ARIA Policy on the use of human biological samples

SCOPE

This policy sets out ARIA's requirements in respect of the planned use of human biological samples in ARIA projects. The policy annex provides applicants with a list of questions that must be addressed in any application for funding that includes the proposed use of human biological samples.

UNDERSTANDING THE REGULATORY REGIME IN RELATION TO RESEARCH

The Human Tissue Act 2004 (HT Act) governs the removal, storage use and disposal of human tissue in England, Wales and Northern Ireland. The HT Act created the Human Tissue Authority (HTA), the regulatory body responsible for the governance, licensing and regulatory compliance for the collection and storage of human tissue in research.

The HTA does not licence the use of human tissue for research purposes and separate ethical approval is required for the use of human tissue in research in addition to the HT Act requirements for a licence for collection and storage.

The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) governs the specific licensing requirements and inspection by the HTA under the HT Act.

Additional details are available in the HTA's Code of Practice and Standards, Code E: Research.

Code E: Research | Human Tissue Authority

UNDERSTANDING THE TYPE OF BIOLOGICAL SAMPLES

In the UK the type of biological sample determines the relevant legislation that applies. Therefore applicants should first determine the types of human biological material that they intend to use to ensure that the correct regulatory regime is applied for their use in a proposed project.

The HT Act governs the collection and storage of 'relevant material': defined as any material from a human body that consists of, or includes, cells. The principle is that if a sample is known to contain even a single living cell, then it is classified as relevant material and the HT Act applies. The majority of human biological samples will be covered by the HT Act.

More details of what is covered with the HT Act are provided by the Human Tissue Authority (HTA) at the following link: Relevant material under the Human Tissue Act 2004 | Human Tissue Authority.

Note that hair and nails from living persons are specifically excluded from classification as relevant material.

If the human biological material comprises gametes and embryos these samples are covered by the provisions of the Human Fertilisation and Embryology Act and the use of these samples as part of a project is not covered in this policy.

CONSENT FROM DONOR FOR COLLECTION, USE AND STORAGE OF HUMAN TISSUE SAMPLES

The HT Act requires that consent is obtained from donors of human tissue for their use or storage unless one of the exceptions apply.

The most relevant exception is that: (i) an HTA approved Research Ethics Committee (REC) has approved the research, (ii) the tissue is taken from a living person and (iii) the research team is not able to identify the donor. For the purposes of the HT Act, a Research Ethics Committee is an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004. Note specifically that university ethics committees are not recognised for the purposes of the exemption from consent.

The other exceptions for consent are where the tissue to be used is imported or is tissue from a human tissue bank which was held prior to 1 September 2006.

If none of these exceptions is in place, then consent will be required from the donors for their samples to be collected, used and stored. The Medical Research Council provides detailed guidance on obtaining consent for collection, use and storage of human biological material from donors: MRC-0208212-Human-tissue-and-biological-samples-for-use-in-research.pdf

If human tissue is provided by a licensed research tissue bank, such as the UK Biobank, the tissue bank may have a generic ethical approval in place for the use of its tissues by third parties. In this case it may not be necessary to obtain separate REC approval. However, this only applies if the use

of the human tissue provided falls within the stated conditions of the generic approval granted for that specific licensed research tissue bank.

The requirements of the generic ethical approval will usually be made clear in the relevant licensed research tissue bank terms and conditions for supply of samples. These terms should be reviewed to determine whether the generic approval will apply.

USE OF HUMAN TISSUE FROM THE DECEASED

If human tissue will be used from deceased donors, the consent for the use of that tissue for research must have been in place prior to its removal and the removal of the material must have been done under an HTA licence.

Any human tissue from deceased donors must be stored at premises with an HTA licence and cannot be used outside of those premises unless a project has received ethical approval (or it is pending) from a recognised REC or the tissue is provided by a licensed tissue bank with a generic ethical approval in place for research.

USE OF BODILY MATERIAL AND CONSENT FOR DNA ANALYSIS

Although DNA is not relevant material under the HT Act, the HT Act does apply to DNA or RNA analysis of bodily material, in this case including hair and nails and there is a requirement for qualifying consent from donors, unless exceptions apply.

The exceptions, similar to the ones above, are that the bodily material is from a living person, the proposed research has approval from a REC and the research team is not able to identify the donor. Without these exceptions in place it is not possible for DNA or RNA analysis to take place on human biological samples.

If the bodily material to be used for DNA analysis comes from deceased donors and the consent given by the deceased for use of their tissue was for research with no specific exception stated for its use for DNA analysis, then tissue can be used for research including DNA analysis, subject always to REC approval for the project or a generic approval being in place from a tissue bank.

ARIA may require evidence that any exceptions from consent for the use of human biological samples for DNA or RNA analysis are or will be in place and the required approvals and licences have been secured before releasing funding.

FUTURE USE

For any storage of human tissue after the end of a project, a new ethical approval will be required. If the storage is not directly in connection with further research and ethics approval is therefore not possible, the tissue could be transferred to a licensed tissue bank or alternatively an HTA licence could be obtained for continuing storage.

ARIA expects that the successful applicants will consider post project implications for any human tissue storage.

LICENSING

The collection and storage of human tissue for research is licensed under the HT Act.

There are exceptions to the requirement for a licence (i) if the samples are held 'incidental to transport' which the HTA considers is no longer than a week, or (ii) if they are held whilst processed to render the material acellular, for example to extract DNA or RNA, or (iii) if the material is from a person who died prior to 1st September 2006 and at least 100 years have elapsed since their death.

Note that even a short period of storage (less than a week) can require an HTA licence if that material is stored for research purposes and not simply prior to transport.

The storage of human tissue as part of a clinical trial must take place on HTA-licensed premises unless there is a REC approval in place, or is pending, for the clinical trial activities.

It is a requirement of ARIA funding for successful applicants to ensure that they either use HTA-licensed premises or obtain an HTA licence for storage of samples or have obtained or applied for REC approval for their project/clinical trial in accordance with the HT Act.

MANAGEMENT OF SAEs AND SARs

SAEs are serious adverse events suffered by a donor of tissues or cells and SARs are serious adverse reactions in a donor or recipient of human tissue or cells.

These events must be reported through the HTA portal: User Account | Human Tissue Authority Portal.

This reporting obligation applies whether you have an HTA licence or are using samples from a licensed tissue bank. More information on this process is set out on the HTA website at: Human application serious adverse event and reaction (SAEARs) reporting | Human Tissue Authority.

Note that if the donation or use of human tissue is part of a clinical trial, there will be additional reporting mechanisms under the requirements of the trial. Reporting through the HTA portal is in addition to those reporting requirements.

DISPOSAL

The HT Act allows for disposal of surplus human tissue as waste with separation of human tissue waste from clinical samples identified as good practice.

If you are aware of the identity of donors as part of your project, they should be informed of how their tissue will be disposed of.

The details of any disposal should be documented.