**GUIDANCE TO CONSENT FOR RESEARCHERS**

An Informed Consent form must be signed by participants of a research study to confirm that they have had sufficient information to enable them to make an informed decision. Its format and details are likely to vary from project to project, depending on the subject matter, but the following guidance should always be adhered to. This is not a complete list of statements, or necessarily pertinent to all studies – it is for guidance only and you may need to include additional information/statements. There is no set format, however researchers/investigators should consider including the sections below.

**Why do I need Informed Consent?**

An Informed Consent form must be signed by participants of a research study to confirm that they have had sufficient information to enable them to make an informed decision. “Signature” can be recorded verbally. Signature can also be entered by clicking a button which instructs that clicking it signifies consent is given.

**How do I obtain Informed Consent?**

You provide the participation with information sufficient to allow them to decide. You then ask them to record their consent to participate in writing or via an audio recording or by an alternative method.

**What is the purpose of Informed Consent?**

The purpose of Informed Consent is to confirm information has been provided on the research carried out and retain a record of the Consent given.

**What types of Informed Consent are there?**

You can obtain Informed consent in writing using the form (adapted) below.

You can obtain the informed consent verbally using a structure similar to the form below.

You may also enable participants to click on a button to signal their consent.

**What to do when participant doesn’t have the capacity to consent**

Parent or guardian or responsible adult consent is required to countersign the consent form.

For participants under the age of 16 (England, Northern Ireland, Wales) and 12 (Scotland).

For vulnerable adults (see the current legal definitions: <https://www.legislation.gov.uk/uksi/2002/446/regulation/2/made>)

Please note: Age of consent will vary from country to country. Check the legal guidance for any country with which you propose to work.

**FOR CONSENT FORM WHERE THE RESEARCH INVOLVES WORKING WITH HUMAN TISSUE ONLY**

Consent is the fundamental principle of the Human Tissue Act 2004, and the HTA Codes of Practice A ([Guiding principles and fundamental principles of consent](https://content.hta.gov.uk/sites/default/files/2020-11/Code%20A.pdf)) and E ([Research](https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf)) are the primary sources of guidance for compliance with this standard. It is legally required to store and use ‘[relevant material’](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004) from the living or deceased for a ‘scheduled purpose’ such as research. Unless an exemption applies, it is an offence to store or use ‘relevant material’ for a ‘scheduled purpose’ without consent or for a purpose not covered by the consent terms.

Individuals taking consent must be trained in accordance with HTA standards or equivalent and should have an understanding of the HT Act. Therefore, they are required to complete the MRC “Research and Human Tissue Legislation” HTA course: <https://byglearning.co.uk/mrcrsc-lms/course/index.php?categoryid=1>.

**WHERE RESEARCH EXCELLENCE FRAMEWORK (‘REF’) IMPACT STUDIES ARE PART OF THE RESEARCH ONLY**

REF Data Protection information[if your research is likely to be part of a REF submission].

Where research participants are asked to provide feedback on the impact of the research, you should add a link to the [Research Excellence Framework Impact Studies Privacy Notice](https://northumbria-cdn.azureedge.net/-/media/services/legal/gdpr/pdf/privnot/research-excellence-framework-notice.pdf?modified=20190625145426).

Seek consent from participants for processing information for the purpose of the REF.

UKRI funded research should consider the long-term use of participant research data, including the potential for further data linkage and preservation of data when obtaining consent. Participants need, as far as possible, to give specific consent if data is to be archived and shared. In some cases it may not be appropriate to archive data, but this should be discussed at the earliest opportunity with an appropriate ESRC data service provider, for example, the [UK Data Service](https://eur02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fukdataservice.ac.uk%2F&data=05%7C02%7Chala.othman%40northumbria.ac.uk%7C56c5e13b72be4d26ee2608dcd25d3b18%7Ce757cfdd1f354457af8f7c9c6b1437e3%7C0%7C0%7C638616545061430906%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=jMWC9AgGMjzAe6RXBhf6CO4NGZ6KiZV65Y%2BoPxxPnEM%3D&reserved=0).

The Northumbria logo is to be included in all Northumbria-generated research.

**HEADINGS TO BE INCLUDED IN THE CONSENT FORM**

**[edit/delete yellow highlighted sections where not applicable to the study]**

**Faculty of [add Faculty info here]**

**Department of [add Department info here]**

**Project Title:** [Use a simplified title if the original title would be too technical]

**Name of Researcher:** [If you are a student researcher, include the name of the Supervisor but not your student ID number]

**Data Protection Information:** [All projects must confirm how research data and any personal data will be managed, used, and retained]

Example: I understand how Northumbria University will process my personal data, and that this information will be used only for the purpose(s) set out in the Participant Information Sheet supplied to me, and my consent to participate in this study is conditional upon the University complying with its duties and obligations under the Data Protection Act 2018 which incorporates General Data Protection Regulations (GDPR). You can find out more about how we use your information here [Research Participant Privacy Notice](https://northumbria-cdn.azureedge.net/-/media/services/legal/gdpr/pdf/privnot/2019researchparticipantprivacynoticev1,-d-,0.pdf?modified=20200206104102).

