National Research Ethics Committee

for COVID-19-related Research

(NREC COVID-19)

AMENDMENT FORM

For ethical review of health research[[1]](#footnote-1) studies directly related to COVID-19.

* All completed amendment forms to be submitted to nationaloffice@nrec.ie

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| **SECTION A: GENERAL INFORMATION** |
| **Date of original submission:** |  |
| **Title of research study:** |  |
| **Name (s) of Principal Investigator:** |  |
| **Date of original REC / NREC COVID-19 Approval:** |  |
| **EudraCT no. (if study is a clinical trial of a medicinal product):** |  |
| **Original REC Letter Ref. No.****(Attach copy of original REC /NREC COVID-19 with amendment form)** |  |

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| **SECTION B: PROPOSED AMENDMENT** |
| **Please provide details of the amendment you wish to make** |
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| **Does this amendment require a Consent Declaration or an amendment to an existing Consent Declaration?** | [ ]  Yes [ ]  No |
| **Is a revised protocol necessary as a result of this amendment?** **If YES, please attach a copy and highlight the changes.** | [ ]  Yes [ ]  No |
| **Is a revised patient information leaflet/consent form necessary as a result of this amendment?** **If YES, please attach a copy and highlight the changes**  | [ ]  Yes [ ]  No |
| **Is a revised advert necessary as a result of this amendment?** **If YES, please attach a copy and highlight the changes.** | [ ]  Yes [ ]  No |
| **Does the amendment affect the safety or the conduct of the participants of the study?**  | [ ]  Yes [ ]  No |
| **If Yes, please provide details:** |  |

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| **Declaration of the Principal Investigator*****This declaration must be signed and sent to the NREC COVID-19. Digital signatures will be accepted.**** I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
* I undertake to abide by the ethical principles outlined in the Declaration of Helsinki my obligations as set out in the International Conference on Harmonisation’s Good Clinical Practice Guidelines (ICH GCP), and for clinical trials, the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (*S.I. No 190 of 2004*).
* If the amendment is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by the Recognised Ethics Committee.
* I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data.

**Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print Name**:      **Date:**       (dd/mm/yyyy)  |

1. Health research is defined according to the Health Research Regulations 2018 (*Regulation 3(2)(a)).* http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf [↑](#footnote-ref-1)