**TEMPLATE FOR EXPLICIT CONSENT FOR RESEARCH**

**HOW TO USE THIS TEMPLATE**

This template should be read and reviewed in conjunction with the guidance on Information Leaflets.

This template will assist you to develop a consent forms that is in compliance with the General Data Protection Regulation (EU) 2016/679 (“**GDPR**”) and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (the “**Health Research Regulations**”).

**What is required for “explicit consent”[[1]](#footnote-1)?**

Please note that the requirement for explicit consent is an additional safeguard which is required in order to be compliant with GDPR and the Health Research Regulations (where relevant). You will also need a lawful basis for the processing of personal data under Article 6 and Article 9 of the GDPR.

# Explicit consent is informed consent which is recorded/documented

In order for consent to be valid, it must be:

* Freely given;
* Specific;
* Informed;
* Unambiguous; and
* Such consent must be recorded by a statement or by a clear affirmative action.

Please see table below for guidance on each of these aspects of informed consent.

# Lawful Basis - Ordinary Personal Data

If processing ‘Ordinary’ personal data[[2]](#footnote-2) then you must satisfy at least one of the lawful bases as set out under [Article 6 GDPR](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#d1e1797-1-1)

# Lawful Basis - Special Category Data (Sensitive Personal Data)

# If processing sensitive personal data[[3]](#footnote-3) then, in addition to the Article 6 lawful basis, you must also satisfy one of the conditions as set out under [Article 9 GDPR](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#d1e1797-1-1)

# Health Research Regulations - Explicit Consent required for Health Research

# In addition to satisfying Articles 6 & 9 GDPR requirements you must also obtain explicit consent for processing personal data for health research purposes. This mandatory requirement is set out under Regulation 3(1)(e) of the [2018 Health Research Regulations](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf).

# Please note that this guidance note may be amended from time to time and does not constitute legal advice

**GUIDANCE ON PREPARING A CONSENT FORM**

This is a sample consent form has been developed to help researchers create their own consent form for research studies and is to be used for example purposes only. It 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 must 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.
* This template has been created to assist researchers to design consent forms for research studies involving participants
* 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.
* If your study does not involve patients, watch out for words like ‘patient,’ ‘future care,’ ‘medical care,’ ‘medical records,’ and ‘storage’ and as they may not apply and may need to be deleted/amended as appropriate.
* Ensure that consent for the **processing of personal data** should be distinguished from other consent requirements that serve as an ethical standard.
* Please ensure that the consent form is clear, concise and as easy to read and understand as possible. Legal jargon or medical terms that a participant may not understand should not be included in the consent form.

**trinity college dublin**

**sCHOOL OF LINGUISTIC SPEECH AND COMMUNICATION SCIENCES**

**Consent Form**

**[INSERT STUDY TITLE HERE]**

**Participant code for study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| **There are X sections in this form. Each section has a statement and asks you to initial 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.**  **Thank you for participating.**  **Please tick the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.** | |
| **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 current ot future [insert information as appropriate – e.g. medical care / therapy / classroom participation / grades in this module]. |  |
| **[If relevant to your study]** I understand that my **medical notes and records** may be looked at by my [investigator and his/her study team] at [clinic / hospital] where it is relevant to the research. I agree that these individuals can access my records. |  |
| I understand that all information will be kept private and confidential and that my name will not be disclosed. |  |
| I understand that I **will not be paid for taking part in this study** other than [insert any costs covered]. |  |
| I know how to contact the research team if I need to. |  |
| 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 agree to being contacted by researchers by [email/phone – delete as appropriate] as part of this research study |  |

|  |  |
| --- | --- |
| **Data processing** | **Tick box** |
| I agree to allow personal information about me to be shared with third parties including; national and international hospitals, and academic research institutions for the purpose of [insert details of research area] research, as described in the Information leaflet[[4]](#footnote-4). |  |
| I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation. |  |
| I understand that there are **no direct benefits to me** from participating in this study. I understand that **results from analysis of my personal information will not be given to me [insert any exceptions – e.g. clinically significant results]**. |  |
| I understand that **I can stop taking part in this study** at any time without giving a reason and this will not affect my future *[insert information as appropriate – e.g. medical care / therapy / classroom participation / grades in this module].* |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Remove the table below if it does not apply to your study – this table will only apply if you placed the paragraph entitled ‘Consent to Future Uses’ in your Information Leaflet** | | | | |
| **FUTURE USE OF INFORMATION** | | | | |
| **RETENTION OF DATA IN THE FUTURE [please choose one or more as you see fit]** | **Y** | | | **N** |
| **OPTION 1:** I give permission for my personal information to be stored for *possible future research* ***related*** to the current study [insert details of research areas] ***only if consent is obtained from me*** at the time of the future research and the research is approved by a Research Ethics Committee. | |  |  | |
| **OPTION 2:**  I give permission for my personal information to be stored for *possible future research* ***related*** to the current study [insert details of research areas] ***without further consent*** being required but only if the research is approved by a Research Ethics Committee. | |  |  | |
| **OPTION 3:** I agree that future research projects into [insert details of research areas] may be carried out by researchers working for **commercial companies.** | |  |  | |
| **OPTION 4:** I understand **I will not be paid for any** future use of my samples/personal information or products derived from it. | |  |  | |

|  |
| --- |
| **Signatures** |

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Participant Name (Block Capitals) Participant Signature Date

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Witness Name (Block Capitals) Witness Signature Date

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

I, the undersigned, have taken the time to fully explain to the above patient 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 OR 3 copies to be made: 1 for participant, 1 for PI and 1 for clinical records if relevant.**

1. Article 4 (11) of GDPR and in accordance with guidelines on consent issued by the Article 29 Working Party [↑](#footnote-ref-1)
2. Please see Article 4(1) for a definition of Personal Data: <https://gdpr-info.eu/art-4-gdpr/> [↑](#footnote-ref-2)
3. Please see Article 9(1) of GDPR for a definition of special categories of personal data/sensitive personal data. <https://gdpr-info.eu/art-9-gdpr/> [↑](#footnote-ref-3)
4. This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with. [↑](#footnote-ref-4)