

**GUIDANCE ON PREPARING A CONSENT FORM**

This is a sample consent form, which has been developed to help researchers create their own consent form for research studies in the fields of scientific, economic, social or historical research for ethical purposes only. If you are conducting health research[[1]](#footnote-1), please use the consent form template available [here.](https://www.tcd.ie/info_compliance/data-protection/assets/docs/TCD_Consent%20Form_Template.docx)

This guidance note does not constitute legal advice and should be read in conjunction with guidance from the relevant research ethics committee.

The Principal Investigator and the research team should prepare a consent form which meets the exact needs of the research study that is being carried out.

Please note the following:

* The consent form should be prepared in conjunction with the Information Leaflet for the research study.
* Not all of points set out in the table below and phrases in this template will apply to your particular study. Each of the consents should be reviewed to determine if they are required for a particular research study and should be amended to take into consideration any specific requirements and/or details of the research study.
* Please ensure that the consent form is clear, concise and as easy to read and understand as possible. Legal jargon or scientific or economic terms that a participant may not understand should not be included in the consent form.
* This consent form is not suitable if parents/guardians are consenting on behalf of their children, or for any form of proxy consent.

**APPENDIX 1 – SAMPLE CONSENT FORM**



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| **STUDY NAME:**  **Centre ID:**  **Identification Number for study:** | |
| **Consent Form** | |
| **The below section should always be included in consent forms. The consents should be reviewed by the Principal Investigator and research team and amended as appropriate in line with the specific requirements and consents being sought from participants.** | |
| **There are X sections in this form. Each section has a statement and asks you to tick the box if you agree. The end of this form is for the researchers to complete.**  **Please ask any questions you may have when reading each of the statements.**  **Please leave the box blank if you do not agree.**  **Thank you for participating.** | |
| **General** | **Tick box** |
| I confirm I have read and understood the **Information Leaflet** for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. |  |
| I understand that this study **is entirely voluntary,** **and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason**. I understand that deciding not to take part will not affect my future access to ( delete as applicable) |  |
| I understand that I **will not be paid for taking part in this study**[[2]](#footnote-2). |  |
| I agree to take part in this research study having been fully informed of the **risks, benefits and alternatives** which are set out in full in the information leaflet which I have been provided with. |  |
| I know how to contact the research team if I need to. |  |
| [I agree to being contacted by researchers by [email/phone[[3]](#footnote-3)] as part of this research study][[4]](#footnote-4). |  |
| [ I agree to take part in an audio recorded individual interview as part of this research study] |  |
| [ I agree to take part in an audio recorded focus group interview as part of this research study] |  |
| **Data** | **Tick box** |
| I understand that any identifiable information about me (personal data), [including the transfer of this personal information about me outside of the EU], will be protected in accordance with the General Data Protection Regulation ( GDPR). |  |
| [I understand that anonymous information from this study may be shared with third party academics worldwide for research and learning purposes]. |  |
| [I understand that the audio recording of my interview will be retained by Trinity College Dublin for x years for use solely by Trinity College Dublin, and then destroyed]. |  |

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Participant Name (Block Capitals) Participant Signature Date

**To be completed by the Principal Investigator or nominee.**

I, the undersigned, have taken the time to fully explain to the above participant, the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date

| | |

**2 copies to be made: 1 for participant, 1 for PI**

1. “health research” means any of the following scientific research for the purpose of human health: (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels; (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; (iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals; (iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; (v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status; [↑](#footnote-ref-1)
2. Amend as appropriate. [↑](#footnote-ref-2)
3. Please include the appropriate relevant details. [↑](#footnote-ref-3)
4. Please delete as appropriate. [↑](#footnote-ref-4)