The Babraham Institute

BI-RES-007 HUMAN RESEARCH POLICY

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Associated policies, procedures and guidance
This policy should be read in conjunction with:
BI-RES-005 Research Integrity Policy BI-HAS-015 Biosafety Policy BI-RES-004 Research Misconduct Policy BI-RES-008 Research Data Management BI-IM-002 Data Protection Policy Record Retention Policy (to follow) Open Data Policy (to follow)

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 health of that natural person and which result, in particular, from analysis of a biological samples from the natural person in question.
"Human Biological Material"	In this policy we refer to human biological material as any biological material that has been from humans and includes Bodily Materials, Relevant Materials, embryos and cell lines.
"Human Research"	In this policy, we refer to human research as research that directly recruits human participants, collects or processes human biological material, and collects or processes human data.
"HRA"	The Health Research Authority.
"NHS"	The National Health Service.
"REC"	Research ethics committee. For the purposes of human research undertaken by the Institute, researchers will need to obtain ethical approval from an NHS ethics committee (NHS REC), who are recognised ethics committees under the Human Tissue Act. Currently, approval from a local research ethics committee (i.e., a university ethics committee) is not sufficient for the purpose of the Human Tissue Act.

"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) terms and conditions, Institute employees on BBSRC or other terms and conditions, and Research Fellows on Institute terms and conditions.
"Staff"	Employees and Babraham Institute registered PhD students.
"Associates"	Research Fellows (honorary), Honorary Members of Faculty, visiting students, visiting researchers and workers (including consultants and secondees), and workers provided by a third party / contractors.

2. Commitment statement

2.1. At the Babraham Institute our mission is to be an international leader in research focusing on basic cell and molecular biology with an emphasis on healthy ageing through the human life course.

2.2. Research and operational excellence are essential to meeting our vision of being at the forefront of research that improves lives. The Institute Values set out our approach to how we operate across all Institute activities, both at an individual level and together as the Babraham Institute. The expectation of the Institute is that each staff member looks to represent and reflect the Institute Values within their own contributions and function, and to support and not hinder the expression of these Values in the work of others.

2.3. We are committed to upholding the highest levels of integrity when conducting human research in line with statutory and regulatory requirements and best practice.

3. Purpose

3.1. This policy outlines the requirements for human research at the Institute. This is research directly recruiting human participants, collecting or processing human biological material,

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 BI-RES-005 Research Integrity Policy) and aligns with the UK Research Integrity Office's (UKRIO's) Code of Practice for Research[1].

4. Scope

4.1. This policy applies to those at the Institute conducting or managing human research and their collaborators. This includes those in the following groups:

- Institute employees on Institute or Babraham Institute Enterprise Ltd (BIE) terms and conditions
- Institute employees on BBSRC or other terms and conditions
- Research Fellows on Institute terms and conditions
- Research Fellows (honorary)
- Honorary Members of Faculty
- Babraham Institute registered PhD students
- Visiting students
- Visiting researchers and workers, including consultants and secondees
- Workers provided by a third party / contractors
- Collaborators of the Institute

5. Principles

5.1. All research recruiting human participants, and collecting or processing human biological material (including relevant material) or personal data, must be registered with the Human Research Team in accordance with the Institute's human research procedure to ensure the Institute holds a record and can support researchers in meeting the ethical, legislative, regulatory and governance requirements.

Details can be found on the Research Integrity pages of The Hub.

5.2. Human participants, material and data should be treated with respect and transparency.

Human participants, material and data should be treated with respect, and before approaching potential donors, researchers should be aware there may be individual, cultural and / or religious differences in the meaning and significance attached to the body or specific parts of it.

5.3. Potential benefits must outweigh risk to participants and donors of data or samples.

Institute researchers should make every effort to maximise the benefits of research while minimising the risks of any harm arising to any individual or organisation. The physical risks involved in donating samples for research will usually be minimal; however, researchers 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.

[1] https://ukrio.org/publications/code-of-practice-for-research/

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

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.

5.5. Appropriate and valid consent must be obtained to: participate in a study; remove, store and use tissue from a living or deceased person; and collect 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.

5.6. All studies recruiting human participants and / or collecting or processing human biological material and / or use of personal data should undergo independent ethical review (with very limited exceptions).

This ensures the rights, safety, dignity and well-being of research participants are safeguarded and, where applicable, legal requirements in tissue legislation are met.

5.7. All personal and medical information relating to research participants must be treated as confidential.

Except where explicit written consent is given to reveal identities, researchers shall respect and preserve the confidentiality of participants' identities and data at all times.

5.8. Researchers should be aware of, and keep up to date with, all ethical, legislative, regulatory and governance requirements relating to their area of research.

All researchers are personally responsible for ensuring they have completed the necessary training to support their research activities. The chief / principal investigator is responsible for identifying training needs for their staff and for ensuring they complete the required training before commencing any human research-related activity.

6. Legal & regulatory framework

6.1. Human research is governed by numerous rules and regulations including the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the Human Fertilisation and Embryology Acts 1990 and 2008, and the Data Protection Act 2018. The primary piece of legislation governing the use of human biological materials in research is the Human Tissue Act 2004. The Human Tissue Act applies to the removal, storage and use of relevant material for scheduled purposes in England, Wales, and Northern Ireland. A comprehensive table of UK legal and regulatory requirements for human research can be found in Appendix 1 of this policy.

7. Ownership, custodianship & gifts of human biological material & personal data

7.1. Legally and ethically, neither researchers nor research organisations can own samples or personal data collected from a donor. Instead, the Institute (rather than the researcher),

shall be considered as custodian of the samples, responsible for the safekeeping of samples and / or personal data, control of the use of the samples and / or personal data, transfer to third parties, and eventual disposal, all in accordance with legislation and the expectations of the donor. Further information in relation to sample management can be found in Section 12 of this policy.

7.2. The Institute treats samples of human biological material donated for research as donations. In this way, a 'gift relationship' between research donors and researchers can be promoted, highlighting the altruistic motivation for participating in research. It is important that the participant understands and agrees to the proposed use(s) of the donated material where this is known. Participants must also be informed as to who will be responsible for custodianship of the sample and control of any personal or confidential data related to it (and under what circumstances custodianship can be transferred to a third party if applicable).

7.3. While an individual researcher may have day-to-day responsibility for management of a collection of human biological material and personal data, it is more appropriate for formal responsibility for custodianship of collections of human biological material to rest with the Institute rather than with individual researchers. This provides greater security for collections, better assurance that donors' rights will be protected and makes it easier to deal with changes in individual circumstances of the research team.

7.4. When a researcher wishes to move samples or personal data to a new location, the agreement of the Institute and the future host organisation must be sought. The terms of the original consent and ethics approval should be reviewed, and an amendment sought if necessary. When a researcher leaves the Institute and sample / personal data collections are to be retained, the Institute will ensure arrangements are put in place for future maintenance and management, and that a named person is identified to take on responsibility for the collection.

8. Licencing

8.1. The Institute does not hold a licence from the HTA to store and use relevant material. Any use of relevant material at the Institute, other than for processing, is permitted under the exemption in s. 1(9) of the Human Tissue Act provided that the research project is covered by appropriate ethical approval.

8.2. It is an offence to carry out research involving creation or use of human or human admixed embryos, including projects involving the derivation of new human embryonic stem cell lines, without a licence from HFEA to cover the research project. For more information on applying for a HFEA Research Licence, please see: https://www.hfea.gov.uk/about-us/applying-for-a-research-licence/.

8.3. HFEA licences are not required to enable use of established human embryonic stem cell lines already derived from an embryo.

9. Research directly recruiting participants

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) where a chief / principal investigator is based at the Institute. Further information in relation to setting up studies directly recruiting participants is available on the Research Integrity pages on the Hub.

10. Consent

10.1. General

10.1.1. Consent must be sought to:

- Participate in a study (for studies that directly recruit participants), under the UK Policy Framework for Health and Social Care Research.
- To remove, store and use relevant material from a living or deceased person, under the Human Tissue Act and the Human Tissue Authority's ("HTA") Codes of Practice, specifically Code A[3], which requires appropriate and valid consent be obtained.
- To use, store or process personal identifiable information under the Data Protection Act 2018.
- To analyse DNA and / or RNA from bodily material.

10.2. Adults who have capacity to consent

10.2.1. For consent to be valid it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. The person consenting should understand what the activity involves, any reasonable or variant treatment and, where appropriate, what the material risks are. The test of materiality is 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach a significance to it'.

10.3. Children

10.3.1. There is no statute in England, Wales or Northern Ireland governing a child's right to take part in research other than a Clinical Trial of an Investigational Medicinal Product (CTIMP). However, children over the age of 16 are presumed capable of giving consent on their own behalf to participate in CTIMPs.

[2] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
[3] https://content.hta.gov.uk/sites/default/files/2020-11/Code%20A.pdf

10.3.2. A child's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed. This will relate to the complexity of the research.

10.3.3. A child's competence may be reflected in their ability to understand and assess risk.

10.3.4. A child's competence to understand will be heavily influenced by how information relating to the research is presented to them. Information must be presented to them in a manner that is age appropriate to maximise a child's ability to understand what is involved in your research.

10.3.5. Even when deemed competent, it is still considered good practice to involve the family in the decision-making process.

10.3.6. If a child is not deemed competent to consent, or in a situation where they are not legally empowered to do so (e.g., in a CTIMP), a child's assent should be sought wherever practical and appropriate.

10.3.7. When seeking a child's assent, it is important that:

- Information given to the child about your study is understandable to them and explains what is involved, and the potential risks and benefits
- The information is provided by staff with experience of working with children
- If the child is capable of assessing the information provided you must consider their explicit wishes, including refusal to take or desire to withdraw.
- It is unusual to ask a child under 5 to sign an assent form; however, their views should still be considered.

10.3.8. Further information in relation to consenting children can be found on the HRA website at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/.

10.4. Vulnerable people: legal representatives & consultees

10.4.1. For studies involving recruitment of vulnerable people e.g. participants who lack the capacity to consent, or those who are not legally empowered to consent (e.g. children recruited in a CTIMP), researchers must have suitable consent processes in place which have been approved by an NHS REC.

10.4.2. It will be necessary to obtain written consent from the legal representative of the vulnerable person, or identify a consultee to advise the vulnerable person. Vulnerable people must be still be appropriately informed and researchers will be required to make every attempt to maximise the capacity of a vulnerable person to understand as much as possible. Further information, including receiving consent from potentially vulnerable people, is available at: https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/research-with-potentially-vulnerable-people/.

10.4.3. Consent to collect samples for a specific research study should be obtained using a study-specific participant information sheet which can be easily understood, and a consent form that have both been approved by an NHS Research Ethics Committee as part of the overall review of the research study.

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. Exemptions to consent for use of relevant material

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. Non-consensual analysis of DNA / RNA

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:

i. Existing holdings can be analysed for DNA provided that the person who has the material 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. In this case, the results can be used for any purpose and consent is not required; or

ii. All of the following criteria have been satisfied in relation to the material:

a) The bodily material is from a living person;
b) The research has ethical approval from a recognised REC; and
c) 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.

If an excepted purpose does not apply, consent must be gained, as outlined above.

10.7. Gametes, fetal tissue & embryos

10.7.1. In the UK, research involving gametes and human embryos, including the derivation of new human embryonic stem cell lines, is governed by the Human Fertilisation and Embryology Act 1990 as amended in 2008, and regulated by the Human Fertilisation and Embryology Authority (HFEA).

10.7.2. Despite being regulated by a different piece of legislation, the consent requirements are the same as under the Human Tissue Act as outlined under sections 10.1.1 to 10.4.6 above. In addition, HFEA has drawn up a list of criteria that must be addressed in information sheets and consent forms given to donors available here[4].

10.8. Biological material sampled / collected from colleagues

10.8.1. The same legal and ethical standards apply to obtaining samples of human biological material from Institute colleagues as would to any other participant in research.

10.8.2. Particular attention must be given to the following when asking colleagues to donate samples:

- The possibility of a perceived obligation to participate and the anxiety that colleagues may feel of not wanting to appear obstructive or difficult;
- Ensuring privacy of research results; and
- Uncovering health-related findings in situations where donors are likely to be known by those working on their samples.

10.8.3. All requests for donations and consent procedures must be conducted by those who do not have a direct managerial or supervisory role with those being asked to donate. Potential participants should be given the opportunity to ask questions about the research from a person independent of their immediate colleagues if possible.

10.8.4. Independent ethical oversight of research involving colleagues is required (see next section for further detail). This should be in the form of a positive opinion from an NHS REC.

[4] https://www.hfea.gov.uk/media/2609/june-2018-code-of-practice-9th-edition-draft.pdf

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. Ethical approval

11.1. General

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 / 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 conditions).

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 Health and Social Care Research, and also involves NHS premises and / or NHS patients and / or NHS staff in England and / or Wales (except tissue banks), you will require HRA approval. This can be selected as part of the process when you submit your study to the NHS REC for approval.

11.3. Exceptions

11.3.1. NHS REC approval is not normally required in the following circumstances:

- Where relevant material rendered acellular within one week of receipt;

  It is important to note that when using the above exemption, you must not commence your research until processing is complete. This exception under the Act is solely for lysing cells, which must take place using a recognised and validated method such as enzymes / buffer solutions or alcohol, or physical processes such as freeze-thaw cycles, prior to the first step of your research. If the use of relevant material forms part of your research, ethical approval will be required.

- Use and storage of relevant material is covered by the generic ethical approval of a tissue bank; or

- Use and storage of relevant material and / or personal data is covered by ethical approval held by a UK collaborator and the Institute is a named collaborator on the research ethics committee application.

If you are receiving relevant material and / or personal data from a collaborator, *i*t is essential that you are aware of the content of any ethics application submitted to a REC. It is your responsibility to ensure that your research has appropriate ethical approval. Researchers are required to obtain copies of such collaborator's ethics application and approval. Please note that *i*nternational REC approval is not recognised for the purposes of the Human Tissue Act. If you are receiving samples considered as relevant material which were collected under ethical approval from a REC outside the UK, you will need to obtain NHS REC prior to taking receipt of the samples. This requirement also applies to relevant material received from an overseas tissue bank.

11.4. Storage of relevant material under ethical approval

11.4.1. As the Institute is not a licenced site, any storage of relevant material at the Institute, other than for processing (where it is rendered acellular within one week of receipt), is permitted under the exemption in s. 1(9) of the Act provided the research project is covered by appropriate ethical approval. Additional information in relation to storage prior to processing can be found here[5].

11.4.2. Relevant material collected or stored by Institute researchers for REC approved studies cannot continue to be stored at the Institute once the REC approval for that study has expired.

11.4.3. Institute researchers may however continue to store relevant material after the end of the REC approved study for a defined period of time (not to exceed 12 months) for verification or quality checking, provided that such storage is detailed in the protocol which is approved by the REC. After this period, legal authority provided by the favourable ethical opinion of the REC to hold relevant material will expire, and the samples must be destroyed in accordance the HTA Codes of Practice and Standards on Research (code E)[6].

11.4.4. In the event the relevant material is to be used for another project, an application for ethical approval must be made before REC approval of the existing project expires.

11.5. Embryonic stem cell lines

11.5.1. Ethical approval must be obtained for research activities requiring a HFEA licence as part of the licence application process.

11.5.2. Ethical approval is not required for research involving the use of established embryonic stem cells lines.

11.5.3. All researchers wishing to work with human embryonic stem cell lines within the UK (whether accessed from the UK Stem Cell Bank, from other sources in the UK or oversees) must inform the Steering Committee through the online application procedure available at: https://www.nibsc.org/science_and_research/advanced_therapies/uk_stem_cell_bank/apply_for_cell_lines.aspx.

11.5.4. Researchers wishing to either import or export human embryonic stem cell lines into or out of the UK should complete the Application to import or export human embryonic stem cell

[5] https://babraham.sharepoint.com/sites/Research-Integrity/SitePages/Relevant-Materials.aspx
[6] https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf

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. Induced pluripotent stem cell (iPS cell) lines

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. Management of samples

12.1. Biosafety

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. Standard operating procedures

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:

- Collection
- Receipt
- Labelling
- Specimen preparation / preservation
- Storage
- Relevant transport arrangements
- Cleaning and decontamination
- Disposal

12.3. Sample tracking

12.3.1. Those carrying out research involving human biological materials must be able to demonstrate full traceability for the human biological material for which they are

[7] https://www.nibsc.org/asset.ashx?assetid=87bbf320-4885-4fb7-8fa1-24e6af99ef01

responsible, from receipt to final disposal or transfer to another researcher / project. The Quality Assurance Manager will test this through traceability audits carried out as part of the periodic QAR audits. In addition, as the final traceability step, they must have established disposal arrangements which are in accordance with the HTA's and HFEA Code(s) of Practice (as applicable).

12.3.2. A formal written record must be made by the researcher responsible for the samples for each and every sample of human biological material held by the Institute to ensure samples continue to be used in accordance with donor consent, and to support the auditing requirements of the Institute.

12.3.3. All study records must contain the following information as applicable:

- Unique reference for the sample
- Study ID
- Identity of person collecting the sample
- Location from where sample was collected
- Date and time of collection
- Confirmation that donor consent to collect the sample was given
- Signature of person collecting the sample
- Exact location sample is stored (building / room / fridge / freezer)
- Date sample stored
- Date sample used
- Date sample received from a third party
- Contact details of third party provider
- Date sample destroyed
- Method of disposal

12.3.4. The samples themselves should be appropriately labelled with the sample ID and study reference but should not contain any information that may lead to the identification of the donor.

12.4. Sample transfer

12.4.1. Receipt of samples from third party organisations must be covered by a material transfer agreement to enable the Institute to ensure the samples have been collected in accordance with applicable law and with appropriate consent and ethical approval. In exceptional cases, e.g., samples are collected on behalf of the Institute as part of an Institute-sponsored study, a material transfer agreement may not be required.

12.4.2. Samples collected by or on behalf of the Institute to be sent to a third party should be traceable and transferred under material transfer agreement. The initial consent form should also include an option to use the samples for future research by other organisations (see Section 10 above).

12.4.3. Please notify the Contracts Manager in the event you wish to send samples to or receive samples from a third party.

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, please see the Data Protection Policy (BI-IM-002).

13.2. Confidentiality

13.2.1. UK GDPR does not prevent research data from being archived and shared for research use by others, as long as the data protection principles are met.

13.2.2. Where data is collected directly from participants, researchers should discuss their intention to reuse participant data in further research and, if appropriate, to deposit in an archive. Any further use of participant data should be appropriately detailed in the participant information sheet. Where participants expect their data to be kept confidential, sharing can only take place with the participant's permission or through another legal avenue if their permission cannot be obtained.

13.2.3. Researchers wishing to access confidential patient information without consent will need to apply to the Confidentiality Advisory Group (CAG) via IRAS. Further information relating to CAG applications is available here[8].

13.3. Personal identifiable data

13.3.1. Personal identifiable data held as part of study data must be stored in accordance with the Data Protection Act 2018 (see the Institute's Data Protection Policy, BI-IM-002). Personal identifiable data includes data which has been anonymised for day-to-day use, but the identification key is held at the Institute.

13.3.2. As part of the Institute study registration process, researchers will be asked to complete a Data Protection Impact Assessment including:

- Location of data
- Who has access (this should be the minimal number possible, e.g., by limited permission or encryption)
- Retention period
- Archiving arrangements

Please note that the act of anonymising personal data would amount to processing for the purposes of the Data Protection Act 2018.

13.3.3. Ethical approval will be required for use of personal identifiable data or special category data (please see Data Protection Policy (BI-IM-002) for more information on special

[8] https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

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. Fully anonymised data, where the key is not held at the Institute, is not classed as personal identifiable data and does not need fulfil the above requirements.

13.4.2. Researchers should give due consideration to whether their data could be linked to publicly available data in order to identify individuals and, where this is in doubt, treat the data as personal identifiable data.

13.4.3. Institute researchers receiving anonymised samples such as DNA / RNA (from which genetic data is produced), or anonymised data, are strictly prohibited from taking any steps to identify, or attempt to identify the donor of such samples or data.

13.5. Genetic data

13.5.1. A sample of anonymous genetic material, such as DNA or RNA, is not itself personal data until it is analysed to produce genetic data.

13.5.2. Genetic data is only personal identifiable data if:

- It can be linked back to an identifiable individual.
- It includes enough genetic markers to be unique to an individual. In this case, genetic data is personal identifiable data and special category genetic data even if names or other identifiers have been removed.

13.5.3. Genetic data will not be considered personal identifiable data where researchers anonymise or aggregate partial genetic sequences or genetic test results, and they can no longer be linked back to a specific genetic identity, sample or profile; patient record; or any other identifier.

13.6. Open data

13.6.1. The Institute promotes publishing of research data in line with its Open Data Policy (to follow). Where data is to be made open, this should be included in the participant information sheet and consent form.

14. Financial considerations

14.1. Sale for profit, whether in cash or in kind, of human biological material collected as part of any research conducted by Institute researchers, whether conducted at the Institute or third party premises, is not acceptable under any circumstances. No inducement to participate should be offered prior to seeking consent, either in the form of payments or of gifts. Reasonable recompense for inconvenience and time contributed to the research and reimbursement of travelling expenses may be offered.

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 Medical Research Council's training on the Human Tissue Act and its related Codes of Practice.
- Anyone working with personal identifiable data must complete the Institute's Data Protection training and the Medical Research Council's Research, GDPR and confidentiality e-learning.
- Biosafety training requirements must be fulfilled (in accordance with the Biosafety Policy (to follow) prior to working with human materials.
- Work with the NHS may require additional training, e.g., Good Clinical Practice and a Research Passport.

15.2. Training is included in induction programmes for new staff and delivered online via the Medical Research Council's Regulatory Support Centre.

15.3. Training must be documented, kept up-to-date, and competency assessed and maintained. A record should be held with the study file. This requirement extends to include short-term visiting researchers and students. Institute researchers will be asked to provide up-to-date copies of the relevant training certificates upon submission of a project to the Human Research Team.

15.4. Training must be completed before starting human research and updated every two years.

15.5. The chief or principal investigator is responsible for ensuring that they, and all researchers in their study are appropriately trained for their role and that proof of completion is available for auditing purposes.

16. Sanctions

16.1. Any suspected breaches of this policy should be reported to the Named Person Responsible for Human Research (the Policy Owner named on the cover sheet).

16.2. The Institute regards any breach of this policy or any breach of the approved terms of a project, as a very serious matter, which may result in disciplinary action in accordance with

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. Further information

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.
- For a non-exhaustive list of materials considered to be 'relevant material' under the Human Tissue Act 2004 please see: https://www.hta.gov.uk/policies/list-materials-considered-be-'relevant-material'-under-human-tissue-act-2004.
- The Human Tissue Authority's Code of Practice 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.
- The Human Tissue Authority's Code of Practice E: Research Code of Practice and Standards available at: https://www.hta.gov.uk/sites/default/files/Code%20E.pdf.
- Health Research Authority/MRC: Consent and Participant Information Sheet Preparation Guidance available at: http://www.hra-decisiontools.org.uk/consent/index.html.
- Information Commissioners Office: What is special category data? Available at: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-is-special-category-data/.
- MRC ethics series – Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines available at: https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/.
- UK Policy for Health and Social Care Research available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/.

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: https://bbsrc.ukri.org/documents/safeguarding-good-scientific-practice/
Relevant Material	**Human Tissue Act 2004**. Relevant material defined in s53. See https://www.hta.gov.uk/policies/list-materials-considered-be-'relevant-material'-under-human-tissue-act-2004 Regulated by Human Tissue Authority
Gametes and Embryos, Hair and Nails from living person	**Human Fertilisation and Embryology Act 1990** **Human Fertilisation and Embryology (Research Purposes) Regulations 2001** **Human Fertilisation and Embryology Act 2008** Regulated by Human Fertilisation & Embryology Authority https://www.hfea.gov.uk
Studies involving human participants	**Human Tissue Act 2004** (See "Relevant Material") **Human Tissue (Quality and Safety for Human Application) Regulations 2007** available at: http://www.legislation.gov.uk/uksi/2007/1523/contents/made The World Medical Association Declaration of Helsinki, entitled "Ethical Principles for Medical Research Involving Human Subjects" available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ UK Policy Framework for Health and Social Care Research available at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ **Good Practice and a requirement under UKRI funded research:** Human Tissue and Biological Samples for Use in Research, available at: https://www.mrc.ac.uk/publications/browse/human-tissue-and-biological-samples-for-use-in-research/

		MRC Good research practice: Principles and guidelines, available at https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/
Personal Data		**Data Protection Act 2018** ***UK General Data Protection Regulation***
Stem Cells		
Embryonic stem cells (ESCs - pluripotent) and embryonic germ cells (EGCs pluripotent)	Derivation:	**Human Fertilisation and Embryology Act 1990** **Human Fertilisation and Embryology Act 2008** **Human Fertilisation and Embryology (Research Purposes) Regulations 2001** HFEA Licence required. Subject to appropriate consent in accordance with HFE Act 1990 and HFEA / Steering Committee criteria and favourable ethical opinion.
	Use in laboratory-based research	Laboratory purposes: established cell lines fall outside the remit of the HFE Act (provided applicable licence conditions are satisfied). Researchers are expected to comply with: - *Code of Practice for the Use of Human Stem Cell Lines* available at: https://mrc.ukri.org/documents/pdf/code-of-practice-for-the-use-of-human-stem-cell-lines/ - MRC Good research practice: Principles and guidelines, available at https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/ - Best Practice for Cell Culture Procedures Researchers must inform UK Stem Cell Bank Steering Committee Ethical Approval not required for laboratory-based research
	Use of ESCs and EGCs 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 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells** available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0023
	Use of ESC-derived or EGC-derived reproductive cells such as oocytes	**Human Fertilisation and Embryology Act 1990** **Human Fertilisation and Embryology Act 2008** **Human Fertilisation and Embryology (Research Purposes) Regulations 2001**

	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	**Human Tissue Act 2004** 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.
	Use	Established cell lines fall outside the remit of the Human Tissue Act Researchers are expected to comply with: - MRC Good research practice: Principles and guidelines, available at https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/ - Best Practice for Cell Culture Procedures
Induced Pluripotent Stem Cells (iPSCs – pluripotent)	Use of relevant material with the intention of deriving iPSCs	**Human Tissue Act 2004** 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.
	Use of iPSCs in laboratory-based research	Established cell lines fall outside the remit of the Human Tissue Act Researchers are expected to comply with: - MRC Good research practice: Principles and guidelines, available at https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/ - Best Practice for Cell Culture Procedures
	Use of iPSC-derived reproductive cells such as oocytes	**Human Fertilisation and Embryology Act 1990** **Human Fertilisation and Embryology Act 2008** **Human Fertilisation and Embryology (Research Purposes) Regulations 2001**

	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.
	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 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells** available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0023