Standard Operating Procedure
Research Governance

Title:	**Informed Consent for Research**		
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	Name and Position	**Signature**	**Date**
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) and Work Instructions (WI) provides the process for obtaining informed consent from a research participant. The Work Instructions outline the informed consent procedures for adults, who are able to give informed consent and the consent process for persons over the age of 16 who lack the capacity to consent. Contained within the appendices are template documents to support the researcher in the preparation of relevant documentation.

2. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff, and students who are conducting research within or on behalf of the University, including research regulated by the Human Tissue Act 2004 (HT Act).

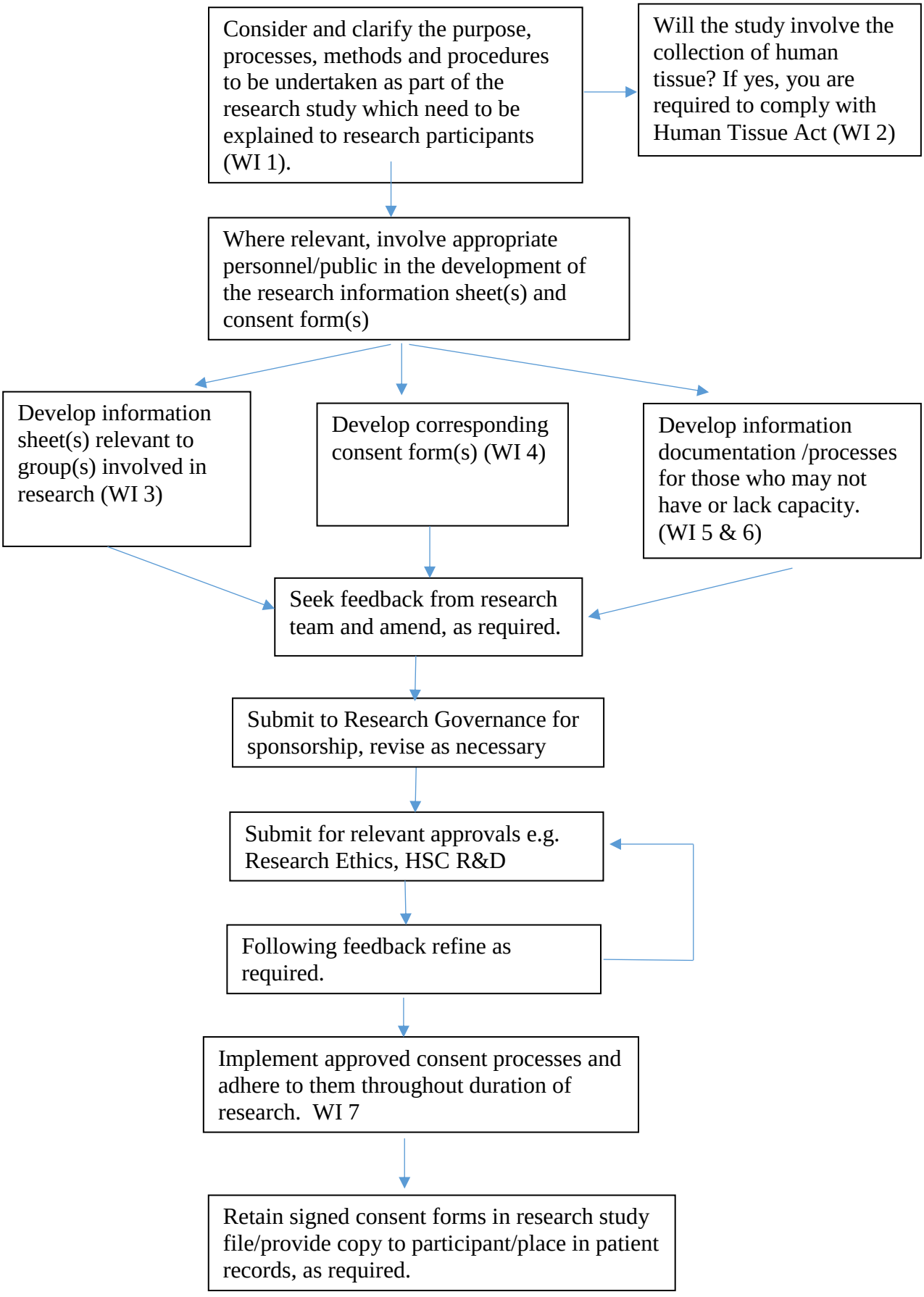
Informed consent is a core ethical principle and it remains at the heart of ethical research. It is every researcher's responsibility to respect the wishes of individual research participants. Therefore, the diversity and level of understanding must be respected when obtaining informed consent. Consent is given freely and only after a person has been informed of the nature, significant, implications and risks involved in the research study.

