**St James’s Hospital / Tallaght University Hospital Research Ethics Committee**

**Model Consent Form**

The Joint SJH / TUH Research Ethics Committee have prepared a model consent form for researchers to use as part of their applications. The form provided is a model: researchers will need to tailor the form to their own research studies. Some studies may require items not stated on the model form and other studies may not require some items stated on the model form. However, in general, most of the items specified on the model form should be included.

Consent for future research: Consent for future research requires a separate consent statement. The Health Research Regulations state that in order for a researcher to conduct health research ‘explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof’.

This means that:

* Researchers are required to obtain **explicit** consent from participants to use their personal data for health research;
* This consent must be obtained **prospectively**;
* The health research must be **specified** to a particular area (usually the case for current studies) or more generally in that area or a health-related area (often the case for future studies);
* Blanket consent (use of a high level statement seeking consent for future unspecified purposes) is not an option and should not be sought.

In relation to the use participant personal data as part of future research studies, the Joint SJH/TUH REC interprets the HRR **as allowing** researchers to seek participant consent to use his/her personal data for future health research purposes providing that:

* The future health research is, at a minimum, **specified** to the general area or a health-related area of the original research and
* The **data processing measures and safeguards** in existence for the original study are in place for any future studies (in addition to any future data processing regulations that may be introduced);
* The participants are **informed as much as possible** when obtaining consent for future use of their personal data.

Although the HRR apply to data processing only, the same standards are applied for research intending to use biological data in future studies.

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| **CONSENT FORM** |

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| **STUDY TITLE** |

To be completed by the **PARTICIPANT**:

|  |  |  |
| --- | --- | --- |
| I have read and understood the information leaflet. | YES  | NO  |
| I have had the opportunity to discuss the study, ask questions about the study and I have received satisfactory answers to all my questions. | YES  | NO  |
| I have received enough information about this study. | YES  | NO  |
| I understand that I am free to withdraw from the study at any time without giving a reason and this will not affect my future medical care. | YES  | NO  |
| I agree to allow the researchers use my information (personal data) as part of this study as outlined in the information leaflet.  | YES  | NO  |
| I agree to allow the researchers access my medical records as part of this study *(if applicable)* | YES  | NO  |
| I agree to be contacted by researchers as part of this study *(if applicable)*  | YES  | NO  |
| I agree to give a [insert sample] sample(s) as part of this study. *(if applicable)*  | YES  | NO  |
| I consent to take part in this research study having been fully informed of the risks, benefits and purpose of the study | YES  | NO  |
| I give my explicit consent to have my data processed as part of this research study’ | YES  | NO  |
| [Statement on future research placed here] *(if applicable)* | YES  | NO  |

|  |  |
| --- | --- |
| Participant’s Name (Block Capitals): |  |
| Participant’s Signature: |  |
| Date:  |  |

To be completed by the **RESEARCHER**:

|  |  |  |
| --- | --- | --- |
| I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he/she could understand. I have invited him/her to ask questions on any aspect of the study.  | YES  | NO  |
| I confirm that I have given a copy of the information leaflet and consent form to the participant.  | YES  | NO  |

|  |  |
| --- | --- |
| Researcher’s Name (Block Capitals): |  |
| Researcher’s Title & Qualifications: |  |
| Researcher’s Signature: |  |
| Date:  |  |