The Babraham Institute

BI-RES-007 HUMAN RESEARCH POLICY

Document reference	
Policy number:	BI-RES-007
Policy	

Contents

1. Definitions

“Bodily Material”	Means material which has come i) from a human; and ii) consists of or includes human cells. Bodily material differs from relevant material as it includes gametes (human sperm and eggs) and hair and nails from the living as well as the deceased
“Chief / Principal Investigator”	The individual responsible for the conduct of the research. Where the research involves more than one site, the principal investigator is the person at each site responsible for the day to day running of the research project.
“Existing Holdings”	An existing holding is defined as the body of a deceased person or relevant material from a human body (whether living or dead) held before the day on which the Human Tissue Act commenced (1 September 2006) for use for a Scheduled Purpose
“Genetic Data”	Article 4(13) of the UK GDPR defines genetic data as personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the /TT0 1 Tf -0.016ma

"Relevant Material"	Material, other than gametes, which consists of or includes human cells for example blood, saliva, and peripheral blood mononuclear cells. Relevant Material is classified as such under the Human Tissue Act. Relevant material does not include embryos outside the human body, or hair and nail from the body of a living person. The Human Tissue Authority provide a number of examples of relevant material: List of materials considered to be 'relevant material' under the Human Tissue Act 2004
"Scheduled Purpose"	The Human Tissue Act lists the purposes for which consent is required, these are called "scheduled purposes". Scheduled purposes are set out in Schedule 1 of the Human Tissue Act and includes 'research in connection with disorders, or the functioning, of the human body'.
"Employee"	Institute employees on Institute or Babraham Institute Enterprise Ltd (BIE) ter "in I 0 Td ((s).3 (a)13.( )Tj359 00.8 (r)-2.8 (

and collecting or processing human data. The policy is designed to support researchers in meeting legal and ethical requirements. It is not intended to hinder research.

3.2. This policy forms part of the Institute's Research Integrity Framework (see B(s)e's Rsowoaie 5.2 (e)

5.4. Donation of human samples or data shall not give rise to financial benefit.

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

11. Ethical approval

11.1. General

11.1.1. Any research study that wishes to directly recruit participants, and 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, used or stored during the study, must be notified to the REC as an amendment.

11.1.4. Relevant material collected for one study may not be used for a different study without first obtaining a favourable opinion by a REC and the initial consent form includes an option allowing for the samples to be used in the new study or for generic research (see Section 10.4.6).

11.1.5. Many research tissue banks have obtained generic NHS REC approval, which may extend to cover research accessing samples within those banks (usually subject to condition(s)).

11.2. HRA approval

11.2.1. If your study is considered as research as defined under UK Policy Framework for Health and Social Care Research and therefore falls under Research Governance Policy Framework for

13. Data management

13.1. Legal & regulatory framework

13.1.1. UK General Data Protection Regulations (UK GDPR) sits alongside the Data Protection Act 2018 to form primary data protection law in the UK. There is also a common law (case law) duty of confidentiality. The principle being that when someone shares personal information in confidence, it must not be disclosed without legal authority or justification. For further information relating to the Institute's procedures for protecting personal data,

category data), whether collected by the Institute or obtained from a third party collaborator. For more information on ethical approval, please see Section 11 above.

13.3.4. Ethical approval will not normally be required for use of data that is fully anonymised (and the key is not held at the Institute) and is not considered to be sensitive or confidential in nature.

13.4. Anonymised & pseudonymised data

13.4.1.

14.2. Recovery of costs by participants in line with the Institute's policies on expenses is acceptable.

14.3. Payments to those participating in Institute research are allowable, provided that the payment is for expenses and time, and is not at a level that would constitute an undue inducement for people to take part in studies. Participant payments should be included in any NHS REC application for ethical approval.

14.4. IP arising from research utilising human biological samples and data may be sold or licenced in accordance with the Institute's Intellectual Property Policy (BI-KEC-001).

15. Training

15.1. Researchers must have appropriate training for the studies they are carrying out. Links are available on the Research Integrity pages on The Hub. This includes the following:

- Researchers who will be involved in seeking consent from human participants must undertake training via the National Institute for Health Research (NIHR) Learn. Researchers will need to create an account to access these programmes.
- Anyone working with, or likely to work with human samples at the Institute, must undertake the

17.2. This policy will be reviewed regularly to incorporate any changes, legislative or otherwise. The next review date is specified on the cover sheet.

17.3. Associated policies, procedures and guidance are listed on the cover sheet. The Policy Owner named on the cover sheet can be contacted with any queries.

17.4. This policy may be varied, withdrawn or replaced at any time by the Institute at its absolute discretion.

Appendix 1 – Legislation & regulations impacting human research

General	BBSRC Safeguarding Good Scientific Practice available at:

MRC Good research practice: Principles and guidelines, available at

BIRES

	or spermatozoa to create embryos for research purposes	HFEA Licence required. Subject to appropriate consent in accordance with Human Tissue Act 2004 and fa ethical opinion.
	Use of IPSCs intended for human application	Human Tissue (Quality and Safety for Human Application) Regulations 2007 available at: http://www.legislation.gov.uk/uksi/2007/1523/contents/made Directive 2004/230 0 14.48 5225T -0.001 0 Tc 0 Tw 3.719.9w 1 ( )Tj ET E04 Tc 0.006 Tw 11.08 rm ([(p)2..8 (i)-8h2 (l)-8 (