A fundamental principle of the Human Tissue Act 2004, consent is required for the removal, storage and use of human tissue – defined as "relevant material" for the living for research in connection with disorders or the functioning of the human body, or, obtaining scientific or medical information which may be relevant to any person including a future person.

Informed consent is also required for the removal, storage and use of relevant material from the deceased.

Note: The Northern Ireland Biobank and Precision Medicine Centre will have their own procedures and requirements and should not follow this SOP.

3. Procedure


Consider and clarify the purpose, processes, methods and procedures to be undertaken as part of the research study which need to be explained to research participants (WI 1).
Will the study involve the collection of human tissue? If yes, you are required to comply with Human Tissue Act (WI 2)
Where relevant, involve appropriate personnel/public in the development of the research information sheet(s) and consent form(s)
Develop information sheet(s) relevant to group(s) involved in research (WI 3)
Develop corresponding consent form(s) (WI 4)
Develop information documentation /processes for those who may not have or lack capacity. (WI 5 & 6)
Seek feedback from research team and amend, as required.
Submit to Research Governance for sponsorship, revise as necessary
Submit for relevant approvals e.g. Research Ethics, HSC R&D
Following feedback refine as required.
Implement approved consent processes and adhere to them throughout duration of research. WI 7
Retain signed consent forms in research study file/provide copy to participant/place in patient records, as required.

4. References

Informing participants and Seeking Consent Informing participants and seeking consent - Health Research Authority (hra.nhs.uk) (last accessed August 2021)

Human Tissue Authority Code of Practice A Guiding Principles and the Fundamental Principle of Consent
https://www.hta.gov.uk/hta-codes-practice-and-standards-0 (last accessed May 2019)

Money and Valuables & Research Code of Practice, Mental Capacity Act (Northern Ireland) 2016. Department of Health. https://www.health-ni.gov.uk/publications/mcani-2016-money-valuables-and-research-code-practice-august-2019

Declaration of Helsinki, 1996 (last accessed May 2019)
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1):
http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html (last accessed December 2019)

5. Work Instructions and Appendices

Work Instructions 1 – Methods of Consent,
Work Instructions 2 – Human Tissue Act, Enduring Consent and Consent Exceptions
Work Instructions 3 – Information Sheets for Adults
Work Instructions 4 – Consent Form
Work Instructions 5 – Informed Consent in Minors
Work Instructions 6 – Informed Consent in person who lack capacity
Work Instructions 7 – Processes and Procedures

Appendix 1 - Consent Form Template

Consent forms may vary according to the nature of the study. The template consent form is suitable for most studies but may require alteration. Text in red or within square brackets indicates wording that should be included if appropriate for the study.

Appendix 2 – Participant Information Sheet Template

Work Instructions 1 – Methods of Consent

1. The normal process for recording consent is through obtaining a written record. However it may not be physically possible to obtain this record, or indeed appropriate and so thought should be given to other forms of consent.
2. Where a researcher deviates from using written consent this must be justified, in particular, to the research ethics committee.
3. The research team must also maintain a written record as to how consent is obtained (think about date, recording the time, location and the method used to record that consent).
4. Alternative methods include:
    a. Use of Verbal Consent – often used when undertaking field work where a consent form may cause harm to a research participant.
    b. On-line – appropriate for questionnaires and survey. A statement can be prepared advising participants that by completing the form it is an indication that they have consented to participate in the research.
    c. Receipt of email – where research being undertaken is via an on-line platform the researcher should email the participant the consent statements. The participant should respond to each and confirm their willingness to participate.

