

**CONSENT DECLARATION APPLICATION FORM**

**-**

**To process or further process[[1]](#footnote-2) personal data for the purposes of the health research study, commencing on or after 8 August 2018**

**PLEASE NOTE**

* The HRCDC is a body formed under statutory instrument ([S.I. No. 314 of 2018](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf) as amended by [S.I. No. 188 of 2019](http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf) and [S.I. No.18 of 2021](http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf)).
* The information provided by you in connection with this application form is subject to the [Freedom of Information Act, 2014](http://www.irishstatutebook.ie/eli/2014/act/30/enacted/en/pdf).
* All references to Regulations herein, are those cited in the [Health Research Regulations](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf).
* All references to Articles herein, are those cited in General Data Protection Regulation (GDPR) [Regulation (EU) 2016/679.](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0679-20160504)
* Detailed data protection guidance can be viewed on the [Data Protection Commission](https://www.dataprotection.ie/en/dpc-guidance) website.
* Detailed guidance on the application process can be viewed on the [HRCDC website](https://hrcdc.ie/guidance/).
* Please also reference the Assisted decision-making act and amendment. [ADMA 2015](https://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/html), [ADMA as amended 2022](https://www.irishstatutebook.ie/eli/2022/act/46/enacted/en/html).
* Electronic signatures are acceptable.
* Please submit a non-scanned PDF (converted from Word).
* Please do not alter the content or lay out of the Application Form.
* **Please consult with the** **data controller’s Data Protection Officer prior to submission.**

Owner: Secretariat, HRCDC

Contact: Secretariat@hrcdc.ie

**PLEASE ENSURE THE FOLLOWING DOCUMENTATION IS PROVIDED.**

**List of Documents needed:**

[ ] **Ethics Approval document *(Note: a copy of the REC application form is not required).***

[ ]  **Data Protection Impact Assessment (DPIA)**

[ ]  **Evidence of the Data Controller’s\* DPO(s) review of the DPIA.**

[ ]  **Participant Information Leaflet, consent / assent forms (if applicable)**

[ ]  **Copy/links to other transparency measures (if applicable)**

[ ] **Signatures of all Data Controller(s)\***

***(Note: Data controller(s) above refers to the data controller of the research study that is seeking the consent declaration. DPO feedback/signatures from an Irish research site (e.g., a hospital) is not sufficient if that site is not a data controller of the research study in question)***

**TITLE OF RESEARCH:**

|  |
| --- |
| **Please provide a short title for the research Study** |
|  |

**LAY SUMMARY OF RESEARCH:**

|  |
| --- |
| 1. **Provide a non-confidential lay summary describing the research (Max 150 words)**

The lay summary will be used of the purpose of HRCDC public records. Please do not use overly technical language or commercially sensitive information. |
|  |

**THE PUBLIC INTEREST CASE:**

*Regulation 5(4)(e)*

|  |
| --- |
| 1. **Describe fully why you believe that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the participant and provide any supporting evidence for your case (Max 500 words)**

It is essential to provide a detailed, thorough response to this question as the public interest case for the research is a key element that facilitates the HRCDC in making its decision. The response should outline how the research may best impact and serve the interests of the participants and public, specifically and/or more generally. Please provide supporting documentation where appropriate. |
|   |

**PART A: APPLICANT DETAILS**

*Regulation 5(4)(b)*

|  |
| --- |
| **Data Controller name and contact details** (Art 4/GDPR) The Data Controller determines how and why personal data is being collected and used (processed) for this health research study. (i.e. study data) Please include the principal business of the Data Controller eg higher education institute, voluntary hospital, single GP, health service provider. |
| Name of organisation: Address: Website:Principal business: General role undertaken by Lead Controller in research study: **If controller(s) based outside Ireland, please confirm the party/parties in Ireland responsible for co-ordinating communications between the sites in Ireland, the data controller and the HRCDC.** Name of Organisation:Main contact in this organisation name and email address:  |

|  |
| --- |
| 1. **Applicant/Principal Investigator name and contact details:**

If the Applicant is the Data Controller, solely in their personal capacity, this should be made clear, and information provided to support that view. eg sole trader, individual with private practice, not an employee of an organisation*.*  |
| Name:Organisation Address: Email: Telephone: [ ]  Data Controller |

|  |
| --- |
| 1. **Lead contact person to receive correspondence in relation to this application, if different from Section 2**
 |
| [ ]  As Above: Name:Address: Email:Telephone:  |

