assessed within the laboratory. You must take account of the inherent toxicity of the chemical within the sample and the volume weight of the sample. Depending on the outcome, adequate procedures should be put in place to protect handlers from exposure. Further advice on chemical safety is available from the University's Safety Service website:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/

**5.5 Is the tissue sample likely to contain a radioisotope used in diagnostic procedure in the person from whom it was derived?**

If the sample is likely to contain a radioisotope, it must be handled in accordance with the University's Ionising Radiations Safety Policy:
(https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/). If advice is required on any aspect of the handling and storage of radioisotope containing materials please contact the University's Radiation Protection Adviser. Further advice on radiation safety is available from the University's Safety Service website:
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/

**5.6 What procedures are in place for the cleaning of contaminated equipment?**

An appropriate procedure for the cleaning and/or sterilisation of equipment exposed to harmful materials should be in place before the receipt of the tissue sample. Any equipment which is to be reused must be cleaned/sterilised after use. Clarification on procedures to be used can be obtained from the University's Biological Safety Officers and/or Radiation Protection Adviser as appropriate.

**5.7 Assessment of risk control measures**

Factors to be assessed in the determination of the risk control measures required include:
(i) the potential for accidental exposure and implementing emergency procedures;
(ii) staff training and competence;
(iii) occupational health requirements;
(iv) the known and potential hazards;
(v) the likely routes of exposure.

**5.8 Risk control measures**

Your judgement on the risk control measures necessary should be based on the following:

(i) minimising or limiting the amounts handled;
(ii) using a fume cupboard or other containment measure for dusts or volatile substances (including volatile radioactive substances);
(iii) using microbiological safety cabinets for materials microbiologically contaminated;
(iv) wearing appropriate gloves for substances absorbed through the skin;
(v) using eye protection;
(vi) avoiding wherever possible the use of sharps;
(vii) using appropriate shielding and remote handling devices for work with radioactive isotopes;
(viii) maximising distance and minimising time for work with radioactive substances;
(ix) using correct waste disposal routes and measures.

A flow-chart to assist with risk assessment is attached in Appendix 1.

### 5.9 Recording risk assessments and control measures

Due to the diversity of activity in different laboratories in which human tissue is handled, each laboratory should have a local SOP, informed by the content of this general SOP. An important part of the local SOP will be a proforma used in the process to record both risks and control measures.

An exemplar recording sheet is attached (Appendix 2). All completed proformas should be filed with other paperwork associated with a particular project (eg project protocol, completed consent forms).

Local SOPs must be maintained and available upon request.

## 6. References

Human Tissue Authority Code of Practice and Standards E Research
https://www.hta.gov.uk/guidance-professionals/codes-practice (last access November 2021)

Human Tissue Authority - definition of relevant material
https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials (last accessed November 2021)

Advisory Committee on Dangerous Pathogens:
https://www.gov.uk/government/groups/advisory-committee-on-dangerous-pathogens (last accessed November 2021)

Advisory Committee on Dangerous Pathogens: The Approved List of Biological Agents (2004)
http://www.hse.gov.uk/pubns/misc208.pdf (last accessed November 2021)

