**Procedure for Best Practice in Ethical Review and Approval of Research Projects Involving the Use of Human Tissue from Healthy Volunteers**

Following guidance obtained from the Medical Research Council, research involving human tissue (Appendix A) should undergo independent ethical review. This ensures the rights, safety, dignity and wellbeing of research participants are safeguarded and also ensures that appropriate legal requirements in tissue legislation are met. The ethical review and approval of non-clinical research involving human participants proposed by staff and students is overseen by six School Research Ethics Committees (SRECs) within the University of Dundee. Each SREC is responsible for maintaining ethical standards of practice in non-clinical research involving human participants which ensures public trust in the conduct of research at the University. It is also the responsibility of project supervisors to be aware of and understand the ethical implications of using human tissue within research before embarking on a project.

The use of heathy volunteer human tissue within non-clinical research projects is routinely carried out within the Schools of Life Sciences and Medicine where the most common tissue type required is blood. The University procedure for determining whether a project requires ethical approval from an SREC (checklist 1) directs researchers proposing projects that involve the use of tissue from consented healthy volunteers, excluding genetic research, to apply for ethical approval to the relevant SREC (in most cases this would be the SMED SLS REC). Healthy volunteer tissue projects that require isolation of genetic material from blood for downstream experiments, for example, should first be notified to TASC Research Governance with proposed ethical approval sought from an NHS REC (East of Scotland Research Ethics Committee).

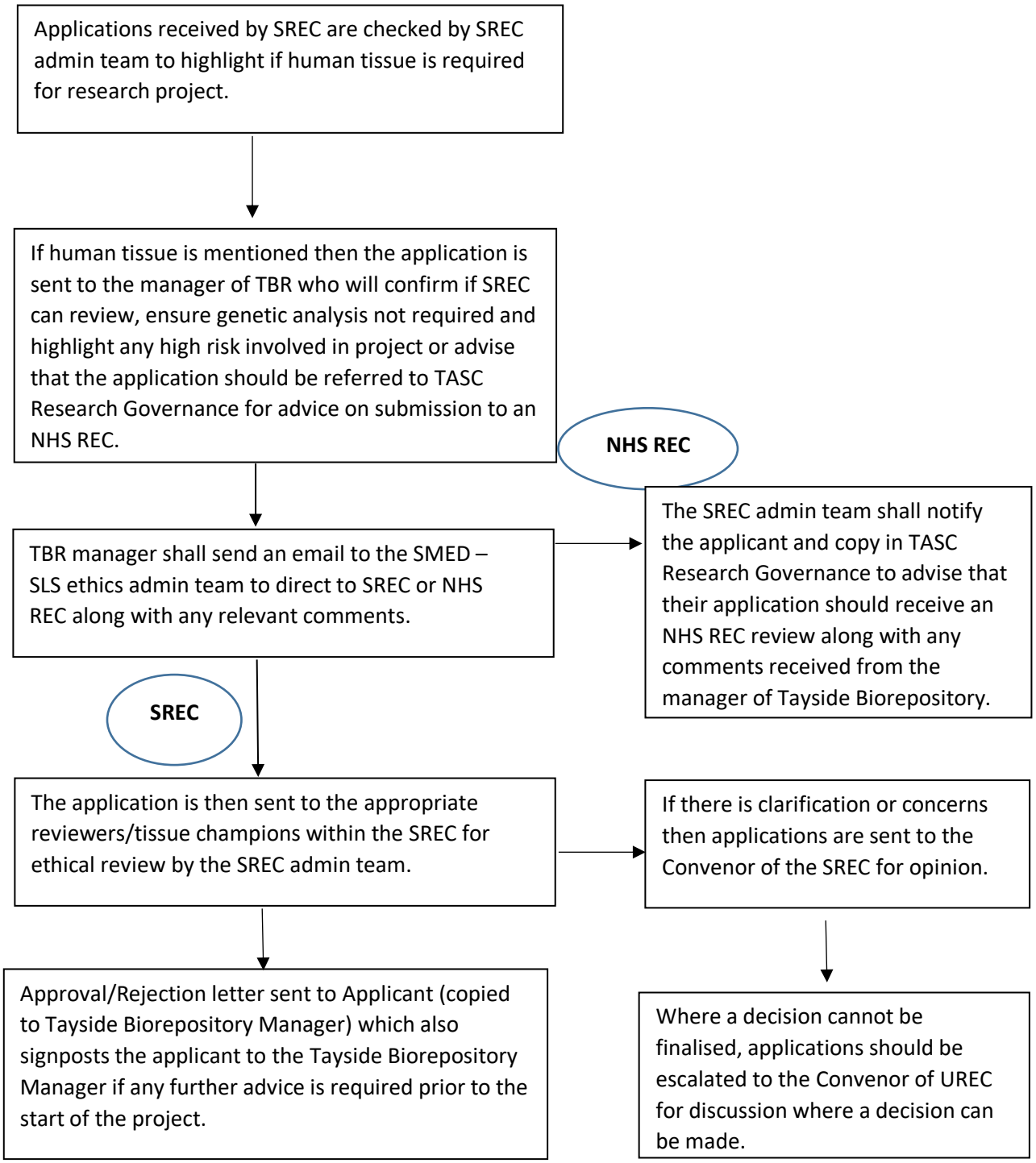
The Human Tissue Act classifies genetic analysis as "DNA…& RNA analysis when used to provide information about DNA for research". Clarification has been sought from the Medical Research Council (MRC) to confirm whether this may include or exclude certain experiments. According to the MRC, a great deal of time was spent discussing this in Parliament but it did not come to any final conclusions so as a result genetic analysis means "having genetic material and analysing it". This definition would therefore include experiments that require sequencing of genetic material or Reverse Transcription Polymerase Chain Reaction (RT PCR). Consequently, the managers of Tayside Biorepository and TASC Research Governance agree that it is appropriate, as an additional safeguard for participants, that these types of project receive ethical approval through an NHS REC to support anonymity and ensure support is in place in case of any potential incidental findings or possible clinical implications.

