# INFORMED CONSENT

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# GUIDANCE ON INFORMED CONSENT FORMS

*The Informed Consent form is signed by participants 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.*

*It should have a brief introduction, stating:*

* *Project details – title, name of researcher*
* *If this is a student project (including Student ID)*
* *Statement of confirmation*
* *Name of participant, signature and date*

*Clear instructions should be given to the respondent. ‘Tick boxes’ are usually easy to understand. Your statements should be written in the first person, for example:*

|  |  |
| --- | --- |
| *I have read and understand the purpose of the study* | *🞐* |
| *I have been given the chance to ask questions about the study and these have been answered to my satisfaction* | *🞐* |
| *I am willing to be interviewed* | *🞐* |
| *I am willing for my comments to be tape-recorded* | *🞐* |
| *I understand that I can withdraw at any time if I change my mind and this will not affect my treatment/education/care* | *🞐* |
| *I am aware that my name and details will be kept confidential and will not appear in any printed documents.* | *🞐* |

*NB: This is* ***not*** *a complete list of statements, or necessarily pertinent to all studies – it is for guidance only.*

*A statement should be included that advises participants they should contact the relevant FA PVC (RI) (giving contact details), should they wish to make a complaint about the conduct of the research.*

*You should provide a space on the form for the participant’s signature alongside your own and make sure the form has a version number and is dated. If your study involves participants with different levels of understanding, for example NHS staff and patients with learning difficulties, or teachers, pupils and parents, you must include separate consent sheets for each sample group.*

*Where participants are unable to give consent, for example young children or people with severe communication or learning difficulties, you must look at the process of assent and have an appropriate form for the person who is going to assent to that person’s participation. You will also need to be aware of the Mental Capacity Act which addresses issues in relation to consent. If you are applying for NHS approval, there is a specific section of the IRAS form that must be completed in relation to capacity to consent.*

*There are two forms of consent:*

* *Direct consent from individuals who can give informed consent*
* *Assent or Proxy Consent for those individuals who are unable to give informed consent.*

*If the procedure changes, all participants must be informed in writing and new consent forms must be signed. All data collected must be rendered anonymous, unless the participants have waived anonymity. Where the research involves a level of risk to participants beyond that encountered in everyday life, an independent witness should also be present to sign the consent form.*

*N.B. If submitting an example to an external Ethics Committee please make sure your form is in line with their requirements.*

*A typical statement of confirmation will look like this:*

*This information will be held and processed for the following purpose(s):*

*(Project title)*

*I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my 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). You can find out more about how we use your information here -* [*Privacy Notices*](http://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notices/)

*Name*

*Signature Date*

*Or, where parental consent is required, the same statement can be applied with the following addition:*

*Child’s Name Child’s Signature*

*Parent’s/Guardian’s Signature Date*

*The signed consent form should be stored securely by the researcher along with other project documentation.*

# CONSENT FORM WHERE NO PERSONAL DATA IS COLLECTED

|  |  |
| --- | --- |
| Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| *please tick or initial   where applicable* | |
| I have carefully read and understood the Participant Information Sheet. | 🞐 |
| I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers. | 🞐 |
| I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. | 🞐 |
| I agree to take part in this study. | 🞐 |
| I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University.  I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my 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).You can find out more about how we use your information here - [Privacy Notices](http://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notices/) | 🞐 |

Name/signature of participant....................................................... Date.....………………..

Signature of Parent / Guardian in the case of a minor...................................................

|  |  |  |
| --- | --- | --- |
| CONSENT FOR TAKING PART IN A STUDY WHICH MIGHT CAUSE PSYCHOLOGICAL DISTRESS WHERE NO PERSONAL DATA IS COLLECTED Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| *please tick or initial   where applicable* | | |
| I have carefully read and understood the Participant Information Sheet. | 🞐 | |
| I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers. | 🞐 | |
| I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. | 🞐 | |
| I agree to take part in this study. | 🞐 | |
| I understand that by taking part in this study I may be exposed to situations that may generate some psychological distress that may become apparent during and/or after the study has finished. I accept the small risk of experiencing psychological distress as part of this research | 🞐 | |
| I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University.  I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my 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). You can find out more about how we use your information here [Privacy Notices](http://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notices/) | 🞐 | |
| Name/Signature of participant....................................................... Date.....……………….. | |
| Signature of Parent / Guardian in the case of a minor........................................... | |
|  | |

# FOR USE IN ONLINE STUDIES WHERE NO PERSONAL DATA IS COLLECTED

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you would like to take part in this study, please read the statement below and tick ‘I agree’

I understand the nature of the study, and what is required from me.  I understand that after I participate I will receive a debrief providing me with information about the study and contact details for the researcher.  I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. I agree to provide information to the investigator and understand that my contribution will remain confidential.   I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University.  I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my 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). You can find out more about how we use your information at [Privacy Notices](http://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notices/)

|  |  |
| --- | --- |
| I agree 🞐 |  |

# FOR USE WHEN TISSUE IS BEING REMOVED BUT NOT STORED AND WHERE PERSONAL DATA IS NOT COLLECTED

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree that the following tissue or other bodily material may be taken and used for the study:

|  |  |  |
| --- | --- | --- |
| Tissue/Bodily material | Purpose | Removal Method |
| *e.g. saliva* | *e.g. for cortisol analysis* | *e.g. via Salicaps* |

I understand that if the material is required for use in any other way than that explained to me, then my consent to this will be specifically sought. I understand that I will not receive specific feedback from any assessment conducted on my samples, but should any kind of abnormality be discovered then the investigator will contact me.

I agree to the University of Northumbria at Newcastle recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in the information sheet supplied to me, and my 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). You can find out more about how we use your information here - Privacy Notices

Name/Signature of participant....................................................... Date.....………………..

Signature of Parent / Guardian in the case of a minor.............................................

|  |
| --- |
| CONSENT FORM WHERE PERSONAL DATA IS COLLECTED |
| Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| *Please tick or initial where applicable -* |
| I have carefully read and understood the Participant Information Sheet. | | 🞐 |
| I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers. | | 🞐 |
| I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. | | 🞐 |
| I agree to take part in this study. | | 🞐 |
| I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University. | | 🞐 |

|  |
| --- |
| Name/Signature of participant....................................................... Date.....……………….. |
| Signature of Parent / Guardian in the case of a minor........................................... |
|  |
|  |

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| --- |
| CONSENT FOR TAKING PART IN A STUDY WHICH MIGHT CAUSE PSYCHOLOGICAL DISTRESS AND WHERE PERSONAL DATA IS COLLECTED |
| Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *Please tick or initial where applicable -* |
| I have carefully read and understood the Participant Information Sheet. | 🞐 |
| I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers. | 🞐 |
| I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. | 🞐 |
| I agree to take part in this study. | 🞐 |
| I understand that by taking part in this study I may be exposed to situations that may generate some psychological distress that may become apparent during and/or after the study has finished. I accept the small risk of experiencing psychological distress as part of this research | 🞐 |
| I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University. | 🞐 |
| Name/Signature of participant....................................................... Date.....……………….. |
| Signature of Parent / Guardian in the case of a minor........................................... |
|  |

# FOR USE WHEN A SURVEY IS BEING CONDUCTED THAT DOES NOT REQUEST DETAILED

# PERSONAL OR PSYCHOLOGICAL INFORMATION BUT WHERE DATA IS COLLECTED

|  |  |
| --- | --- |
| Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| *Please read and tick the boxes below* | |
|  | |
| The investigator has explained to me the nature of the study, and what is required from me. They have given me a debrief sheet providing me with their contact details. I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. I agree to provide information to the investigator and understand that my contribution will remain anonymous and confidential | 🞐 |

|  |  |
| --- | --- |
| I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University. | 🞐 |

# FOR USE IN ONLINE STUDIES WHERE PERSONAL DATA IS COLLECTED

|  |
| --- |
| Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you would like to take part in this study, please read the statement below and click ‘I agree’

I understand the nature of the study, and what is required from me.  I understand that after I participate I will receive a debrief providing me with information about the study and contact details for the researcher.  I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice. I agree to provide information to the investigator and understand that my contribution will remain confidential.   I also consent to the retention of this data under the condition that any subsequent use also be restricted to research projects that have gained ethical approval from Northumbria University.

|  |
| --- |
| I agree 🞐 |

# FOR USE WITH ORGANISATIONS

Project title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Student ID No. (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Completion of this form is required whenever research is being undertaken within any organisation (**separate arrangements** apply in the case of ***health*** and ***care*** and ***policing*** *and* ***custody*** organisations: please consult your research supervisor, principal investigator or Departmental Ethics Lead). This applies to research that is carried out on the premises, or is about an organisation, or members of that organisation or its customers, as specifically targeted as subjects of research.

The researcher must supply an explanation to inform the organisation of the purpose of the study, who is carrying out the study, and who will eventually have access to the results. In particular, issues of anonymity and avenues of dissemination and publications of the findings should be brought to the organisations’ attention.

**Researcher’s Statement** that must detail the following as they relate to the organisation:  
a) aim of the research; b) sample size and recruitment method/s; c) participant numbers; d) participate time commitment required; e) methods; f) timescale; g) contribution requested from organisation’s management – *e.g*. distribution of questionnaire; h) extent to which the researcher needs physical access to premises and the nature of this access; i) benefits of the research for the organisation:

A senior organisation manager, director or representative must give consent:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position/Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Organisation Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location/s where the research is permitted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anonymity must be offered to the organisation if it does not wish to be identified in the research report. Confidentiality is more complex and cannot extend to the markers of student work or the reviewers of staff work, but can apply to the published outcomes. If confidentiality is required, what form applies?

[ ] No confidentiality required

[ ] Masking of organisation name in research report

[ ] No publication of the research results without specific organisational consent

[ ] Other by agreement as specified by addendum

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

This form can be signed via email if the accompanying email is attached with the signer’s personal email address included. The form cannot be completed by phone, rather should be handled via post.

---------------------------------------------------------------------------------------------------------------------

If the organisation is a University of Northumbria Faculty, please complete the following:

|  |  |
| --- | --- |
| Start/End Date of Research /  Consultancy project: | Start:  End: |
| Programme  Year  Sample to be used: seminar group,  entire year etc. |  |
| Has Programme Director/Leader, Module Tutor being consulted, informed. |  |