

**CONSENT DECLARATION AMENDMENT REQUEST FORM**

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**To request an amendment to a consent declaration**

**PLEASE NOTE**

* Pre-submission advice can be sought from the Secretariat to advise on whether the nature of the change requires a formal amendment; [Secretariat@hrcdc.ie](mailto: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 Amendment Request form
* **Please consult with the** [**guidance notes**](https://hrcdc.ie/wp-content/uploads/2021/11/HRCDC-Guidance-Notes-Amendment-Request-Application-Form-V1.pdf)
* **Please consult with the Data Controller’s Data Protection Officer prior to submission**

***Note: where an amendment request form is submitted for consideration, the HRCDC reserves the right to request that the Applicant/data controller submit a full new consent declaration application for consideration if this is considered appropriate in the context of the proposed changes to be made.***

Version 4.1

Date: January 2023

Owner: Secretariat, HRCDC

Contact: [Secretariat@hrcdc.ie](mailto:Secretariat@hrcdc.ie)

**PART A: APPLICANT DETAILS**

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| **Application Reference ID:** |
| **Title of Research:** |
| **Data Controller(s):** (Organisation) |
| **Applicant(s)/Principal Investigator:**  If the Principal Investigator is regarded as the Data Controller, solely in their personal capacity, please indicate. |
| Name:  Address:  Email:  Telephone:  Data Controller |

**PART B: AMENDMENT DETAILS**

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| **Indicate the nature of the amendment by ticking one or more of the boxes below. Please provide brief details of the changes that are the subject of this amendment.** Note: Please read the accompanying amendment form guidance for Applicants. Please also note that the scenarios provided are examples and not a definitive or exhaustive list for when an amendment request form should be submitted. |

1. **Research purpose/aims/objectives**

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| **(i) The purpose of the research, and therefore the purpose of the data processing, has changed or expanded beyond that outlined in the original application that was considered by the HRCDC and for which the consent declaration was made.**  e.g., expanded, or additional disease areas, interventions, participant cohorts etc. not detailed in the original application  e.g., the purpose, aims or objectives of the study has changed or expanded from the original application |
| Details: |

1. **Scope of research and data processing**

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| **(i) Change in data controllership (i.e., the addition/change/removal of the data controller or of a joint data controller)**  e.g., The Principal Investigator moves to another organisation, bringing the research and data into new controllership; a new organisation (e.g. hospital/University etc) is also determining how and why the personal data is being used.  Where a data controller has been removed, please provide information on what has happened the personal data previously processed by that controller (e.g., has the controller deleted or transferred the personal data). |
| Details: |
| **(ii) Change of data processor(s), or addition of a new data processor.**  The Data Controller engages with a new data processor to carry out aspects of the research |
| Details: |
| **(iii) The jurisdiction of data processing for the research has changed**  e.g., personal data will be processed outside of Ireland, or outside the EEA |
| Details: |
| **(iv) The extent, source and/or nature of personal data being used for the research study, has changed or expanded.**  e.g., this may be additional personal data from new sources (e.g., a new dataset not previously referenced); more extensive processing of personal data the previously referenced (e.g., data will be collected and processed from more participants then originally planned) etc. |
| Details: |
| **(v) An amendment/change has been submitted to the Research Ethics Committee, that affects the data processing and the scope of the consent declaration.** |
| Details: |
| **☐ (vi) Other additional changes to processing activities outside the scope of the original declaration will be carried out**  e.g., additional processing of sensitive personal data not covered under the consent declaration, such as whole genome sequencing  e.g., the addition of a new site for data collection not previously referenced (i.e., new hospital, care home etc. have been added as a study site).  e.g., the transfer of data to/from different organisations |
| Details: |
| **(vii) An extension to the duration of the consent declaration is required.** |
| Details: |

1. **Assent/Consent protocol**

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| **(i) A** **change to the proxy assent and/or consent protocol is made and has the requisite ethics approval.**  Please provide amended participant information leaflets and associated assent/deferred consent forms |
| Details: |

1. **Attached Conditions**

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| **(i) An amendment to a condition attached to the declaration is requested.** |
| Details: |

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| **Expanding on the above, please provide a non-confidential lay summary outlining the reason(s) for seeking an amendment to the declaration (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. Please specify how the amendment differs from the detail of the original application. |
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**PART C: JUSTIFICATION**

