

**CONSENT DECLARATION ANNUAL REVIEW FORM**

It is a standard condition of a consent declaration, that the Data Controller must submit an Annual Review to the HRCDC as required by Health Research Regulations. Please complete the Annual Review application form and return it to Secretariat@hrcdc.ie

**PLEASE NOTE**

* Pre-submission advice can be sought from the Secretariat; Secretariat@hrcdc.ie
* 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) and 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 within this form is subject to the [Freedom of Information Act, 2014](http://www.irishstatutebook.ie/eli/2014/act/30/enacted/en/pdf)
* Please do not provide surplus documentation unless specifically requested
* Electronic signatures are acceptable
* Please submit a non-scanned PDF (converted from Word)
* Please do not alter the content of the Annual Review Form
* Please consult with the Data Protection Officer of the Data Controller
* **Please carefully read the explanatory notes in each section**

Version 3.1

Date: December 2022

Owner: Secretariat, HRCDC

Contact: Secretariat@hrcdc.ie

**PART A: APPLICANT DETAILS**

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| **Application reference ID**Include the reference ID to any amendments approved by the HRCDC, as appropriate |
| Ref ID:  |
| **Title of Research** |
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| **Data Controller(s)**Name all joint data controller organisations, if more than one  |
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| **Applicant/Principal Investigator:**  |
| Name:Email: Telephone:  |

**PART B: PROGRESS OF THE RESEARCH STUDY**

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| **Provide a brief overview of the progress of the research study to date (Max 200 words)** Please include an overview of the general deliverables and impacts of the study to date. Please use non-technical language and non-confidential information. If the outputs of study have been published, please cite any references as appropriate.  |
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| **Comment on any material changes to research study**-Please comment on any changes that have been made to the research study, such as data controllers, purpose, the scope of data processing, additional personal data being processed, research ethics approval amendments etc. -If material changes have been made, explain why it was not necessary to notify the HRCDC of these changes by way of an applying for [an amendment](https://hrcdc.ie/wp-content/uploads/2021/11/HRCDC-Guidance-Notes-Amendment-Request-Application-Form-V1.pdf) to the consent declaration.  |
| [ ]  No changes have been made Details of changes made: |

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| **Comment on any breaches that have occurred that affect the integrity of the Declaration and the protection of data subjects**As a standard condition of a consent declaration, Applicants are to report on breaches that may have occurred (e.g., data ransom, unauthorized data access etc.)  |
| [ ]  No breaches have occurred Details of breach, who was informed and actions taken: |

**PART C:** **CONSENT DECLARATION**

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| **Is the consent declaration still valid, or required?** If the consent declaration has expired since the date made by the HRCDC, or is no longer required, please outline how the personal data that was processed under the consent declaration, has been destroyed or rendered fully anonymised, or if explicit consent has subsequently been obtained from the study participants. Generally, outline how the exit strategy has been implemented.  |
| [ ]  Valid/required [Please complete section 4][ ]  Expired [ ]  No longer requiredDetails:  |

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| **Consent declaration requirement: Provide an update on the Exit strategy including IF different from the information provided in the original application**If the consent declaration is still required, please provide an overview of any alternatives being considered or taken to remove the requirement for a consent declaration such as anonymisation of data, destruction of data, or seeking explicit consent from participants. Generally, provide an update on how the exit strategy will be implemented. |
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| **i) Outline how the specific Conditions attached to the consent declaration and amendments if applicable, have been met**Please provide substantiating documentation or evidence where appropriate e.g. - Where conditions are a **specific reporting requirement** of the HRCDC, please report on the status and implementation of the condition. - Where conditions relate to transparency measures, provide privacy/data protection notices, publicity campaigns, website links, other relevant documentation. - Where conditions relate to public and patient involvement (PPI), please comment on PPI feedback, engagement and how the study has implemented PPI advice or feedback.- Where conditions relate to the consent and assent protocol, please comment on how the advice of the HRCDC has been taken into consideration. - Where conditions relate to security measures, please comment on implementation of enhanced measures. |
| [ ]  Not ApplicableCondition 1: Condition 2: *Repeat if necessary* |
| **ii) Outline why specific Conditions attached to the consent declaration and amendments if applicable, have not been met**Please provide substantiating documentation or evidence where appropriate. Where conditions have not been met, clearly outline the challenges experienced or mitigating actions taken, or what progress has been made to date. |
| [ ]  Not ApplicableCondition 1: Condition 2: *Repeat if necessary* |

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| **i) Outline how Recommendations made by the HRCDC, including those made to approved amendments, have been considered**Please provide substantiating documentation or evidence where appropriate. - Where recommendations relate to transparency measures, provide privacy/data protection notices, publicity campaigns website links, other relevant documentation. - Where recommendations relate to public and patient involvement (PPI), please comment on PPI feedback, engagement and how the study has implemented PPI advice or feedback- Where recommendations relate to the consent and assent protocol, please comment on how the advice of the HRCDC has been taken into consideration.- Where conditions relate to security measures, please comment on implementation of enhanced measures. |
| [ ]  Not ApplicableRecommendation 1: Recommendation 2: *Repeat if necessary* |
| **Outline why Recommendations made by the HRCDC, including those made to approved amendments, may not have been considered and/or implemented.**Please provide substantiating documentation or evidence where appropriate. Where recommendations were not considered, clearly outline the challenges experienced or mitigating actions taken.  |
| [ ]  Not ApplicableRecommendation 1: Recommendation 2:*Repeat if necessary* |

**PART C: PATIENT & PUBLIC**

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| **Provide details of Patient and Public feedback**Please provide details of any engagement that you have had with patients and the public regarding any aspect of the study: eg the consent process, the assent process, transparency, impact and benefit of the study, data breaches, issues and the steps taken to resolve them. If participants have requested that their data is withdrawn from the study, comment on the actions taken to ensure this has been respected. |
| [ ]  None[ ]  Addressed in Section [•] aboveDetails:  |

**PART D: OTHER**

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| 1. **If changes have been made to the original Data Protection Impact Assessment**
2. **summarise the changes made,**
3. **provide feedback/advice of the Data Protection Officer.**

Please outline any specific risks highlighted by the DPO, and advice provided to mitigate any risks. Please attached a copy of the updated DPIA. Where the application is from joint data controllers, the advice of each data controller’s DPO must be attached.  |
| [ ]  No ChangesSummary of Changes: Feedback/Advice of DPO: [ ]  Copy of Updated DPIA attached |

**SIGNATURE PAGE TO FOLLOW**

**PART E: SIGNATURES - DATA CONTROLLER(S)**

DATA CONTROLLER #1

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| 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 Annual Review to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein is correct.  |
| Applicant Name:Organisation: Title: Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

JOINT - DATA CONTROLLER #2

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| 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 Annual Review to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein is correct.  |
| Applicant Name:Organisation: Title: Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |