Obtaining Informed Consent for Research Participation.

Purpose:

To describe Liverpool John Moores University's procedure for obtaining informed consent from participants in ethically approved research projects.

Application

This policy applies to all Principal Investigators (PIs), staff and students involved in obtaining informed consent from research participants including those obtaining consent for the removal, storage and use of human tissue samples from healthy volunteers for research purposes. Where a research project involves NHS patients including access to human tissue samples from NHS patients ethical approval must be sought via the National Research Ethics Service (NRES). Following notification of full, unconditional approval via NRES Liverpool John Moores University (LJMU) REC must be informed as detailed on the LJMU Research Ethics Website. All other research projects involving human participants eg LJMU staff / students, members of the public or healthy volunteers must seek ethical approval via LJMU REC.

This policy applies to all research projects requiring full ethical approval via LJMU REC.

Responsibilities for implementation:

All research staff and students involved in obtaining consent for research
Designated Individual for Human Tissue
Persons Designated for Human Tissue

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Summary of Key Points

1. Participants entered into research at Liverpool John Moores University must receive full information about the study with appropriate time to consider whether they wish to take part.
2. This information should ideally be provided in both verbal and written format.
3. Written documentation consists of a participant information sheet and an informed consent form, both of which must be approved by an appropriate research ethics committee (REC).
4. Participant information sheets and consent forms must be written in lay language and must contain all the information necessary for the participant to give informed consent including, but not limited to, the risk and benefits involved, the purpose and design of the study.
5. Consent must be freely and voluntarily given with no coercion.
6. Once a participant has given consent he/she is free to withdraw consent without giving a reason. The decision to withdraw will not prejudice the participant's legal rights.
7. The participant must be allowed sufficient time to ask questions and consult with family or friends prior to giving consent.
8. Where possible both the person taking consent and the participant should sign the consent form.
9. The participant information sheet and consent form should be in duplicate – one copy is given to the participant and one is retained by the researcher.
10. Where research involves children as participants consent must be sought from the parent, guardian or carer or from a person with gatekeeper responsibility such as a head teacher.
11. Where consent for the removal, storage and / or use of human tissue samples is being sought the following must apply:
    a. Participant information sheets and consent forms must include adequate information on the nature of the tissue samples taken and their subsequent use.
    b. The consent form should ask the donor or their representative for their explicit consent for the use of their tissue for research purposes.

1. INTRODUCTION

Definition

Informed consent is a process by which a participant voluntarily confirms their willingness to participate in a particular piece of research, after having been informed fully of all aspects of the research that are relevant to the decision to participate.

All participants entered into research at Liverpool John Moores University must receive full information about the study with appropriate time to consider whether they wish to take part.

A participant may only be entered into a research project after they have received detailed information about the research project and they have given their written consent. The explanation of the study should be given by the researcher or the person identified in protocol and/or approved research ethics committee (REC) application. This information should be provided in both verbal and written format.

Written documentation consists of two elements:-

- The Participant Information Sheet (PIS). Describes the study in layperson's terms.
- The Informed Consent Form (ICF). Documents that informed consent has been taken, when and by whom.

The PIS and ICF must be approved by the University REC before any participant can be recruited into the study. Any amendments subsequent to this approval must be submitted to the REC for approval.

The person obtaining consent and giving information must possess an in-depth knowledge of the proposed research. This is usually the Principal Investigator.

Consent must be given freely and voluntarily by the participant with no coercion from any party. It must be made clear that should consent be given, the participant has the right to withdraw at any time from the study, without giving a reason for their withdrawal. The decision to withdraw will not prejudice their future legal rights.

Consent for research involving children

Where children are identified as the participants of a research project consent must be obtained from a parent or from someone with parental responsibility e.g guardian, carer or a person with a gatekeeper role for example a head teacher.

Where research is to be undertaken within a school environment there are two procedures open to researchers to obtain consent to carry out research involving children; Opt-In and OptOut.

- Opt-out. The researcher and Head Teacher agree that explicit parental consent is not required. Researchers, having obtained the written consent of the Head for their project,

provide parents with an information sheet and give them the opportunity to opt their children out by filling in and returning a form to the school.

- Opt-in. The researcher and Head agree that the study requires explicit parental consent. Researchers send parents an information sheet and ask them to complete an opt-in form giving permission for their child to take part in the study.

For applications to LJMU REC Opt-In should be used as default. However a case may be made to the REC that opt-out is used, given the particular circumstances of the project, in particular relating to the levels of risk involved. Studies involving vulnerable children should always be subject to opt-in. If an opt-out procedure is permitted the researcher must allow at least two weeks for a response.