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| **Please justify/explain why the proposed changes that affect the consent declaration are proportionate and remain within the scope/purpose of the research for which the consent declaration was made, such that the changes should be considered as an amendment request.** The HRCDC reserves the right to request that the Applicant/data controller submit a new application for consideration if this is considered appropriate in the context of the proposed changes to be made. The determination as to whether the changes should be considered as an amendment or new application will be made by the HRCDC on a case-by-case basis, having due regard to the type & extent of changes to be made in comparison to the original application/study. The response to this section will help to inform this determination. |
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**PART D: ETHICS AND AGREEMENTS**

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| **Have the proposed changes been submitted to and approved (or provisionally approved) by the requisite Research Ethics Committee (REC)?** Please provide the REC approval letter/amended REC approval letter where applicable, or details of the opinion from the REC. |
| Name REC:  Date of REC approval (or provisional approval):  Copy of REC approval(s) Attached  Confirmation that the REC approval specifically covers the amendments to the health research study  No REC approval  Other comments: |

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| **If the amendment relates to alternative/new data sources, has the data controller of the data source agreed in principle for this access to be provided?** **Please also comment on the agreements/arrangements that will be put in place.**Please provide evidence of any authorization if relevant. |
| Not applicable  Details: |

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| **If the amendment relates to new data controllers and/or data processors, please outline what arrangements are or will be in place between the new data controllers and/or data processors to reflect the new roles and responsibilities** |
| Not applicable  Data Controller - Data Controller arrangement in place  Data Controller - Data Processor contractual arrangements in place  Details: |

**PART E: CONSENT**

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| 1. **In what way was obtaining consent or reconsenting the participant(s) formally considered, in the context of the amendment being applied?**   Was consent discussed with a research ethics committee, subject matter experts, collaborators, patient public representatives, advocacy groups? Please substantiate the rationale with supporting evidence where possible. |
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**PART F: THE PUBLIC INTEREST CASE**

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| **The consideration of an amendment request by the HRCDC will require the public interest element involved to be identified by the Applicant; this includes where the category of the initial HRCDC application did not require a public interest case to be made.**  **Accordingly, in the context of the nature of the study changes, please briefly describe the applicable public interest aspect of the proposed amendment.**  **If it is the case that the public interest outlined in the initial HRCDC application (if provided) remains applicable for this proposed amendment, please indicate this with reasons why. Otherwise, if the previous public interest is not applicable or if a public interest case was not initially required, then please outline a new applicable public interest element for this amendment.**  (Note: There may some limited scenarios where a proposed change does not require a public interest element to be considered i.e., a purely technical, non-substantive change (e.g., extending the duration of a consent declaration for a study that did not require a public interest initially). However, it is expected that most amendments will require an applicable public interest element to be identified by the Applicant). |
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**PART G: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS, PPI**

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| 1. **Please describe what revisions to the current transparency arrangements and/or PPI engagement have been or will be made, with regards to the changes as described in this application.**   Consider for example, data protection policies, public notices, publicity campaigns, information leaflets, websites, engagement with representative patient and public representative groups/advocacy groups etc. If no change is intended to be made, outline the reasons why. Please provide supporting documentation where possible. |
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| **2. Please identify any additional technical and organisational measures/arrangements to be implemented.**  - Consider access restrictions to the personal data being processed, to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.  - Consider additional or new encryption techniques, passwords, pseudonymisation techniques, firewalls etc.  - Consider how the data will be further safeguarded by for example, destroying the master list/key, deleting or returning personal data etc |
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| **3. Provide details of any changes made to the Data Protection Impact Assessment (DPIA) and please summarise the findings of the Data Protection Officer (DPO), if relevant.**  **Please attach copy of updated DPIA and DPO feedback with the changes clearly highlighted.** |
| Copy of DPIA attached  Details of changes to DPIA:  Name of DPO #1:  Advice of DPO#1:  Name of DPO #2:  Advice of DPO#2: |

**PART H: 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 application to the HRCDC. 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 HRCDC. |
| Applicant Name:  Organisation:  Title:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:  Read and acknowledged by an authorised representative within the Organisation of the Applicant  [This should be an appropriate and competent authority eg Data Protection Officer, Legal Counsel]  Name:  Title:  signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |

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 application to the HRCDC. 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 HRCDC. |
| Applicant Name:  Organisation:  Title:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:  Read and acknowledged by an authorised representative within the Organisation of the Applicant  [This should be an appropriate and competent authority eg Data Protection Officer, Legal Counsel]  Name:  Title:  signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |