**Participant Information Leaflet - Content Requirements as per HSE Consent for Research Policy, v1.0, December 2022**

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| a) Introductory section: | a1 | • A statement stipulating that the study involves research |
|  | a2 | • The voluntary nature of the participation |
|  | a3 | • The right to withdraw, and any caveats or conditions to the withdrawal of personal data |
|  | a4 | • The fact that the prospective participant’s decision to participate or not participate will not have an impact on their medical care |
|  | a5 | • Encouragement to read all information and to ask questions and consult with their general practitioner (GP), family, and friends if they are unsure |
|  | a6 | • What happens if the participant changes their mind |

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| b) Information about the proposed research study: | b1 | • What the study is about and why it is being conducted |
|  | b2 | • Who the research/study partners are, and their nature (commercial, academics, etc.) |
|  | b3 | • Why the person is being asked to participate |
|  | b4 | • Estimated number of participants |
|  | b5 | • Process of randomisation, if appropriate |
|  | b6 | • Duration of participation |
|  | b7 | • How the study will be carried out (when is the study taking place and what is its duration, where is study taking place (where are potential participants being recruited from, and where will the intervention take place), what (what is the nature of the study and what is its purpose and anticipated benefits and side-effects), how (how will it be conducted, e.g., through interventional medical product or placebo) |
|  | b8 | • What is within and outside of the study scope |
|  | b9 | • Benefits and risks of participation in the study |
|  | b10 | • What will happen to the participant during the study |
|  | b11 | • Any proposed genetic/genomic testing, and the fact that this would constitute research-related testing, not diagnostic-grade testing |
|  | b12 | • What happens if something goes wrong during the study (if applicable) |
|  | b13 | • How the participant will receive information on the outcome(s) of the study |
|  | b14 | • Whether the participant will receive the results of medical tests or investigations performed as part of the study, or the results of incidental findings (see also Section 3.4) |
|  | b15 | • If using human biological material, details of where it will be stored, who will have access to it, how it will be discarded and after what time period, etc. |
|  | b16 | • Any potential secondary use of personal data or biological material (see Section 2.3). |

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| c) Information about data protection and security: | c1 | • What information about the participant will be used for the study, including access to medical records |
|  | c2 | • What personal data will be used for any planned secondary research, and how it will be managed |
|  | c3 | • GDPR Article 6: lawful basis for the processing of the participant’s personal data and associated rights |
|  | c4 | • GDPR Article 9: condition relied upon for the processing of the participant’s personal health data |
|  | c5 | • Method by which it will be ensured that personal data processing is minimised |
|  | c6 | • Information about the use (or processing) of personal data required |
|  | c6.1 | o The identity of the organisation(s) (or ‘data controller(s)’) that is/are determining the ‘why’ and means by which personal data will be used, and the purposes for which the data are intended |
|  | c6.2 | o The identity of joint data controllers |
|  | c6.3 | o Where possible, the identity of any third-party collaborators or commercial parties that will receive personal data for the purpose of the study |
|  | c6.4 | o The identity of any third party (or processor) that may be acting under the instruction of the data controller(s) specifically for the purpose of the study, such as contractors. |
|  | c7 | • How data will be shared |
|  | c8 | • How the use and sharing of data will be governed |
|  | c9 | • Whether the data will be transferred outside of Ireland (or outside of the EU/European Economic Area (EEA)) |
|  | c10 | • How data will be stored |
|  | c11 | • How long data will be retained, and when they will be destroyed |
|  | c12 | • What risks to confidentiality exist, and how confidentiality will be protected |
|  | c13 | • Limits of confidentiality and researcher obligations under Children First Act 2015 (see Section 5.5) |
|  | c14 | • Security arrangements and who will have access to personal data |
|  | c15 | • A statement outlining the rights of the individual with regard to their personal data |
|  | c16 | • Planned anonymisation and subsequent sharing/dissemination of personal data: |
|  | c16.1 | o Anonymising personal data constitutes processing in its own right. Where researchers intend to anonymise research participants’ personal data, including for further processing or making such anonymised data publicly available, they must seek the consent of the research participants for such processing. |
|  | c17 | • Any potential secondary research uses of data. |

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| d) Costs, funding, and approval: | d1 | • Information about REC approval, including: |
|  | d1.1 | o The name and contact details of the REC that gave ethical approval to the research |
|  | d1.2 | o Whether any of the persons carrying out the research may have any conflict of interest |
|  | d1.3 | o The date ethical approval was given by the REC |
|  | d1.4 | o Reporting arrangements agreed with the REC |
|  | d1.5 | o Any conditions attached to the research by the REC. |
|  | d2 | • Who is organising and funding the study, including: |
|  | d2.1 | o Who is conducting the research |
|  | d2.2 | o Who is funding the research and if the funder is a commercial sponsor |
|  | d2.3 | o Whether the research is being done as part of an academic qualification |
|  | d2.4 | o Whether the researcher or research team is receiving any compensation, financial or otherwise, to carry out the study |
|  | d2.5 | o Whether the results will be disclosed for commercial purposes |
|  | d2.6 | o Whether there will be any cost or compensation for participating in the study, particularly details regarding if and how expenses will be covered. |

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| e) Contact information: | e1 | • Contact information in respect of the research project, including who to contact with regard to PIL-related queries, and who to contact in the event of a complaint |
|  | e2 | • Contact information for data protection purposes, including who participants can contact directly to enable them to exercise their data protection rights (e.g. the data protection officer, and/or a specific member of the research team) |
|  | e3 | • The name of the PI/lead researcher and their contact details |
|  | e4 | • The institutional affiliations of the members of the research team |
|  | e5 | • Website/web page details if one has been set up for the study. |

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| f) Other information: | f1 | • The potential commercial use of research findings |
|  | f2 | • The withdrawal of consent process and limitations (i.e. at what point in time personal data may be withdrawn or no longer withdrawn from the study) |
|  | f3 | • Post-study access to study-related interventions or medication |
|  | f4 | • Distress protocols |
|  | f5 | • Training and safeguards that are in place (e.g. Garda Vetting) |
|  | f6 | • Registration and adherence to associated professional guidelines/codes of conduct in the case of professionals who have a professional registration body |
|  | f7 | • Details of how study results will be published and disseminated. |

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| g) Consent for storage, maintenance, and secondary research use of identifiable personal data or identifiable biological material | g1 | • A description of the types of secondary research that may be conducted or the potential secondary uses for the personal data or biological material | Include as much detail as possible | NB - For broad consent to be valid, researchers must ensure that secondary use of personal data or biological material continues to be within the area of research specified in the original consent. |

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|  | g2 | • Details about ethical approval requirements for secondary research studies using the participant’s personal data and/or human biological material. |
|  | g3 | • Permission to re-contact the participant to seek permission for secondary research using their personal data and/or human biological material outside the scope of the original consent. |
|  | g4 | • How and when the biological material/personal data will be managed/destroyed once they are no longer required. |
|  | g5 | • Details on the process for feedback of information arising from the research study where this could impact the participant’s health, such as secondary or incidental findings. |
|  | g6 | • The lawful basis for processing personal data and associated rights. |
|  | g7 | • Information must be provided regarding whether the biological material will be identifiable, pseudonymised, or irrevocably anonymised, and how personal data will be managed. |
|  | g8 | • How the participant’s biological material/personal data will be kept confidential. |
|  | g9 | • Whether data or biological material may be shared with other parties in the future should be provided; this should include the types of institutions or researchers that might conduct research with the participant’s personal information or biological material in the future, with the option to indicate that consent is given to the research being undertaken by: o Only researchers in the unit to which the biological material was donated o Any academic researcher in Ireland, or in the European Union (EU) o Any academic researcher globally o Industry-funded researchers. |
|  | g10 | • Information on how long the personal data or biological material may be stored, maintained, and used, including details about locations in third countries not covered by the GDPR. |
|  | g11 | • If any of the intended research uses will, or may, involve the participation of commercial entities, the prospective research participant must be provided with the option of considering their inclusion or exclusion from this component of the study. |
|  | g12 | • Participants may be given the choice to opt in or out of receiving information about the research results. If this is not possible, a statement to that effect should be included. |
|  | g13 | • Participants should be informed about how they can access information about the research that takes place as a result of their broad consent (such as via website updates, a newsletter, etc.). |
|  | g14 | • Transparency measures should include information about how participants can withdraw their consent and data, or ask for destruction/disposal of banked tissue, if they wish to do so. |
|  | g15 | • The withdrawal of participants’ personal data or human biological materials may not be possible after a certain point in time. For example, their personal data may have been anonymised prior to storage and cannot be separated from the pool of participants’ personal data, or their contributions may have been widely disseminated through publications and/or published reports. Researchers must justify any limitations to the withdrawal of personal data or human biological materials to their REC, and these limitations must be explained to participants during the consent process. |
|  | g16 | • Relevant contact information, and what such contact information may be used for (e.g. who to contact regarding research-related harm). |

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| h) Consent related to incidental findings of health and social care relevance |  | see policy | page 45 |
| i) Disclosure of important incidental findings of a genetic nature |  | see policy | page 46 |

**Participant Consent Form - Content Requirements as per HSE Consent for Research Policy, v1.0, December 2022**

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| tiered consent . . . granulated set of consent options |
| the option to indicate either ‘Yes’ or ‘No’ in the Consent Form |
| Consent can be documented by initialling or ticking boxes labelled ‘Yes’, or by writing the answer ‘Yes’ after each statement. Such statements must include sufficient specific detail with regard to both the participation in the study and the processing of the participant’s personal data. |
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| • In the case of an online questionnaire (if this is the only method used to gather data), an option to ask further questions of the researchers could be provided. If the participant has no further questions, then a tick box (or boxes) can be used to confirm consent next to the required statements for consent (particularly if layered consent used). |
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| NB - For broad consent to be valid, researchers must ensure that secondary use of personal data or biological material continues to be within the area of research specified in the original consent. |
| tiered consent . . . granulated set of consent options |
| e.g. secondary use for specified categories of disease rather than for any disease |
| e.g. help participants make deliberate choices with regard to the information they do or do not want to receive |
| e.g. help participants make deliberate choices whether they want to be contacted |
| e.g. help particpants make deliberate choices regarding future secondary data processing (i.e. including the anonymisation of their data) and secondary use of their data |

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| When a secondary use for research purposes includes genetic analysis, |
| When a secondary use for research purposes includes genetic analysis, the type of genetic analysis likely to be undertaken must be identified. |
| Whole genome sequencing requires explicit consent, including outlining the risks entailed in such analysis being performed, and the possible ownership of such data by private or commercial interests. |
| The right to withdraw genetic data, and clear information on how to do so, must also be provided. |

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| tiered consent . . . granulated set of consent options |
| e.g. help participants make deliberate choices with regard to the information they do or do not want to receive |
| the prospective participant’s preference with regard to disclosing incidental genetic findings that may be of relevance to family members (for example, there may be reasons to inform blood relatives of potential genetic risks). |