National Research Ethics Committee for COVID-19 -Related Health Research (NREC COVID-19)

Annual Progress Report

**INSTRUCTIONS**

* The Principal Investigator must submit an ‘Annual Progress Report’ to the National Office for Research Ethics Committees on the anniversary date of final ethics approval and for every year thereafter for the duration of the study
* All sections of the application form should be completed. If a section does not apply, select “No” or “N/A”, or enter “N/A” in the text box, as appropriate
* Digital signatures are accepted and encouraged
* Please provide a copy of this report to your Research Office or equivalent body in your research institution
* All communications to the NRECs and questions on the process should be directed to the National Office: nationaloffice@nrec.ie

1.0 General information

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| 1.1 NREC Application Code |
| Click or tap here to enter text. |

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| 1.2 Study Title |
| Click or tap here to enter text. |

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| 1.3 Date of Final Ethics Approval (Date on which you received your letter of final approval) |
| Click or tap to enter a date. |

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| 1.4 Principal Investigator details |
| Name: | Click or tap here to enter text. |
| Title: | Click or tap here to enter text. |
| Institution: | Click or tap here to enter text. |
| E-mail:  | Click or tap here to enter text. |

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| 1.5 Is your study registered on a publicly accessible database? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide the name of the publicly accessible database and the registration number | Click or tap here to enter text. |
| If No, what are your reasons for not registering your study? | Click or tap here to enter text. |

2.0 Commencement and Termination Dates

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| 2.1 Study Duration |  |
| What was the study start date? |  |
| Click or tap to enter a date. |  |
| Has the study finished?***Note:*** *If the study is completed, you will need to complete and submit a ‘End of Study Report’* |  |
| [ ]  Yes [ ]  No |  |
| What is the expected study end date? |
| Click or tap to enter a date. |

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| 2.2 Have there been any variations to the proposed start or end dates? |
| [ ]  Yes [ ]  No |  |
| If Yes, please give details below:***Note:*** *If the study was terminated prematurely, please describe any potential implications for research participants as a result of this, and steps taken to address them.* |  |
| Click or tap here to enter text. |  |

3.0 Study Modifications

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| 3.1 Have any substantial amendments been made to the study during the preceding 12 months? |
| [ ]  Yes [ ]  No |  |
| If Yes, please give NREC Amendment Code for each substantial amendment made | Click or tap here to enter text. |

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| 3.2 Have any amendments or modifications been made to the study that have not required ethics approval during the preceding 12 months? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details | Click or tap here to enter text. |

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| 3.3 Have there been any breaches to the study protocol that the NREC have not been notified of? |
| [ ]  Yes [ ]  No |  |
| If Yes, please enclose a report of any serious breaches not already notified to the NREC. | [ ]  Yes [ ]  No |

4.0 Study Participants

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| 4.1 Recruitment information |  |
| Proposed total number of participants in the study (specific to Ireland): | Click or tap here to enter text. |
| Number of participants recruited to date (specific to Ireland): | Click or tap here to enter text. |
| Participant withdrawals from study: |  |
| a) Number lost to withdrawal of consent | Click or tap here to enter text. |
| b) Number lost to follow up | Click or tap here to enter text. |
| c) Number lost to death | Click or tap here to enter text. |
| d) Number lost to other causes (please state what the causes were) | Click or tap here to enter text. |

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| 4.2 Has there been any serious difficulty recruiting participants or accessing samples / data? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details: | Click or tap here to enter text. |

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| 4.3 Have there been any unexpected adverse events during your study? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details: |  |
| Click or tap here to enter text. |  |
| If Yes, did you report the adverse event to the NREC COVID-19? |  |
| [ ]  Yes [ ]  No |  |

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| 4.4 Have any additional concerns arisen about the safety of participants in this study? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide additional information:  |
| Click or tap here to enter text. |
| Outline any measures undertaken / proposed to maintain patient safety. |
| Click or tap here to enter text. |

5.0 Knowledge Exchange and Dissemination

**Note:** The NREC-COVID-19 strongly promotes the ethical responsibility of researchers to share COVID-19-related knowledge widely, openly and rapidly.

The NREC COVID19 affirms its commitment to the [Statement on Data Sharing in Public Health Emergency](https://wellcome.ac.uk/coronavirus-covid-19/open-data). The Committee encourages best practice in data dissemination during the pandemic in line with calls from the WHO and the European Union for rapid open sharing of data to counter the coronavirus outbreak (including the launch of the [European COVID-19 Data Platform](https://www.covid19dataportal.org/) and the [WHO Bulletin COVID-19](https://www.who.int/bulletin/online_first/COVID-19/en/)  platform).

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| 5.1 Have any engagement or dissemination activities related to the study been undertaken over the past 12 months? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details in the following categories: |  |
| Peer Reviewed Publications | Click or tap here to enter text. |
| Non-Peer Reviewed Publications | Click or tap here to enter text. |
| Policy Documents, Regulatory Data, Working Papers, Government Documents | Click or tap here to enter text. |
| Conference Presentations | Click or tap here to enter text. |
| Cochrane Systematic Reviews | Click or tap here to enter text. |
| Datasets, Databases or Code | Click or tap here to enter text. |
| Has this study informed or had an impact on policy such as public health? | Click or tap here to enter text. |
| Public Outreach or Engagement Activities | Click or tap here to enter text. |
| Other Study Impacts | Click or tap here to enter text. |

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| 5.2 Are there any other developments in the study that you wish to report to the NREC COVID-19? |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details below: |  |
| Click or tap here to enter text. |  |

6.0 Final Declaration

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| Declaration of Chief Investigator |
| * I certify that the information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
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| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print Name**: Click or tap here to enter text.**Date:** Click or tap to enter a date. (dd/mm/yyyy)  |