Work Instructions 2 – Human Tissue Act - enduring consent and consent exemptions

1. The HT Act permits the seeking of enduring and generic consent to facilitate the use of human tissue in future research. The following should be considered and detailed when seeking enduring consent:
    - Likely nature of the future research (eg disease states to be studied or genetic analysis, creation of cell lines or use in animal models)
    - Whether the tissue could be shared with other collaborators or commercial partners (within the UK and abroad).
    - If tissue samples will be anonymised
    - Whether any future research will be subject to ethical approval.

    Note: When enduring consent has been obtained ethical approval for future research projects may be sought from Faculty Research Ethics Committees, if appropriate. Consent Forms providing enduring and generic consent must be retained for the same duration as the human tissue samples are stored under the HTA licence.
2. There are exceptions to consent requirements under the HT Act. Consent for research is not required if:
    - The material is an 'existing holding' (i.e. collected prior to the 1st September 2006);
    - The material is imported;
    - The material is from a living person and the researcher is unable to identify the person and the specific research project is approved by a recognised REC (i.e. ORECNI or the equivalent statutory REC). University RECs are not considered to be recognised RECs for this purpose.
3. Consent is not required for imported material though, mechanisms must be in place to provide assurance that the tissue has been obtained with valid consent.
4. Research involving the use of previously collected tissue (or information) from which individual past or present NHS/HSC users could be identified must be approved by a recognised REC.

Work Instructions 3 - Development of Information Sheets (for Adults)

When developing the information sheets the research team should describe the study and explain:

1. Why the participant has been approached and assure them that their privacy and confidentiality will be maintained throughout the study;
2. The purpose of the study and any relevant background information. The approximate number of participants involved in the study;
3. What the procedures for the study will be i.e. the number of study visits, any blood tests/investigations, including all invasive procedures;
4. What human tissue will be collected (if any), the amount of tissue required, how it will be used (including genetic analysis, transfer abroad or commercial research), stored and disposed of as appropriate;
5. The potential benefits. Where there is no intended clinical benefit the participant should be made aware of this;
6. The foreseen risks or inconveniences to the participant;
7. The alternative procedure(s) or course(s) of treatment that may be available, and importantly, the potential benefits and risks;
8. The availability of compensation, should something go wrong;
9. The anticipated expenses, if any, to the participant and if there are any payments to be made;
10. That the person's participation is voluntary and that they may refuse to participate or withdraw, at any time, without any prejudice to them or their future care;
11. That the study records / participants medical records will be open to audit/monitoring by the appropriately identified persons within or on behalf of the Sponsor i.e. the University and/or Trust and the necessary regulatory authority(ies). The participant should be assured that their confidentiality will be maintained;
12. That giving informed consent does not necessarily mean the participant will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria;
13. Where a study is co-sponsored a copy of the signed consent form may be held by both organisations.
14. The language used to explain the study should be as non-technical as is practical and should be understandable to the participant. In addition, an appropriate and accessible format should be used when obtaining consent;
15. The research participant should be provided with a contact point where he/she may obtain further information about the study;
16. The information sheet should be printed on the appropriate headed paper, depending on the Sponsorship arrangements for the specific study;
17. The correct title, version number, and IRAS ID where applicable should be clearly visible.

Work Instructions 4 – Consent Form

1. Should be printed on the appropriate headed paper, depending on the sponsorship arrangements for the specific study;
2. The correct title and version number for the study should be clearly visible and relates to the written information sheet given to the participant;
3. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the participant ample time and opportunity to inquire about details of the study and decide whether or not to participate;
4. Prior to the person's participation in the study, the written informed consent form should be signed and personally dated by them, or by their legally acceptable representative, if applicable, and by the person who conducted the informed consent discussion;

5. Once all parties have signed the written informed consent form, the participant should receive a signed and dated copy, together with the information sheet and any other written information in relation to the study. For all other studies, a copy of the consent form should be maintained in the study file, as appropriate;
6. Neither the research participant nor their representative should be coerced or unduly influenced to participate in the study.

