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must identify and mitigate the risks of information from laboratory tests or linked data of a sample causing harm to the donor or their interests.

Researchers may not sell for profit samples of human biological material or personal data they have collected. Research participants should never be offered any financial inducement (beyond expenses or a minimal participation payment) to donate samples or personal data.

Potential participants should always be informed in advance and in understandable terms of any potential benefits, risks, inconvenience or obligations associated with the research that might reasonably be expected to influence their willingness to participate.

9.1. Where a chief / principal investigator is based at the Institute, the Institute manages studies directly recruiting participants (including via a third party or collaborator) in line with the UK Policy Framework for Health and Social Care Research[2].

9.2. The Institute will act as sponsor and provide appropriate insurance for approved studies with NHS REC approval (and appropriate paperwork, i.e., participant information sheets and consent forms) w

10.4.4. Consent should be recorded in writing when possible (and always when legally required). If the person giving consent is unable to write or is giving verbal consent, this should be clearly documented, including when consent was given and for what purposes. Consent should ideally be witnessed, normally by the researcher, signed by the witness and kept for future reference. PLEASE NOTE: all consent forms should be stored in accordance with the Institute's Data Protection Policy (BI-IM-002) and retained for a period of 30 years from the study completion date in the case of MRC funded studies, and 10 years from the study completion date for all other studies in accordance with the Institute's Record Retention Policy (to follow).

10.4.5. Participant information sheets and consent forms should include information relating to a participant's right to withdraw, and clearly set out how a participant can exercise this right. Study teams must be appropriately informed of the protocol procedure for withdrawing participants, and appropriately document any such withdrawal.

10.4.6. In the event some samples or data may remain at the end of your research study, and it is intended that that these could be used for further research, then the initial consent form should include an option to the use the samples or data for future, ethically approved research and unspecified research. In the event the consent form does not include this option, donors will need to be re-consented prior to any further use of the samples. Such re-consent will need to be obtained prior to the original study's REC approval expiring. Further information in relation to storage of relevant material under ethical approval can be found under section 11.4 of this policy.

10.5.1. The following are exemptions for the requirement of consent for use of relevant materials:

Existing Holdings: The Human Tissue Act's requirements of consent are not retroactive, so legally, it is not necessary to seek consent under the Human Tissue Act to store or use an existing holding for a scheduled purpose.

Imported Tissue: The consent provisions of the Human Tissue Act do not apply to imported tissues, however it is considered as good practice for mechanisms to be in place providing assurances that the tissue has been obtained with valid consent.

Material from the body of a living person: Another statutory exception is where all of the following criteria have been satisfied in relation to the material:

i. The bodily material is from a living person;

ii. The research has ethical approval from a recognised REC; and

iii. The person carrying out the analysis is not in possession, and not likely to come into possession, of information from which the person from whom the material came could be identified.

10.6.1. It is a criminal offence to hold bodily material with the intention to analyse DNA without qualifying consent unless for an excepted purpose outlined below:

10.8.5. Institute researchers are prohibited from collecting tissue from their own persons without first completing a consent form and obtaining ethical approval.

11.1.1. Any research study that wishes to directly recruit participants, and / or use relevant material, bodily material for analysis of DNA / RNA, gametes human embryos, including for the derivation of new cell lines, and personal identifiable data must be approved by a REC.

11.1.2. The ethics review process will check the arrangements for participation, consent, storage and use of samples and data.

11.1.3. Any change in the study, including the way the samples will be collected and

lines into or out of the UK form[7] and submit their application to the Secretary of the Stem Cell Steering Committee by email (stemcellsecretary@headoffice.mrc.ac.uk).

11.6.1. iPS cells have similar properties to human embryonic stem cells but are derived from foetal and adult cells. Research involving the use of relevant material with the intention of deriving iPS cell lines will be subject to the Human Tissue Act 2004.

12.1.1. Biological or genetic modification risk assessments must be carried out as required and submitted to the Institute Biosafety Officer (trevor.smith@babraham.ac.uk) prior to receipt of any human samples. All health and safety rules and guidance and any applicable Safe Operating Procedures for use of human biological materials must be followed in accordance with the Biosafety Policy (BI-HAS-015).

12.1.2. Human research at the Institute cannot be done on Biosafety Level 3 samples (or samples with specified BBVs), either known or suspected.

12.1.3. All research using human biological materials must take place at Biosafety containment 2.

12.1.4. Any human biological materials known to be positive for BBV or other ACDP hazard group 3 or 4 pathogens are prohibited and must not be brought on to Institute premises.

12.1.5. Prior to working at biosafety containment 2, all researchers must meet the requirements specified in Section 1 of the H&S Biological and Genetic Modification Safety Hub page.

12.2.1. Those carrying our research involving human biological materials must follow the appropriate Institute Human Biological Material standard operating procedures (SOPs) covering the following activities:

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13.1.1. UK General Data Protection

14.2.

The Babraham Institute Disciplinary Policy BI-HR-005. In appropriate circumstances, the Human Research Team may make recommendations to the Babraham Executive Committee (BEC) to withhold, suspend or withdraw approval of research.

17.1. Additional sources of information are as follows:

A comprehensive Code of Practice relating to the generation of new human embryonic stem cell lines is available at: https://www.nibsc.org/asset.ashx?assetid=f757b815-45e9-442f-807e-5364ec7f8e08.

Human Fertilisation & Embryology Authority – Applying for a research licence available at: https://www.hfea.gov.uk/about-us/applying-for-a-research-licence/

Integrated Research Application System (IRAS) website available at: https://www.myresearchproject.org.uk/Signin.aspx.

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	MRC Good research practice: Principles and guidelines, available at https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/
Personal Data	*UK General Data Protection Regulation*

Stem Cells

Embryonic stem cells (ESCs - pluripotent) and embryonic germ cells (EGCs pluripotent)	Derivation:

	or spermatozoa to create embryos for research purposes	HFEA Licence required. Subject to appropriate consent in accordance with Human Tissue Act 2004 and favourable ethical opinion.
Somatic stem cells (fetal - multipotent)	Derivation	Consent (see 'Code A: Guiding Principles and the Fundamental Principle of Consent available at: https://www.hta.gov.uk/sites/default/files/HTA%20Code%20of%20Practice%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent%201.pdf.) and ethical approval required.