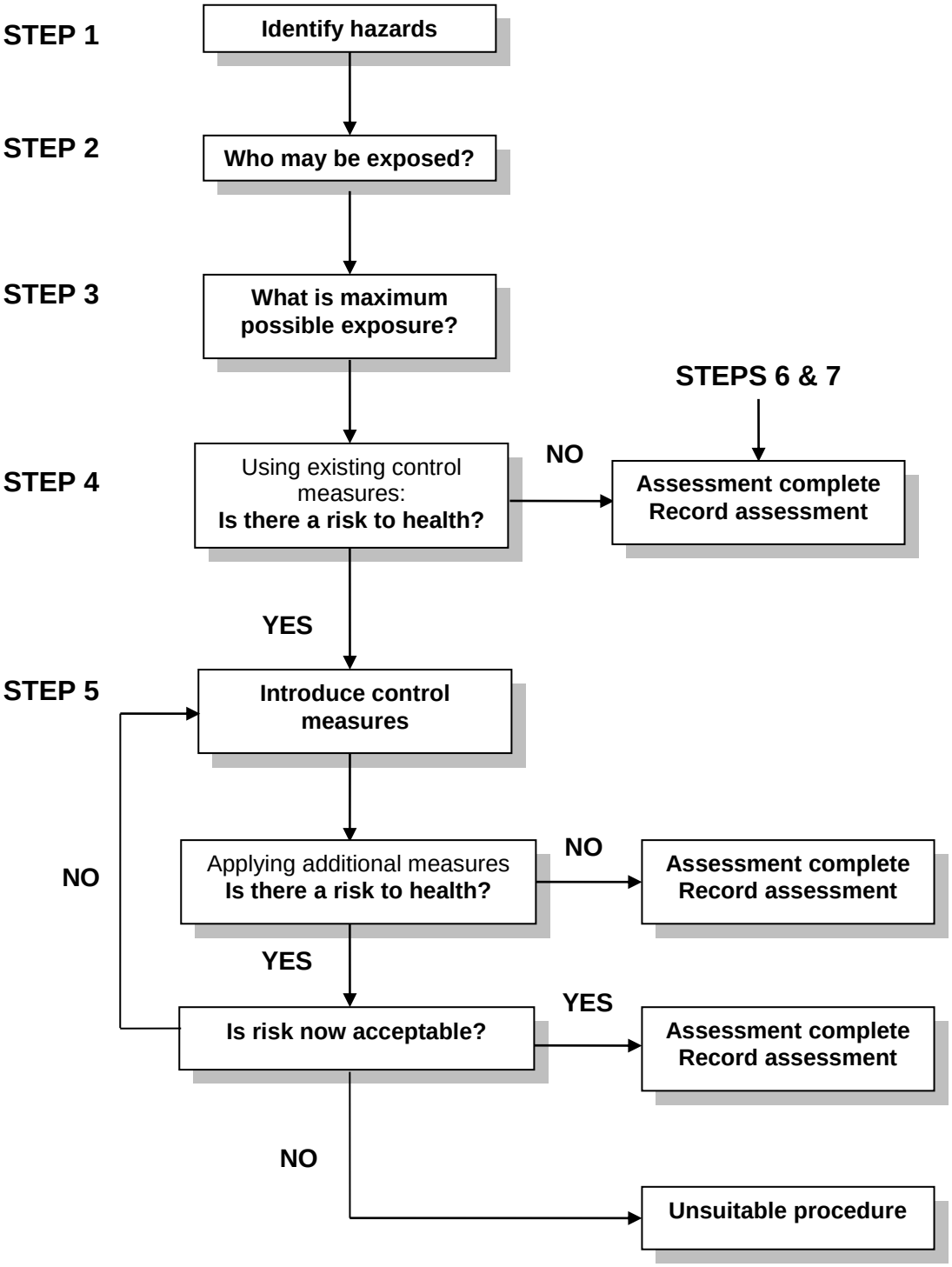
Advisory Committee on Dangerous Pathogens TSE Risk Management Subgroup:
https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group (last accessed November 2021)

QUB Safety Service
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last accessed November 2021)

## 7. Appendices

Appendix 1 Generic Flowchart for Risk Assessment;
Appendix 2 Example Risk Assessment (Health and Safety);
Appendix 3 Guidance on Dealing with Radioactive Spillages;
Appendix 4 Cleaning of Equipment Contaminated with Human Tissue.

## Generic Flowchart for Risk Assessment



## Example Risk Assessment (Health and Safety)

| | | |
|---|---|---|
| School/Department/Unit: | Work activity: | |
| Assessment completed by: | Date completed: | Review Period: |

| Activity (task step) | Hazards | Who might be harmed | Existing Control Measures (What are you already doing?) | Severity (1-4) | Likelihood (1-4) | Risk Level (L,M,H, VH) | What further action is necessary | Final risk rating | Action by whom & by when |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

Put the date the assessment was completed and put in a review date, normally annually unless the task, person or equipment changes

