National Research Ethics Committee
for COVID-19-related Research
(NREC COVID-19)

APPLICATION FORM

For ethical review of health research[1] studies directly related to COVID-19.
Submit all completed applications to
nationaloffice@nrec.ie

[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

APPLICATION OVERVIEW

This application form pertains to both clinical studies of medicinal products and devices, and non-clinical trial research involving human participants. The form is inclusive of information required for those studies where it is considered necessary to seek a Consent Declaration from the Health Research Consent Declaration Committee (HRCDC) for the processing of personal data related to the research. This integrated approach will facilitate the Consent Declaration process being carried out in parallel to the ethics review.

- Only applications that have secured funding, or conditional offers of funding, should be submitted.
- This application form should be completed and submitted by the Principal Investigator (the person who takes primary responsibility for the conduct of the study). It should be filled out in language comprehensible to a lay person.
- It is important that all questions are answered as fully as possible so that consideration of the application is not delayed by the need to seek more information.
- Applications should be submitted with a completed checklist and relevant documentation.
- Where applicable, the NREC will submit the application to the Secretariat of the HRCDC for its consideration.

PLEASE NOTE

- There are mandatory and optional components to this form; consider carefully which optional components apply to your study.
- Electronic signatures are acceptable.
- Submit a non-scanned PDF, if possible.
- Do not alter the content or lay out of the Application Form. (If it is altered, it may be returned to the applicant and delay the process.)

This form was developed in consultation with the HRCDC and adapted from the '*Standard application form For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004 (2018)', and the 'Application for a Recognised Research Ethics Committee (REC) Opinion on a Clinical Trial on a Medicinal Product for Human Use'.*

CONTENTS

1.0 GENERAL INFORMATION
(Mandatory)

1.1 Title of the research study

1.2 Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet. (Max 500 words)

1.3 Please provide a brief summary of the study background and need for the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.
(Max 500 words)

1.4 Principal Investigator details

(If the point of contact for the review process is not the Principal Investigator, please include their name, contact details and role in the study in the text box below.)

Name:

Title:

Position:

Institution:

Qualifications:

Address:

Mobile:

E-mail:

(Please submit a 2-page CV for the Principal Investigator)

Additional contact point, if applicable.

Please confirm the Data Controller of the study.

The Data Controller determines how and why personal data is being collected and used (processed). If the Data Controller differs from the Principal Investigator, please include the name, role, institution, contact details and general role undertaken by Data Controller in the research study.

1.5 Is this a multi-site study?

Yes No

i) If Yes, please submit a list of all proposed sites in Ireland and proposed Principal Investigators at each site including contact no. and e-mail. For data protection purposes, please also confirm the data controller/data processor relationship to the Principal Investigator's organisation.

(for each site include information on the name and location of the site, the lead investigator at each site, mobile numbers, relevant email addresses and the relationship to lead Site)

ii) If Yes, have you received permission from each of the above sites in Ireland to conduct this study? (Max 200 words)

(If your study is a clinical trial, Site specific Assessment Forms must be included with the application for each site proposed as per SI No 190/2004 European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004.)

iii) If Yes, please outline what arrangements will be in place between the Lead Data Controller site and other joint-data controllers and/or data processors of the personal data. (Max 200 words)

(e.g. Controller to Processor agreement, data and material transfer agreement, memorandum of understanding, terms of use etc. If unclear about data controller / data processor requirements, please visit the 'Data Protection Commission' website for more information, and consult with your organisation's Data Protection Officer as necessary.)

2.0 STUDY DESCRIPTORS (Mandatory)

2.1 Please tick the box(es) that best describes your research study.

(Health research categorisations adapted from C. Collins (2008) Irish College of General Practitioners 'Guide to Conducting Research'.)

- ☐ Basic (social research) – to understand and describe social phenomena;
- ☐ Basic (medical research) – investigation of human or animal samples (e.g. biochemical, genetic) carried out in a laboratory;
- ☐ Applied (policy/action research) – to provide useful knowledge to apply to a problem or inform change;
- ☐ Evaluative (assessment/appraisal) – to establish the efficiency, effectiveness, safety and/or success of a program/ intervention;
- ☐ Epidemiological – the study of disease occurrence (distribution and determinants);
- ☐ Clinical – the study of patients who have a particular condition;
- ☐ Other (Please provide details below).

2.2 Please specify the research question(s)/aim(s)/objective(s).

(If a study protocol is available, please ensure that the study protocol has been provided for the review of the committee. Protocols for Clinical Trials are a mandatory requirement.)

2.3 What is the anticipated start date of this study?

2.4 What is the anticipated duration of this study?

2.5 Provide information on the study design.

(The study design chosen should be appropriate to achieving the aims and objectives stated.)

2.6 Provide information on the study methodology. (Max 300 words)

(Please ensure that you provide copies of any instruments / questionnaires etc. referred to in your response.)

2.7 Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

(It is important to get the advice of a statistician in relation to all research studies. The statistician will advise whether a statistical approach is relevant to this particular research study.)

2.8 Will treatment / intervention be withheld from research participants as a result of taking part in the study?

Yes No Not applicable

i) If Yes, please give details.

2.9 What are the potential adverse effects, risks or hazards for research participants taking part in the study?

(All research on human beings carries the possibility of harm. Whether the risk of harm is acceptable or not depends on the importance of the question being addressed and the likelihood of a meaningful result from the study as well as the extent and severity of the possible harm. Harms can be physical, psychological, psychosocial or other and can include pain, discomfort, inconvenience or change to lifestyle. Even seemingly innocuous questionnaires can upset patients and / or change the way they view or manage their illness. It is also wise to classify the harms listed. Harms can be classified as serious, non-serious, transient etc. It is also useful to committees if you state the risk (probability) of the harms occurring, where this is possible: the risk of harms occurring can in some studies be stated with accuracy.