*Regulation 5(4)(b)*

|  |
| --- |
| 1. **Joint Data-Controller(s) name and contact details** (Art 26/GDPR)

e.g. consider co-investigators, collaborators etc and others that may also be determining how and why personal data is being used (processed) for the study.  |
| [ ]  Not applicable Name of organisation:Name of lead Collaborator/Co-Investigator:Address/website:Principal business: Role undertaken by Joint-Data Controller in research study: *Repeat details above if more than one joint controller* |

*Regulation 5(4)(b)*

|  |
| --- |
| 1. **Joint Data-Controller(s): Please outline what arrangements are in place between the Joint Data-Controllers to reflect the roles and responsibilities** (Art 26/GDPR)

Example arrangements maybe data transfer agreements, inter-institutional agreements, contractual arrangements etc |
| [ ]  Not applicable Details:  |

*Regulation 3(1)(b)(iv)*

|  |
| --- |
| 1. **Data Processors(s) name and contact details** (Art 28/GDPR)

A Data Processor acts on the instruction of the Data Controller or another data processor (in a subcontracting relationship for example). Include any sub-contractors, service providers, academic institutions carrying out testing/analysis, data processing on the instruction of either the Data Controller or data processor, for this study.  |
| [ ]  Not applicable Name of organisation:Name of lead contact:Address/website: Principle business:Role undertaken by Processor in research study: |
| 1. **Controller-Processors: Please outline what legal agreements, contracts or legal acts are in place between the Controller(s) and Processor**(Art 28/GDPR)
 |
| [ ]  Not applicable Other details:  |

*Regulation 3(1)(b)(v)*

|  |
| --- |
| 1. **Please specify any Sponsor and/or funder(s) for the research study**
 |
| [ ]  Not applicable Name of organisation:Name of lead contact:Address/website: Principle business:Role undertaken by Sponsor/funder in research study: |

*Regulation 3(1)(b)(vi)*

|  |
| --- |
| 1. **Please specify any third party (other than a joint data controller or data processor) with whom it is intended to share any of the data obtained (including where it has been pseudonymised or anonymised) and the purpose of such sharing.**
 |
| [ ]  Not applicable Name of Organisation:Principle Business:Purpose of Sharing: Jurisdiction: Details of data being shared:  |

|  |
| --- |
| 1. **Jurisdiction of data processing for the research**

(Ref: <https://www.dataprotection.ie/en/organisations/international-transfers>, (Chapter V/GDPR.)  |
| 1. Is it proposed to process /transfer any personal data outside of the State?

[ ]  Yes [ ]  No 1. If Yes, please specify the recipient countries.

[ ]  Non-EEA[ ] EEA 1. If Non-EEA please identify the legal basis for the transfer of personal data below:

[ ]  on the basis of an Adequacy Decision,[ ]  using the safeguard of Standard Data Protection clauses, [ ] using the safeguard of [ ]  using the safeguard of Standard Data Protection clauses, Binding Corporate Rules, [ ]  on the basis of approved Codes of Conduct, [ ]  on the basis of approved Certification Mechanisms, [ ] on the basis of a legally binding and enforceable instrument between public authorities or bodies,[ ]  on the basis of a Derogation1. [ ]  Please confirm that a Transfer Impact Assessment (TIA) has or will be undertaken prior to the transfer of data to a third country that is not covered by an adequacy decision.
2. If a legal basis for transfer of personal data outside the EEA has been identified in iii) above, please name the country(ies) of transfer and outline what arrangements are in place, governing the transfer:

[ ]  Not applicable Country:Legal basis for transfer:Country: Legal basis for transfer:  |

*Regulation 5(4)(c)(vii)*

|  |
| --- |
| 1. **Please list all Research Ethics Committees (RECs) involved in approval of the research and attach a copy of outcome letter from each REC**

NOTE: The HRCDC cannot consider applications if REC approval, or provisional approval, is not in place.  |
| Name of REC: Date of REC approval (or provisional approval): [ ]  Copy of REC approval(s) attached.[ ]  Confirmation that the REC approval specifically covers the health research study outlined in this application form.[ ]  If provisional REC approval in place, please provide a copy of Applicant responses to queries raised by the REC(s) This information is **not necessary** if full REC approval is in place. Repeat above details if there are multiple REC approvals for multi-site data processing |

**PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA BEING USED**

|  |
| --- |
| 1. **Indicate (i) the start date of the research and (ii) expected duration (months)**

This information assists with informing the HRCDC of the duration of the consent declaration, if made. |
|  |

|  |
| --- |
| 1. **Describe the nature, objective and deliverables of the research (Max 1 Page).**

Please provide non-confidential information if possible. Please do not use overly technical language or commercially sensitive information*.*  |
|  |

|  |
| --- |
| 1. **Provide an overview of the proposed design and methodology of the research and its expected outcomes.**

**(Max 2 Pages)**Please complete Appendix I of this application form. Provide non-confidential information if possible. Do not use overly technical language or commercially sensitive information. Please include details of the number of anticipated participants in the research study, participant inclusion and exclusion criteria, consent process.  |
| [ ]  Appendix I completed. Please note it is not necessary to provide the full study protocol  |

*Regulation 5(4)(c)(i)*

|  |
| --- |
| 1. **i)** **Please list/describe the personal data which will be obtained and used for the research (Art 4, 9 GDPR)** eg names, date of birth, age, gender, clinical data (if so, what kind), addresses, economic data (if so what kind), ethnicity
 |
|  |
| **ii) Identify the data sources from which the personal data will be obtained**e.g. Medical records, General Practice records, Hospitals, Health Service providers, registries, databases, questionnaires, social media etc.  |
|  |
| **iii) Describe how you will ensure that only the minimal amount of personal data will be****collected and used, and the personal data will go no further than is necessary for the** **purpose of attaining the research objective (Ref Article 5 GDPR)** This question relates specifically to the data minimisation principle.  |
|  |
| **iv)**  **Has the data controller of those data sources listed in ii) agreed to provide the data, should a consent declaration be made. (for example external organisations such as registries, CSO, GPs etc as needed by the studies)**  |
| - |
| **v) If relevant, outline what arrangements will be in place between the Data Controller of the research study and the Data Controller of the personal data sources noted in your response to part (iv) above.**eg data and material transfer/sharing agreement, memorandum of understanding, terms of use etc |

|  |
| --- |
|  |

|  |
| --- |
| 1. **i)** **Describe the data processing activities that will be carried out during the life cycle of the research, without the explicit consent of the participant. A simple data flow diagram should be provided if possible** (Art 4(2) GDPR) Consider activities such as: accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction.
 |
|  |
| **ii)** **Will the research study involve genomic and/or genetic data generation, analysis and further processing?**Genetic data is considered personal data in accordance with the GDPR(Recital 34) the European Data Protection Board ([EDPB response/Section 51](https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf)).  |
| [ ]  Not applicable 1. Describe how genetic / genomic data storage, analysis and transfer will be managed and include details on any third-party providers in this area and arrangements for maintaining the security / back up of the data.
2. Describe the safeguards that are in place to manage the transfer of data.
3. Describe the analysis techniques that will be used in the study. e.g. Whole genome sequencing, exome sequencing, targeted DNA panels, microarray, RNA sequencing. The purpose of this question is to determine the type of data that will be generated as a result of this analysis.
 |

*Regulation 5(4)(c)(i)*

|  |
| --- |
| 1. **Explain why the research requires that personal data be obtained and processed rather than fully, irrevocably anonymised data (Recital 26 GDPR)** NOTE: pseudonymised or de-identified data may also be considered personal data. For example this may be required to ensure traceability of a participant, as the study requires.
 |
|  |

*Regulation 5(4)(c)(ii)*

|  |
| --- |
| 1. **Describe the safeguards that will be in place to ensure that personal data will not be processed in such a way that damage or distress is, or is likely to be, caused to the participant**
 |
|  |

*Regulation 5(4)(c)(iv)*

|  |
| --- |
| 1. **Confirm that there will be no disclosure of the personal data, unless that disclosure is required by law, or the participant has given his or her explicit consent to the disclosure**
 |
|   |