An example Consent Form is provided in Appendix 1.

Work Instructions 5 - Informed Consent of Minors

Minors

1. Under the HT Act, a child is defined as a person under the age of 18 years. The Clinical Trials Regulations, 2004 definition of a minor takes precedence for clinical trials of an investigational medicinal product.
2. Under the Clinical Trials Regulations, 2004, a minor is a person under the age of 16 years.
3. For other research (i.e. non-clinical trial) young people aged between 16 and 18 are usually competent to give consent. If a young person under the age of 16 years has sufficient understanding what is involved and is deemed competent of making an informed decision then he/she can give consent to take part in the proposed research, (i.e. 'Gillick competence'[1]). The involvement of those with parental responsibility in the decision should be encouraged, even if the young person is deemed competent. When a child or young person is not deemed competent, parents or those with parental responsibility can consent on their behalf. The child or young person should be informed of the nature of the research in a manner appropriate to their age and their assent obtained as well. The process by which competency is determined should be documented.
4. Careful consideration must be given before proceeding with the research when there is discordance between the parent/guardian and the child/young person regarding participation.
5. Researchers involved in the consent and recruitment of children and young people must have appropriate consent training.
6. The minor should be given information about the study according to his/her level of understanding and from staff with experience of working with the young person.
7. The Participant Information Sheet should be written in age appropriate language that the minor can understand, with different versions for different age groups. There should also be a version produced for the legally acceptable representative, as appropriate.

Work Instructions 6 – Informed Consent from persons lacking capacity to consent

Northern Ireland

1. The Mental Capacity Act (Northern Ireland) became law on 09 May 2016 and the Code of Practice governing research (Money and Valuables & Research) was implemented on 01 October 2019.
2. A person is deemed to lack capacity if, at the material time, he or she is “unable to make a decision for him or herself about the matter, because of an impairment of, or a disturbance in the functioning of the mind or brain”.
3. It is the researcher’s responsibility to enrol a participant onto a research study, subsequently the researcher must be cognisant of the requirements of the MCA. In particular, that the

[1] Gillick competence is the term used in medical law to describe a young person's ability to make a decision regarding consent, The Gillick case (Gillick v West Norfolk and Wisbech Health Authority) determined that where a young person has sufficient understanding to enable them to fully comprehend what is proposed, he or she can consent to treatment themselves.

interests of the person must at all times be assumed to outweigh those of science and society and;

i. the research must be connected with the condition which is the cause or contributed to an impairment of, or a disturbance in the function of, the mind or brain or its treatment;
ii. there must be reasonable belief that research of comparable effectiveness cannot be carried out if the project has to be confined, or relate, to persons who have capacity to consent only;
iii. it must have the potential to benefit the person and that the burden of the research project is proportionate to the benefit or be intended to provide knowledge of causes or treatment, or care, of persons affected by same or similar conditions as the person;
iv. nothing can be done to the person to which the person appears to be:
    - objecting except for where the act is done to prevent harm or reduce pain or discomfort;
    - contrary to an effective advance decision to refuse treatment;
    - contrary to a written statement made by the person when they had capacity;
v. if the person indicates (in any way) a wish to be withdrawn from the project then the person must be withdrawn without delay.

4. The researcher must also consult with a person who is engaged in caring or who is interested in the welfare of the person protected by the MCA. The person consulted cannot be engaged with the person in a professional capacity and must be prepared to be consulted. In the event that no one is willing to be consulted, as a last resort, someone must be appointed.
5. If the person consulted advises that the person's wishes, feelings, beliefs and values are such that they would likely not take part in the research, the person must be withdrawn from research already started and they cannot take part in new research.

England and Wales

The legal framework that governs the inclusion of adults with incapacity intrusive research (non-CTIMP) in England is the Mental Capacity Act 2005. In England and Wales advice should be sought from a consultee on whether an adult lacking capacity to consent would wish to be included in the research study or not. Consultees do not give consent on behalf of the incapacitated adult, but rather to provide an opinion on the views and feelings of the potential participant. Consultees in England and Wales are:

i. Personal consultee, i.e. a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity;
ii. If not available or unwilling to give advice then a nominated consultee i.e. a medical professional who is independent of the study can do so.

