

**CONSENT DECLARATION AMENDMENT REQUEST FORM**

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**To request an amendment to a consent declaration that has been made to a Data Controller, by the HRCDC**

**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
* 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))
* 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), if possible
* Please do not alter the content of the Amendment request Form
* **Please consult with the Data Controller’s Data Protection Officer prior to submission**

Version 1

Date of Approval: 18th March 2020

Next review due: Jan 2021

Owner: Secretariat, HRCDC

Approved by: Brigid McManus, Chair HRCDC

Contact: Secretariat@hrcdc.ie

**PART A: APPLICANT DETAILS**

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| Application Reference ID:  |
| Title of Research:  |
| Data Controller(s): *(organisation)*  |
| Applicant/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 amendment** |
| [ ]  Change of data controller(s) *(Where there is no change to the purpose of the research study, personal data sources, personal data items)**eg Principal Investigator moves to another organisation, bringing the research study and data into new controllership.*  |
| Details:  |
| [ ]  Change of data processor(s)*(Where there is no change to the purpose of the research study, personal data sources, personal data items)**eg the Data Controller engages with a new data processor to carry out aspects of the research study.*  |
| Details: |
| [ ]  An extension to the declaration duration is required |
| Details: |
| [ ]  The purpose of the research study, using the personal data, has changed |
| Details: |
| [ ]  The extent and/or nature of personal data being used for the research study, has changed*eg* *This maybe additional identifiable personal data*  |
| Details: |
| [ ]  The jurisdiction of data processing for the research has materially changed*eg Personal data maybe processed outside of the Members States*  |
| Details: |
| [ ] The source of the personal data has changed *[Please complete Section* 4] |
| Details: |
| [ ] Additional processing activities outside the scope of the original declaration will be carried out |
| Details: |
| [ ]  An amendment to a condition attached to the declaration is requested |
| Details: |
| [ ]  An amendment to the research study has been submitted to the Research Ethics Committee *[Please complete Section 3]* |
| Details: |
| [ ] An amendment to the Data Protection Impact Assessment form has been made  |
| Details: |
| [ ]  Other*Please Specify* |
| Details: |

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| Expanding on Section 1; 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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| Has an amendment to the research study been submitted to a Research Ethics Committee (REC)? *Please provide the 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 approvalOther comments:  |

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| If amending the data sources, has the data controller of the data source agreed in principle for this access to be provided? *Please provide evidence of any authorization if relevant*.  |
| [ ] Not ApplicableDetails:  |

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| If the amendment relates to new data controllers and/or data processors, please outline what arrangements are in place between the new data controllers and/or data to reflect the new roles and responsibilities |
| [ ]  Not Applicable[ ]  Data Controller - Data Controller arrangement in place[ ]  Data Controller - Data Processor contractual arrangements in placeDetails:  |

**PART C: 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 group? Please substantiate the rationale with supporting evidence where possible.*  |
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**PART C: THE PUBLIC INTEREST CASE**

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| Describe why it is in the public interest for the amendment to be granted. (Max 250 words)*Please provide supporting documentation where appropriate. Consider whether the public interest case is materially different from that outlined in the original application. If your original application was an* ***AF2*** *category, please tick ‘Not Applicable.’* |
| [ ]  Not Applicable Details: |

**PART D: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS**

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| 1. Please describe what revisions to the current transparency arrangements have been/will be made, to reflect the changes that the amendments will bring about.

*- Please provide supporting documentation/evidence where possible. Consider for example, data protection policies, public notices, publicity* *campaigns, information leaflets, websites etc.* *- If no change is intended to be made, please outline the reasons why.*  |
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| 1. Please identify any additional technical and organisational measures/arrangements being implemented.

*- Please consider access restrictions to the personal data being processed, to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.* *- Please considered additional or new encryption techniques, passwords, pseudonymisation techniques, firewalls etc.**- Please 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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| 1. If changes have been made to the original Data Protection Impact Assessment, pleasesummarise the findings of the Data Protection Officer. (Max 500 words)
* *Please outline any specific risks highlighted by the DPO, and advice provided to mitigate any risks.*
* *Please attached a copy of the DPIA. Where the application is from joint data controllers, the advice of each data controller’s DPO must be attached.*
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| [ ]  Copy of DPIA attachedName of DPO #1:[ ]  Advice of DPO#1: Name of DPO #2:[ ]  Advice of DPO#2:  |

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

DATA CONTROLLER #1

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| I, the Applicant, hereby certify 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:Read and acknowledged 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: |

DATA CONTROLLER #1

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| I, the Applicant, hereby certify 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:Read and acknowledged 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: |