*Regulation 5(4)(d)*

|  |
| --- |
| 1. **If the research involves linking / merging the personal data from this study with different /external sources of information, please describe what is involved, other parties involved and the purpose of this merging. Please detail the safeguards that will be in place to protect the participants personal data, in this instance.**
 |
|   |

|  |
| --- |
| 1. **Describe the Exit Strategy, i.e. when the research study will no longer require a consent declaration.**

Consider the following:* The point when the research study personal data will be rendered irrevocably anonymised, returned or destroyed.
* If explicit consent has been obtained, a consent declaration may no longer be required.
* Where relevant, consider at what point the master list/key that codifies the personal data, if applicable, will be destroyed.
 |
|   |

**PART C: CONSENT**

*Regulation 5(4)(e)*

|  |
| --- |
| 1. **Why is it not possible to obtain explicit consent from the research participant(s) to process their personal data for this research study? Please provide the rationale for this decision with supporting evidence, where possible.**

Consider the HRCDC guidance notes. If consent is not possible to obtain due to a lack of decision-making capacity, please complete Part C, Section 4 if applicable. |
|   |
| 1. **Please provide an estimation of the numbers of Irish participants involved in the research and that will be covered by a consent declaration, if made**
 |
|  |

|  |
| --- |
| 1. **In what way have the requirements of the Assisted Decision-Making Act 2015 and amendment 2022 (ADMA) been considered in the study design.**

Note: A consent declaration may not be required, if the research participants have decision supports in place as provided for in the ADMA. (refer to HRCDC website guidance) If a co-decision making agreement / decision making representative agreement is in place it will need to specify health research for it to be considered explicit consent. This cohort of participants do not need to be considered as part of the consent declaration.  |
| [ ]  Not applicable  |

|  |
| --- |
| 1. **i) Briefly outline how the decision-making capacity of a research participant(s) is determined.** For those participants that do not have decision supports in place and / or the agreements do not reference Health Research, describe how functional capacity has been assessed and the guiding principles of the ADMA considered in the determination of capacity throughout the study.
 |
| [ ]  Not applicable Brief outline of assessment of capacity process: Answer:  |
| **ii) Where proxy assent is being used as a safeguard in place of explicit consent, please outline the process in place to ensure the proxy chosen is the most appropriate individual who can communicate the will and preference of the participant.** NOTE: proxy (relative, participant representative or advocate, friend, as appropriate) assent for data processing on behalf of an individual that lacks decision making capacity has no lawful basis. However, proxy assent should be used as a suitable safeguard, in additional to seeking a consent declaration. **Please provide study information leaflets and associated assent forms, and other documentation as relevant.**  |
| [ ]  Not applicableBrief outline of how you identify the proxy :  |

|  |
| --- |
| 1. **Will consent from the participant(s) be sought at any stage during the research study?**

If deferred consent/consent-to-continue is being obtained, please expand further. This answer will tie in with Part B, Section 11, exit strategy. Provide proposed study information leaflets and assent form, deferred consent forms and other relevant documentation as relevant. |
|  |

|  |
| --- |
| 1. **Withdrawal of consent and/or assent: Please describe the process for managing the withdrawal of consent / assent throughout the study.**

i.e. what will happen to the personal data if (i) proxy assent is not provided or is withdrawn and/or (ii) if the participant does not provide deferred consent. As part of this outline what happens to the personal data already collected and any follow up data. Please outline how this process has been communicated to the participant.  |
|  |
| 1. **Public, Patient Involvement (PPI) activity is considered an important data protection safeguarding measure when participants cannot provide explicit consent. Please outline what PPI has been undertaken regarding the particular research study contained in this application.**
 |
| 1. **Please document which PPI persons / groups have been / will be consulted as part of the research project.**
 |
| 1. **Document which part of this research project will they be involved in, for example review of information leaflets, transparency measures, study design etc.**
 |

**PART D: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA**

*Regulation 5(4)(a)(i), Regulation 5(4)(a)(ii)*

|  |
| --- |
| **Identify the legal basis under Article 6 and the relevant condition under Article 9 for the proposed processing of the personal data** (Ref Art 6 and Art 9 GDPR)Please consult with the Data Controller’s Data Protection Officer as necessary  |
| 1. **Article 6 legal basis:**
2. **Article 9 condition:**
 |

**PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING**

*Regulation 3(1)(d)*

|  |
| --- |
| 1. **Transparency is an important data safeguard especially when explicit consent cannot be obtained. Specify the arrangements that are or will be in place to ensure that personal data from this study are processed in a transparent manner and that any information in relation to the study is easily accessible and easy to understand to participants and/or the public. (Art 5 GDPR)**. eg data protection policies, public notices, publicity campaigns, information leaflets, websites, engagement with representative / patient/advocacy groups etc*.* Please provide supporting documentation where possible.
 |
|  |

*Regulation 3(1)(c)(iv)-(viii)*

|  |
| --- |
| 1. **Identify the technical and organisational measures/arrangements in place to:**
2. **limit access to the personal data being processed, to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.**
 |
|  |
| 1. **log persons individually who access and process the personal data**
 |
|  |
| 1. **protect the security of the personal data concerned.**

eg encryption techniques, passwords, pseudonymisation techniques, firewalls.  |
|  |
| 1. **anonymise, archive or destroy personal data once the research study has been completed.**

Consider how the data will be further safeguarded by for example, destroying the master list/key, deleting or returning personal data etc. |
|  |
| 1. **evaluate, on an ongoing basis, to ensure continued effectiveness of data protection and compliance with GDPR requirements e.g.,** **monitoring of study, contracts etc. . (Ref Recital 78/GDPR, Art 32/GDPR)**
 |
|  |

*Regulation 3(1)(b)(vii)*

|  |
| --- |
| 1. **Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the research**
 |
|   |

*Regulation 3(1)(c)(i)&(ii), Regulation 5(4)(c)(vi), Regulation 5(4)(d),*

|  |
| --- |
| 1. **i) Data Protection Impact Assessment**

Please attach a copy of the DPIA, which has been reviewed by the data controller (s) Where there are joint data controllers, a single DPIA will suffice, but the review of each joint data controller’s DPO needs to be included:  |
| [ ]  Copy of DPIA attached. |
| **ii) Please outline/attach the advice of the Data Controller’s Data Protection Officer(s) (DPO) regarding the data protection risks of the research study.** Please outline any specific risks highlighted by the DPO below, and the advice provided to mitigate these risks. |

|  |
| --- |
| Name of DPO #1:[ ]  Advice of DPO#1: Name of DPO #2:[ ]  Advice of DPO#2:  |

**SIGNATURE PAGE TO FOLLOW**

**PART G: Signatures of behalf of the data controller(s) of the study are required**

DATA CONTROLLER #1

|  |
| --- |
| I, the Applicant, hereby declare that:[ ]  I am duly authorised by my organisation (Data Controller), [ ]  I am the duly authorised Data Controller,to submit this application to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein is correct. I hereby understand that any decision made by the HRCDC is based on the accuracy of the information provided herein, or any subsequent information provided to the Health Research Consent Declaration Committee.  |
| Applicant Name:Organisation: Title: Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Please provide an acknowledgement that this application form has been reviewed by an authorised representative within the Organisation of the Applicant: [this must be an appropriate and competent authority eg Data Protection Officer, Legal counsel]Name: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

|  |
| --- |
| **Signature of Applicant/Principal Investigator (if not a data controller)** |
| Name: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Read and acknowledged by an authorised representative within the Organisation: [this must be an appropriate and competent authority eg Data Protection Officer, Legal counsel] |

DATA CONTROLLER #2 (if joint controllers)

|  |
| --- |
| I, the Applicant, hereby declare that:[ ]  I am duly authorised by my organisation (Data Controller), [ ]  I am the duly authorised Data Controller,to submit this application to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein is correct. I hereby understand that any decision made by the HRCDC is based on the accuracy of the information provided herein, or any subsequent information provided to the Health Research Consent Declaration Committee.  |
| Applicant Name:Organisation: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

**APPENDIX - I**

|  |
| --- |
| **PART B, Section 3: Design & Methodology of Research (Max 2 Pages)** **Please note it is not necessary to include the full text of the study protocol.**  |
|   |

1. **Data Processing:** carrying out the following with personal data: eg accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction ([Ref Art 4(2)/GDPR)](https://gdpr-info.eu/art-4-gdpr/) [↑](#footnote-ref-2)