In emergency situations in England and Wales, adults lacking capacity to consent may be recruited without the prior advice of a consultee if the following apply

i. Treatment needs to be given urgently;
ii. It is not reasonably practicable to seek advice from a consultee;
iii. The procedure is approved by a NHS Research Ethics Committee; and
iv. A consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings.

Scotland

The legal framework that governs the inclusion of adults with incapacity in non-CTIMP research in Scotland is the Adults with Incapacity (Scotland) Act 2000. Under this legislation, a legal representative can be asked to give consent on behalf of an adult who lacks the capacity to do so themselves. Those who are able to act as a legal representative in non-CTIMPs, in Scotland are:

i. Adult's Welfare Guardian or Welfare Attorney, if not appointed:
ii. The adult's nearest relative.

There are no 'exemptions' or alternatives for the involvement of adults not able to consent for themselves in non-CTIMP research in emergency situations.

Work Instructions 7 – Consent process and procedures

1. The Informed Consent Form(s) and Participants Information Sheet(s) must be approved by an appropriate Research Ethics Committee, as outlined in SOP QUB-RGEI-003 on the Ethical Approval of Research.
2. Potential research participants should be identified and approached and given a verbal explanation of the study. Appropriate visual aids should be used, such as diagrams, to explain the study. Participants should also be provided with the up to date and approved Information Sheet(s) regarding the study;
3. Consent is best taken in a private area, ensuring the protection of the potential participant's dignity and affording them respect. It also enables the potential participant to ask questions. Potential participants must be given the time to ask questions throughout the information process and be given adequate and appropriate answers;
4. The Consent Form and any other written information to be provided to participants should be revised whenever important new information becomes available, that may be relevant to their consent. This in turn may determine their willingness to continue participating in the study;
5. The communication of this information should be documented;
6. Depending on the information being imparted to a study participant, it may be appropriate for them to be re-consented to continue their involvement in the study;
7. Neither the investigator, nor study staff, should coerce or unduly influence a participant to continue with their participation in a study;
8. If a capable adult gives informed consent to take part in a study in accordance with the conditions outlined in Work Instruction 6 above, and subsequently becomes unable to give informed consent by virtue of physical or mental incapacity, the consent previously given when capable remains legally valid, however, as with any research participants cognisance should always be taken as the person's willingness to continue with participation.
9. If a capable adult refused informed consent, and subsequently becomes unable to give informed consent, the refusal is legally binding.
10. All participants entering into a research project/clinical study must have given their informed consent before they can become involved in the research study. In addition, researchers must remember that informed consent is an ongoing requirement, so they must ensure that participants continue to understand the information relating to the study and any changes in that information and continue to consent throughout the duration of the study.

CONFIDENTIAL

CONSENT FORM

Participant Identification Number:_____

Title of Project:	
Chief Investigator:	
Study Number:	

Please initial box

1. I confirm that I have read, or had read to me, and understand the information sheet dated dd/mm/yyyy, version xx for the above study. I have had the opportunity to ask questions and these have been answered fully. ☐

2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without my legal rights [or medical care] being affected. ☐

3. I understand the study is being conducted by researchers from Queen's University Belfast and that my personal information will be held securely on University [or Trust] premises and handled in accordance with the provisions of relevant Data Protection legislation. ☐

4. I understand that data collected as part of this study [and relevant sections of my medical records] may be looked at by authorised individuals from Queen's University Belfast [and] regulatory authorities [or NHS/HSC Trust] where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information. ☐

5. I agree to take part in the above study. ☐

X. I agree to my GP being informed of my participation in the study [and to my GP/Consultant being informed of any abnormal test results]. ☐

X. I understand that the information I provide may be published as a report. Confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications. ☐

X. I understand that this study is confidential but there are limits to this confidentiality. Revelations that are criminal [or in clear breach of good medical practice] may require confidentiality to be broken by the researchers. ☐

