**GUIDANCE ON PREPARING AN INFORMED CONSENT FORM FOR HEALTH RESEARCH**

This template **Informed Consent Form (‘ICF’)** has been developed by Trinity College Dublin together with the **Participant Information Leaflet (‘PIL’)** template to help the Principal Investigator and research team meet the requirements of the Health Research Regulations 2018 (‘HRR’), the information provision obligations of Article 13 of the EU General Data Protection Regulation 2016 (‘GDPR’) and consent requirements as set out under Article 7 GDPR.

You should draft your PIL to ensure that the intended research participant is fully informed as to what they are consenting to in the ICF. The PIL and ICF should be read together.

This template ICF is to be used for exemplar purposes only. It does not constitute legal advice.

Some points to note:

* The consents should be reviewed by the Principal Investigator and research team and amended as appropriate to the participant. If there are diverse cohorts, the ICF should be tailored individually to that audience (for example, patients, healthcare workers, carers, other professionals etc.).
* Please draft your ICF in line with the specific requirements of your research study (for example, parent/guardian of a child (consent on behalf of the child), proxy consent (i.e. consent on behalf of another), assent of a child (ICF tailored to the child), consent for those with intellectual disability) etc.
* **Each ICF must be tailored to the audience. One size does not fit all. It is not a tick-box exercise.**
* Some of the sections in the template may not apply to your research study. If they do not apply, please delete or amend as appropriate.

The ICF has two sections.

**Section one** relates to general understanding of the research study.

**Section two** is the consent from the individual.

* In order for consent to comply with the law, it needs to be divided into two separate sections:
  1. Consent to take part in the research project
  2. Consent to use of personal information
* Your consent form should be clear, concise and easy to read. The participant should clearly understand what they are consenting to.
* Legal jargon or medical terms and /or acronyms should not be included.
* If your study does not involve patients, please do not use words like ‘patient,’ ‘future care,’ ‘medical care,’ ‘medical records,’ Instead, use words like ‘participant’, ‘volunteer’ etc.

**SAMPLE INFORMED CONSENT FORM**

|  |  |
| --- | --- |
| **STUDY:**  **Recruitment Site:** | |
| There are **two sections** in this form.  **Section 1** contains statements of understanding and asks you to tick each if you understand. Please ask any questions you may have when reading each of the statements.  **Section 2** asks for your informed consent. Please select either ‘yes’ or ‘no’ to indicate your choice.  Thank you for participating.  The end of this form is for the researchers to complete. | |
| **1. General Understanding** | **Tick** |
| I confirm that 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 taking part in this study is entirely voluntary. I understand that not taking part will have no negative impact on me. |  |
| I understand that I can leave this study at any time without giving a reason. I understand that leaving this study will not affect my (insert detail as applicable - e.g. medical care), now or in the future. |  |
| I understand that I will not be paid for taking part in this study or receive any benefits from any products developed as a result of this research study. |  |
| I know how to contact the research team if I need to. |  |
| **By ticking each box above and choosing my options below and signing this document I agree to participate in ‘X’ study as described in the Participant Information Leaflet.** | |
| **2. Consent** |  |
| I agree to take part in this research study, having been fully informed of the risks and benefits in the participant information leaflet provided to me. | **Yes No**   |  |  | | --- | --- | |  |  | |
| I agree to the use of information about me (personal data) including (*insert detail as applicable - e.g. information taken from my medical notes and records and/or information from focus group meetings etc.*) being used by the research team for this research study as described in the participant information leaflet. | **Yes No**   |  |  | | --- | --- | |  |  | |
| I agree to information about me (personal data) being shared with other academic research institutions (*insert detail as applicable - e.g. research institutes, hospitals, not for profit organisations etc.*) for the purpose of research in the area of [INSERT DETAIL].  (i) In Europe  (ii) Internationally | **Yes No**   |  |  | | --- | --- | |  |  | |
| I agree to information about me (personal data) being shared with (*insert detail as applicable - e.g. for-profit commercial research or biopharmaceutical companies etc.*) for the purpose of research in the area of [INSERT DETAIL].  (i) In Europe  (ii) Internationally | **Yes No**   |  |  | | --- | --- | |  |  | |

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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 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 participant information leaflet and consent form to the participant with contact details of the study team.

Researcher name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title and qualifications \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Copies to be created and retained: 1 for Participant, 1 for PI and 1 for Hospital Records (where appropriate).**