Following discussions with the SMED-SLS SREC it has been established that some support is required to ensure that members of the committee feel confident in reviewing human tissue studies using consented healthy volunteers and ensuring that applicants have the opportunity to obtain support in best practice for conducting human tissue research within the University of Dundee.

It has been proposed that this additional support shall include human tissue applications being sent to the manager of Tayside Biorepository who shall either: (i) confirm that the project can be reviewed by the SREC, does not include genetic analysis and highlights any risks that should be mitigated or (ii) advise the SREC that the project does involve genetic analysis and should be submitted to TASC Research Governance and NHS REC for approval. Once the committee has reviewed the application for any ethical implications, project approval shall signpost the researcher

to the Tayside Biorepository Manager should they wish to discuss any aspect of the project or to receive any further support that may have been highlighted within the project protocol; the Tayside Biorepository Manager will be copied in (a standard decision letter template has previously been developed for this). Furthermore, support and training shall be provided on best practice using human tissue and ethical considerations by the Manager of Tayside Biorepository with the emphasis placed upon providing guidance to allow committee members to confidently assess applications.

The following flowchart summarises the approval process in place for the SMED-SLS ethics committee for applications involving non- clinical human tissue projects.



**Appendix A: Supplementary List of "relevant" human tissue**

Definitions:

Bodily Material: Is any tissue or sample that consists of human cells, this includes gametes, and hair and nails from the living or deceased. It excludes: Embryos outside the body; cells manufactured outside of the human body (e.g. established cell lines) and/or any extracted cellular components where no whole cells remain (e.g. extracted DNA and RNA are not classed as bodily material).

Exceptions include tissue that has been:

1- divided or created outside the human body
2- treated, processed or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Relevant human tissue (see table below) is defined as "material, other than gametes, which consists of or includes human cells". All research involving relevant material should be conducted in accordance with the conditions of ethical approval.

Although outside the definition of relevant human tissue, gametes fall within the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

This list is not intended as exhaustive or exclusive and is intended to provide guidance in respect of a number of tissue types that may be considered relevant bodily material.

| Tissue Type | Considered relevant material by human tissue authority |
|---|---|
| Antibodies | No |
| Bile | Yes |
| Blood | Yes |
| Bone Marrow | Yes |
| Bones/Skeletons | Yes |
| Brain | Yes |
| Breast Milk | Yes |
| Breath condensates and exhaled gases | No |
| Buffy coat layer (interface between plasma and blood cells when blood is separated) | Yes |
| Cell lines | No |
| Cells that have divided in culture | No |
| Cerebrospinal Fluid (CSF) | Yes |
| Cystic Fluid | Yes |
| DNA | No |
| Eggs (Ova) | No |
| Embryonic Stem cells (cells derived from an embryo) | No |
| Embryos (outside the body) | No |

| | |
|---|---|
| Extracted material from cells e.g nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids | No |
| Faeces | Yes |
| Fetal Tissue | Yes |
| Fluid from cystic lesions | Yes |
| Gametes | No |
| Hair (From deceased person) | Yes |
| Hair (From living person) | No |
| Joint aspirates | Yes |
| Lysed cells | No |
| Mucus | Yes |
| Nail (From deceased person) | Yes |
| Nail (From living person) | No |
| Nasal and Bronchial Lavage | Yes |
| Non-blood, derived stem cells (derived from the body) | Yes |
| Non Fetal Products of conception (The amniotic fluid, umbilical cord, placenta, membranes) | Yes |
| Organs | Yes |
| Pericardial Fluid | Yes |
| Plasma (if there is a risk that small numbers of platelets or other blood cells are present) | Yes |
| Plasma (treated to render acellular) | No |
| Platelets | Yes |
| Pleural Fluid | Yes |
| Primary cell cultures (whole explant/biopsy present) | Yes |
| Pus | Yes |
| RNA | No |
| Saliva | Yes |
| Serum | No |
| Skin | Yes |
| Sperm cells (spermatozoa) | No |
| Sputum (or Phlegm) | Yes |
| Stomach Contents | Yes |
| Sweat | No |
| Teeth | Yes |
| Tumour tissue samples | Yes |
| Umbilical Cord blood stem cells | Yes |
| Urine | Yes |