X. I understand that what is discussed during the [interviews or observations or focus group] is confidential with the exception that if I disclose information that indicates that I am at risk of harming myself or others, or in danger of being harmed by someone else, the researcher is legally obliged to pass on this information to [insert appropriate persons]. ☐

X. I understand the [interviews or observations or focus group] will be [tape recorded or video recorded] and there is a possibility of direct quotation being used in publications. ☐

X. I agree to gift my samples to Queen's University Belfast and I consent to the storage and use of my sample for future research, including genetic analysis and commercial research. I understand that I will not benefit financially from any research. ☐

X. The potential benefits of keeping my [blood or other tissues] for future research have been explained to me and I consent to the storage and use of my [blood or other tissues] for future research, including genetic analysis and commercial research. I understand that I will not benefit financially from any research. ☐

X. The potential benefits of keeping my blood or other tissues for future research have been explained to me and (please choose one)

(i) I consent to the storage and use of my blood or other tissues for future research, to include: ☐

Genetic analysis
Commercial research
Transfer abroad
Creation of immortal cell line
Use in animal models

OR

(ii) I do not wish my blood or other tissues to be used for any purpose other than this study ☐

X. I agree to being contacted at a later date and invited to take part in future studies of a similar nature. I understand that I am only agreeing to receive information and I am under no obligation to take part in any future studies. If you decide not to consent to being contacted in the future it will not have any influence on your involvement in this particular research study [and will not affect any standard of care that you receive]. ☐

Name of Participant (please print)	Signature	Date
Name of Person Taking Consent (please print)	Signature	Date

Chief Investigator or Researcher Contact details:

[HEADED PAPER]

Participant Information Sheet

Use the following headings as appropriate.

Title of study: Is the title understandable to a lay person? If not, a simplified title should be included.

1. Invitation Paragraph

This should explain that the patient is being invited to take part in a study. Participation in a study is not required or expected.

'You are being invited to take part in a research study. Before you decide whether or not to take part it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.'

2. What is the purpose of the study?

The background and aim of the study should be given here in clear language which will be understandable to a lay person.

3. Why have I been chosen?

You should explain how the patient was chosen and how many participants will be in the study.

'You are invited to participate in this study because you [give reasons].'

4. Do I have to take part?

You should explain that taking part in research is voluntary. For example

'No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. If you choose to take part, you can change your mind at any time and withdraw from the study without giving a reason. A decision to withdraw will not affect the standard of care you receive'

5. What will happen to me if I take part?

You should describe how long the participant will be involved in the research, if they will need to attend appointments or visit a clinic and where this will be, how long will the visits take and what will happen

during the visits. You should explain if there are additional expenses in attending these appointments and if these will be covered. Details of any procedures, interventions or lifestyle changes involved must also be described (eg blood tests, interviews, questionnaires, food dairies, exercise programmes, focus groups etc).

If the study involves human tissue then details of the type of tissue and how much will be obtained, used and disposed should also be included. The University has a licence from the Human Tissue Authority for the storage of relevant material under the Human Tissue Act. If enduring consent is being sought for use in future studies then this can be described here (include genetic analysis, transfer abroad or commercial use, development of immortal cell lines or use in animal models is relevant). For example:

'With your permission, we would like to store some of the samples you have given us at the end of the study for future use. These samples will be stored in Queen's University Belfast. Storage of these samples will enable us to undertake more research if new knowledge and technology becomes available. We do not know for sure what these future studies will be but they may involve genetic analysis, sharing samples with collaborators abroad or research in collaboration with partners such as commercial companies. Anonymised data collected as part of the study may also be used to understand the sample analyses. You can indicate on the consent form if you agree to let us retain samples for future use.'

If consent to access medical records is being sought then details regarding the type of information sought from the medical records and who will be accessing these should be included in this section.

6. What are the possible risks or disadvantages of taking part?

Any potential risks or disadvantages associated with the research should be made clear. Examples include side effects of treatments, discovering health related findings, risk associated with procedures, possible impact on insurance etc. Measures to minimise any risk can also be included. For example:

'There is a small risk of bruising and fainting associated with providing a blood sample. A fully trained individual will take the blood samples to ensure that any discomfort is kept to a minimum.'