**Where children or vulnerable groups are involved in the study. (delete where none are involved)**

[Relevant information regarding safeguarding should be included here.]

This should include Northumbria University guidance at the following link which includes contact information for the Designated Safeguarding Officer (DSO): <https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/governance-services/safeguarding/>]

**Where human tissue is involved in the study (delete where none included)**

**Scope of Consent:**

Under the Human Tissue Act the scope of consent may be specific or generic. Specific consent imposes limitations on the use of the tissue for research. Generic consent typically only applies to research and involves obtaining consent to a broad remit of research allowing the tissues to be used for more than one research project. It is considered good practice by the HTA to obtain generic consent to avoid the necessity to obtain further consent in the future. Consent must still be valid whether specific or generic.

Suggested text for retaining samples for future use:

* We would also like to seek your consent so that any remaining samples may be stored and used in possible future research – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to you and securely at Northumbria University under the University’s Human Tissue Research Licence (no 12495).
* Some future studies may be carried out by researchers other than the current team, who ran the first study, which may include researchers working for commercial companies. Any samples or data used will be anonymised, and you will not be identified in anyway. If you do not agree to this any remaining samples will be disposed of in accordance with the Human Tissue Authority’s codes of practice.

**Duration of consent:**

Consent may be enduring, or it may be time limited. For research, it is advised that such consent should be enduring. This should be clearly indicated to the person. Enduring consent is in force until the person withdraws their consent.

**SECTIONS TO INCLUDE ON A CONSENT FORM**

|  |  |
| --- | --- |
| **COMPULSORY SECTIONS OF A CONSENT FORM** | *Please initial this box to confirm consent* |
| I have read and understood the purpose of the study and have had the chance to ask questions about the study and these have been answered to my satisfaction |  |
| I understand that my participation is voluntary and that I am free to withdraw at any time and that this will not affect my treatment/education/care |  |
| I understand the processing of my personal information required as part of my participation and the lawful basis for processing, as described in the Participant Information Sheet*.* (If lawful basis is consent and explicit consent ONLY) I consent to my personal data being processed. |  |
| **OPTIONAL SECTIONS OF A CONSENT FORM** |  |
| (If appropriate) I consent to my pseudonymised research data being stored and used by others for future research. |  |
| (If appropriate) I understand that my research data may be published as a report. |  |
| (If appropriate) I consent to the retention of my personal information [specify what personal information will be collected] for X number of weeks, for the purpose of being re-contacted |  |
| *(*If appropriate) I consent to being [audio and/or video] recorded and understand that the recordings will be [specify storage procedure: destroyed within X number of weeks after the data has been collected / destroyed immediately after transcription and/or stored anonymously on password-protected software and used for research purposes only]. |  |
| (If appropriate) I agree to give a sample of (**blood, saliva, muscle tissue etc, as appropriate)** for research in this project. I understand how the sample will be collected, that giving a sample for this research is voluntary and that I am free to withdraw my approval for the use of the sample at any time without giving a reason. |  |
| (If appropriate) I understand that, as set out in the information sheet, samples and data given as part of the study will be collected and used for future research including by external organisations in the UK and overseas, and in the commercial sector. |  |
| (If appropriate) The potential benefits of keeping my (**blood, saliva, muscle tissue etc, as appropriate)** for future research have been explained to me and (please choose one)  I agree that the samples I give, and the information gathered about me, can be stored by Northumbria University (HTA Licence number 12495) for possible use in future studies. I understand that some of these studies may be carried out by researchers other than the current team who ran the first study, including researchers working for commercial companies.  **OR**  I do not wish my samples to be used for any purpose other than this study. |  |
|  |
| (If appropriate) Where *Research Excellence Framework (‘REF’)* Impact studies are part of the Research  **REF Data Protection information** [If your research is likely to be part of a REF submission]. DELETE where not relevant.  *As a UK Higher Education institute, Northumbria University has an obligation to advance knowledge and education through its teaching and research activities. To fulfil this obligation, research participants may be asked to provide feedback on the impact of our research to comply with the requirements of the REF. You can find out how we use your information for the* [Research Excellence Framework Impact Studies Privacy Notice](https://northumbria-cdn.azureedge.net/-/media/services/legal/gdpr/pdf/privnot/research-excellence-framework-notice.pdf?modified=20190625145426).  *I understand that my data will be processed for the purpose of the REF, and consent is conditional upon the University complying with its duties and obligations under the Data Protection Act 2018 which incorporates General Data Protection Regulations (GDPR).* |  |
| By signing this Consent Form, I confirm that I am willing to take part in this research study. |  |

**SIGNATURES**

**(NOTE: THIS MAY BE REPLACED BY A CLICK BUTTON TO SIGNIFY CONSENT)**

|  |  |
| --- | --- |
| **Name of Participant in full** | **Signature of Participant** |
|  |  |
| **Date of Participant’s signature** |  |

[To be included where the consent of parent/guardian is required]

|  |  |
| --- | --- |
| **Name of Participant in full e.g. name of child/vulnerable adult** | |
|  | |
| **Name of Participant’s Representative (Parent/Guardian/Representative) in full** | **Signature of Participant’s Representative** |
|  |  |
| **Date of Participant’s Representative’s signature** |  |