It is seen as best practice that the child is also provided with verbal and, where applicable, written information regarding the study and that the child's assent to participate is gained. This information should be provided in a suitable format. Where a parent, guardian or gatekeeper has consented on behalf of the child but the child does not wish to participate the wishes of the child will outweigh those of the parent, guardian or gatekeeper.

Consent for the removal, storage and use of human tissue samples for research purposes

Where a research study involves the removal, storage or use of human tissue samples consent must be obtained in accordance with the requirements of The Human Tissue Act 2004 (HT Act) and the associated Code of Practice issued by the Human Tissue Authority (HTA) – Consent.

If the participant is a competent adult only they are permitted to give consent. Consent for the storage and use of tissue from children must be sought from the child's parent or from a person who has parental responsibility.

To give informed consent participants must understand the following:

- The nature and purpose of what is proposed and be able to make a balanced judgement.
- How the sample will be obtained, how the tissue will be used and any possible implications for its use such as genetic tests.
- If tissue is to be stored for future research in an identifiable manner, participants should be told of any implications this may have e.g being contacted by researchers or their medical records being accessed.
- Participants should be told whether the consent they are giving is generic (for use in any future research project approved by a REC) or specific. If specific detailed information about the project should be provided in line with good practice.
- Participants should be told if their samples will, or could be, used for research involving the commercial sector. Appropriate information should be given on the range of possible activities.

Consent for the removal, storage and use of human tissue samples from the deceased for research purposes

Where an adult has, whilst alive and competent, given consent to the storage and use of their tissue for research purposes following their death then that consent is sufficient in law. In all other cases consent must be sought from either a nominated representative (such representatives must be appointed in writing and witnessed prior to the donor's death) or from a person in a qualifying relationship. Qualifying relationships are ranked in the following order (highest first):

1. Spouse or partner
2. Parent or child
3. Brother or sister
4. Grandparent or grandchild
5. Niece or nephew
6. Stepfather or stepmother
7. Half-brother or half-sister
8. Longstanding friend

Any member of staff or student wishing to undertake a research project involving the removal, storage or use of tissue from the deceased must seek further guidance from the University's Designated Individual and the University REC.

PROCEDURE

1) The Principal Investigator is responsible for the conduct of the informed consent process. Ideally the principal investigator will obtain the participant's consent
2) The Principle Investigator is responsible, where possible, for ensuring the participant receives a comprehensive verbal explanation of the research.
3) The Principal Investigator is responsible for providing written information in the form of a participant information sheet approved by the University Research Ethics Committee. The format of the consent form should be that described on the University Research Ethics Website.
4) The participant information sheet must contain the following core information written in lay terms and approved by the University REC
    a. That the study is a research study and which, if any, aspects are novel.
    b. Any risks or benefits to the participant
    c. The purpose of the study
    d. The procedures involved
    e. Where, when and who will see the participant
    f. The study design
    g. Where applicable any arrangements for reimbursement of expenses
    h. Participant responsibilities if they participate
    i. Any exclusion criteria which may affect the participant continuing with the study
    j. Who will have access to participant's data/information
    k. Contact details for further information

l. A statement informing the participate that their involvement is voluntary and that they are free to withdraw at anytime

5) The Principal Investigator allows the participant adequate time to decide whether to take part in the study. Ideally the participant should be able to take the information away to consider it.
6) The Principal Investigator gives the participant every opportunity to ask questions before consenting.
7) The Principal Investigator makes clear to the participant that declining to take part in the research will not affect their legal rights.
8) The Principal Investigator ensures the participants understand that they are free to withdraw from the study at any stage without providing a reason.
9) Where possible the participant signs and dates the consent form in the presence of the Principal Investigator.
10) Where possible the Principal Investigator signs and dates the consent form in the presence of the participant.
11) All signatures should have the name of the person signing printed clearly beneath the signature.
12) The consent form should be in duplicate
13) One consent form and participant information sheet should be given to the participant. A second set is retained by the researcher.
14) The Principal Investigator is responsible for ensuring the information process continues throughout the participation in the study.

RELATED DOCUMENTS

Liverpool John Moores University Research Ethics Application Form and Guidance
Liverpool John Moores University Participant Information Sheet Template and Guidance
Liverpool John Moores University Consent Form Template and Guidance
https://www.ljmu.ac.uk/ris/research-ethics-and-governance/research-governance/sops-templates-and-forms
The Human Tissue Act 2004 - http://www.legislation.gov.uk/ukpga/2004/30/contents The Human Tissue Authority Codes of Practice
https://www.hta.gov.uk/guidance-public/public-guides-hta-codes-practice