The task or activity i.e. mowing the lawn

| School/Department/Unit: Estates Gardening | Task/Work activity: Mowing lawn | |
|---|---|---|
| Assessment completed by: A. N. Other | Date completed: 20-May 2011 | Review Period: 1 Year |

| Activity (task step) | Hazards | Who might be harmed | Existing Control Measures (What are you already doing?) | Severity (1-4) | Likelihood (1-4) | Risk Level (L, M, H, VH) | What further action is necessary | Final risk rating | Action by whom & by when |
|---|---|---|---|---|---|---|---|---|---|
| Filling the mower with petrol | Fire, explosion | Operator and others in vicinity during filling with fuel | Fuel stored in appropriate labelled container. Petrol filling undertaken outside in open area away from sources of ignition. Pre-use checks for leaks. | 3 | 1 | M | Warning notice to be displayed in workshop. Operator to be provided with filling funnel to avoid spills. | L | A.N. Other Supervisor 20-05-11 |

Identify any steps in the task i.e. filling the lawn mower with petrol

Identify hazards or injury causes

Identify who may be harmed i.e. staff, students and or general public

**Calculate risk rating**: Probability **multiplied by** severity i.e. 3 (Probability) x 1 (Severity) = 3 Medium

A risk matrix is a tool used in the risk assessment process, it allows the severity of the risk and probability of the event happening to be determined, by multiplying the two outcomes.

In layman's terms – How likely is it to happen and how bad it would be if it happened.
If a number of people are likely to be exposed to a hazard then this would need to be taken into consideration.
The traffic light colour scheme gives a clear indication of whether or not the classification is high, medium or low.

| Severity | Probability | | | |
|---|---|---|---|---|
| | Unlikely | Possible | Likely | Very Likely |
| Very Minor | 1 | 2 | 3 | 4 |
| Minor | 2 | 4 | 6 | 8 |
| Significant | 3 | 6 | 9 | 12 |
| Major | 4 | 8 | 12 | 16 |

| Risk Rating | |
|---|---|
| Score | Risk Level |
| 1-2 | Low |
| 3-6 | Medium |
| 8-9 | High |
| 12-16 | Very High |

For scores of 8 or more (high), further action must be taken to reduce the risk.
If further advice is required contact the Safety Service.

## Guidance on Dealing with Radioactive Spillages[1]

Spillages of radioactive material must be cleaned up without delay. This is to prevent the spread of contamination and in the case of gamma and "hard" beta emitters to eliminate unnecessary exposure to penetrating ionising radiation.

Small Spillages (Small discrete areas, Activity < 250µCi)

***Liquid Spills***

- double glove;
- drop a handful of paper tissues on the spillage (do not mop around the area as this will spread the contamination);
- lift the damp tissues with tongs and dispose of the material in the radioactive waste bin;
- work quickly, but carefully, to avoid exposure to ionising radiation;
- repeat the process until the surface is dry;
- then monitor to confirm the area has been decontaminated.

***Solid Spills***

- cover the area with "moist" paper tissues (wet wipes);
- proceed as for liquid spill procedure above.

If the area appears clean and dry but the contamination persists (as confirmed by monitoring), try to remove the contamination using a cleaning agent such as Decon 90. If the contamination refuses to shift consider your options carefully before resorting to drastic action. For example, spills of a short-lived radioisotope such as P32 can be covered by a suitable shield (10mm of Perspex for P32) until the activity has decayed away.

In some circumstances it may be necessary to completely remove the contaminated surface. In such cases advice must be sought from the University Radiation Protection Advisor (URPA) before proceeding.

Large Spillages (Spills scattered over large areas, Activity > 250 µCi)

- establish the facts as quickly as possible;
- treat casualties and contaminated individuals firstly;
- decontaminate the facilities and equipment;
- avoid spreading contamination on contaminated casualties;
- avoid spreading contamination outside the area of the incident;
- use the radiation spill kit.

Those involved in the incident should be encouraged to remain calm and not to move about unduly to avoid the spread of contamination. The Departmental Radiation Protection Supervisor (DRPS) and the URPA should be summoned as soon as possible to provide advice on monitoring, decontamination and to oversee the incident management.

It is important to establish as soon as possible the radionuclide(s) involved; the activity handled; how much has been spilt (volume and activity) and if the contamination has been contained within the area of the incident.

In order to prevent the spread of contamination to outside of the radionuclide laboratory, access to it should be carefully restricted as soon as possible after the incident occurs. The

[1] Please note that this is not a definitive guidance note for chemical contamination as the procedures will vary considerably and be dependent on the nature of the chemical spilled. It is important that advice is sought from the appropriate office.

area should be carefully demarcated with hazard warning signs and warning tape (in spill kit) and preferably guarded by a responsible individual.