If there is a likelihood of discovering health related findings about a participant during the research which may affect their well-being (eg abnormal blood test results) permission to contact their GP/Consultant should be sought prior to study participation and consent for information to be shared obtained.

7. What are the possible benefits of taking part?

Don't over inflate the benefits of the research as this could be seen as being coercive. Where there is no intended direct benefit to the participant from taking part this should be clearly stated. If the research may provide wider benefits to society or to others with a similar condition in the future this can be included.

8. What if something goes wrong?

You should inform participants how complaints will be handled and what redress is available to them. Depending on the nature of the research this may be through the HSC Trusts Complaints Department or in accordance with the University's Complaints from Research Participants Standard Operating Procedure. For example for QUB:

If you have any concerns about any aspects of the study, you can contact the Chief Investigator, insert contact details. Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at Queen's University Belfast (Telephone: 028 9097 2529; Email: researchgovernance@qub.ac.uk).

Or for example the Belfast Health and Social Care Trust:

If you have a concern about any aspect of this study, you can speak with the Chief Investigator, insert contact details. If you remain unhappy and wish to make a formal complaint you may do so by contacting the Belfast Heath and Social Care Trust's Complaints Department. You can contact them at Complaints Department, Musgrave Park Hospital, McKinney House, 6th Floor, Stockman's Lane, Belfast BT9 7JB. Telephone: (028) 9504 8000, Email: complaints@belfasttrust.hscni.net.

Arrangements for compensation/insurance should also be included in this section as appropriate. The indemnity arrangements will be confirmed as part of the review by the Research Governance Team prior to agreeing Sponsorship.

9. Will my taking part in this study be kept confidential?

You should detail the type of information to be collected, explain how and where data will be stored securely and for how long.

If personal data is to be shared with 3rd parties (eg collaborators at other Universities, transcribing service provider) it must be described in this section. If data will be transferred outside the European Economic Area then this should also be made clear.

If there are limits to the confidentiality then these must also be explained. For example, in some types of research there may be a possibility that a participant could provide the research team with information that indicates a risk of harm to a child, criminal behaviour or medical malpractice and this may need to be reported to an appropriate authority. For such reporting disclosure of personal information may be

required. It must be made clear to participants when such limitations to confidentiality exist. If the research team will be contacting a patient's GP/Consultant to inform them of the study and their patient's participation then this should be indicated and consent should be obtained as appropriate.

The Health Research Authority have issued transparency wording to ensure compliance with GDPR and this wording must be included in the PIS. Details on the wording and associated guidance is available here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors
The specific wording for your study should be included in the PIS and a link to the University's generic Research Privacy Notice http://www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants.html .

*The University expects primary data to be held securely for a minimum period of 5 years after the completion of a research project. However, researchers must be aware of and comply with any specific requirements of the funding body relating to longer periods of data retention.

10. What will happen to the results of the research?

You should tell patients what will happen to the results of the research. Do you intend to publish? Will you provide the participants with a summary of the results at the end of the study or can the participants contact the research team if they wish to obtain a copy? It should be made clear that any identifiable information will not be used in publications, unless explicit consent is being sought to attribute them to participants by name. If the research involves interviews and there is a possibility of direct quotations being used in publications/presentations this should be stated.

11. Who is organising and funding the research?

You should include details of the organisation or company sponsoring or funding the research. If the research is also being undertaken for an educational qualification (eg PhD) this should be made clear.

12. Who has reviewed the study?

You can give the name of the Research Ethics Committee that has reviewed the study. For example:
This study has been reviewed by the Office for Research Ethics Committees Northern Ireland (ORECNI).

13. Contact for Further Information

You should give contact details should potential participants require further information about the study. Remember not all participants will have access to the internet and email so include phone numbers as

appropriate. For students, personal mobile phones should not be used as contact points for participants to obtain further information.

Thank you for your interest in this study and for taking the time to read through this information sheet.