No-one should be permitted into the area unless they are wearing the appropriate personal protective equipment (PPE) i.e. overshoes, disposable coveralls and double gloves (in spill kit).

No-one should be permitted to exit the area unless they have undergone contamination monitoring (overseen by DRPS or URPA) and have removed and bagged up their PPE.

On arrival, the “clean-up” team should make a clean walkway into the area by rolling out some benchkote with its absorbent side down (in spill kit). In this way, the team can attend to casualties, contaminated individuals and clean up the spill without standing in contamination and spreading it.

If there are casualties, then the provision of first aid must be given priority. The URPA, a trained first aider, will give advice and oversee the treatment of casualties such that the spread of contamination and exposure of the rescue team to ionising radiation is minimised.

In general, contamination clothing should be removed and bagged up. Contaminated wounds should then be irrigated under running water and reasonable bleeding encouraged until monitoring indicates wounds are free of contamination. The casualties may then be removed from the scene for further treatment. The feet and hands of carers and casualties should be carefully monitored before they exit the scene.

Similarly, contaminated clothing should be removed from non-injured but contaminated individuals. Then any areas of contamination identified on the skin (usually hands, face and legs) should be rubbed gently with cotton wool until monitoring indicates the contaminated area is clear. Care must be taken not to spread the contamination over the skin and not to abrade the skin thereby creating a route of entry into the body for contamination. These individuals may then be allowed to leave the scene provided their hands and feet are free of contamination.

Disposable coverall etc should be provided as a temporary replacement for discarded clothing.

If the spill is from a gamma or high energy beta emitter, the clean-up team may find that the high background created by the spill makes monitoring of individuals and the environment very difficult. It is then important to identify and remove the main part of the spill first (ie stock vial or material readily seen) and then to deal with the remainder of the contamination afterwards. Once the stock vial and waste wipes and tissues are shielded behind lead, small splashes of contamination should now be readily identified and dealt with using the procedure for “small spills” given above. Drips on to the floor should be dealt with firstly and then the floor. Work from the outside of the spill inwards.

If the spillage is from a very short half-life isotope such as Technetium 99m (6 hours); then once casualties and contaminated individuals have been dealt with, it would be better to await the decay of the spill rather than expose the cleanup team to unnecessary risks.

If the spillage cannot be removed, it may be necessary to cover it with a suitable shielding material in the interim.

Finally, an investigation into the incident should be carried out and a report prepared and forwarded to the URPA. Losses of radioactive material through spillage must be accounted for on the Isostock programme. Spillages in excess of certain activity must also be reported to the HSE and the Radiochemical Inspectorate.

## Cleaning Of Equipment Contaminated With Human Tissue

*These procedures are "generic" and may need to be modified according to the equipment concerned and materials involved.*

**1.** Has the equipment been contaminated with tissue that may contain a Transmissible Spongiform Encephalitic (TSE) agent?

For human specimens this would be material from patients with Creutzfeldt-Jakob disease, Gerstmann Straussler-Scheinker syndrome, fatal familial insomnia or Kuru. ***If so, refer to Biological Safety Officer[1] as this will require special conditions and handling.***

**2.** If **not** used for potential TSEs proceed as follows:

*If electrical equipment - switch off and disconnect from mains.*

Assess parts to be cleaned – can these be cleaned *in situ* or do they need to be removed by a competent person?

Has the equipment been used with material containing potentially infectious agents?

**If not**, clean by wiping with paper towel dampened in water and mild detergent. Take care if sharp edges are involved or if in proximity to electrical circuits.

Appropriate personal protective equipment (eg gloves) must be used when cleaning equipment contaminated with human tissue.

If the contamination maybe potentially infectious assess what category of infectious agent may be present. For category 2 agents refer to COSHH assessment covering project for appropriate method of disinfection.

For potential category 3 agents ***refer to Biological Safety Officer[1] as this will require special conditions for disinfection and handling.***

[1] List of School Biological Safety Officers (https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/HealthandSafetyPoliciesandGuidance/PoliciesandProceduresLibrary/BiologicalSafety/)