It is recognised however that for many studies the risk (probability) of harm occurring will not be quantifiable. Where relevant, please also state in your answer what measures will be put in place, if any, to ensure the risk of these harms occurring is minimised.

Include any information about engaging with the study population to assess the likelihood and potential severity of harm as well as acceptability.

Note 1: Please ensure any relevant harms listed in response to this question are clearly outlined in any Information Leaflets related to this study.

Note 2: All serious adverse events occurring during the course of this research study must be reported as per each committee's local guidelines in this matter. Note: The term 'serious adverse event' is more typically associated with clinical trials of medicinal products. A generic definition for a 'serious adverse event' outside of SI No 190/2004 is not available. Hence, please report all Serious Adverse Events in line with each committee's local definitions and guidelines in this matter.)

2.10 What are the potential benefits of the research study?

(There may be a direct benefit for research participants. There may be a benefit for the researcher in terms of academic qualification or career advancement. There may be a benefit for the healthcare in general or for an organisation / site or service. There may be a benefit to a pharmaceutical company, device manufacturer, charity etc.)

2.11 What procedures are in place to monitor the health of the research participants during the study or when they are no longer involved in the study? Please state if not applicable.

(Some research studies may involve special arrangements in this regard. However, it is recognised that in many research studies, especially those involving staff members, monitoring of the health of participants is neither appropriate nor necessary. Please provide details however if the health of participants is being monitored. Participants should also be informed of this monitoring in all relevant Information Leaflets. Committees will also have a particular interest in knowing if the study/trial itself is being monitored / overseen by an Data Safety Monitoring Board. Again, a DSMB is neither appropriate nor necessary for many research studies.)

2.12 Please comment on how study results will be made available.

(Include information on dissemination of results to participants, the research community and the wider general public.)

3.0 STUDY PARTICIPANTS (Mandatory)

*Please state if any of the following questions are not applicable to the study, and briefly explain why.

3.1 How many research participants, including controls, are expected to participate at each site in Ireland?

(State total number of participants.)

3.2 Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen. It is important to obtain the advice of a statistician in relation to all research studies.

3.3 How will research participants and controls be identified and recruited?

(Please indicate how participants and controls will be identified and by whom for the study e.g. letter of invitation, verbal approach when attending the clinic, poster advertisement, web advertisement etc. Please ensure that you provide copies of all letters and advertisements referred to in your response for review.)

3.4 What are the inclusion criteria?

(Please be careful when responding to this question especially if there is more than one grouping of research participants. Please state the inclusion criteria for each group of research participants.)

3.5 What are the exclusion criteria?

(Please be careful when responding to this question especially if there is more than one grouping of research participants. Please state the exclusion criteria for each group of research participants.)

3.6 What criteria exist for withdrawing research participants prior to completing the study? (Max 100 words)

3.7 i) Will the participants be from any of the following groups? Tick as appropriate

- Children under 18 (Children under 16 under SI No 190/2004)
- Adults who are unconscious
- Adults in emergency situations
- Pregnant women / women of child-bearing age
- Adults suffering from dementia
- Adults with learning disabilities
- Adults who have a terminal illness
- Adults with mental illness
- Prisoners
- Healthy volunteers
- Those who could be considered to be vulnerable or have a particularly dependent relationship with the investigator, e.g. those in care homes, students assessed by the investigator.

ii) Please justify their inclusion, outlining how the study is expected to benefit research participants.

*NB. Parts 4 and 5 of Schedule 1 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 clearly outline the conditions and principles that apply in relation to the treatment of Minors or Incapacitated Adults who are participants in medical research.

3.8 Will research participants be reimbursed for expenses?

(Research participants may be reimbursed for lost earnings, travel costs and other expenses incurred. Another acceptable form of reimbursement might be the provision of free medicines or services. Compensation for the time and inconvenience involved in research participation (e.g. payment at minimum wage level) might also be permissible as research participants should not be expected to bear the costs that relate to taking part in a study. However, it is important to note that compensation is understood to mean a recompense for losses sustained e.g. time away from work. Any reimbursements or compensation that might be offered to prospective participants should first be approved by a REC in order to ensure that they are measurable and do not reflect any undue inducement by encouraging people to act against their better judgment or take unnecessary risks.)

Yes (expenses only) Yes (compensation for time) No Not applicable

i) If Yes, please clarify.

3.9 Will they receive any incentives for taking part in the study?

(There may be instances where research participants will be paid for any inconvenience and time given to the study. Payments may be financial or non-financial, e.g. entry into prize draws, gifts vouchers, book tokens. Payment that is disproportionate to the time involved or is likely to encourage participants to take risks, is ethically unacceptable. The timing of payments must be such that they do not constitute undue inducement.)

Yes No Not applicable

i) If Yes, please clarify.

3.10 Will the participant's general practitioner be notified of his or her participation in the study?

(If Yes, please ensure permission is sought from the research participant for the researcher to make contact with the research participant's general practitioner. If the general practitioner is being informed, please provide a copy of the letter to the GP for review by the committee. Patient safety should be the key factor in deciding whether it will be necessary to inform the participant's General Practitioner.)

Yes No

i) If Yes, please clarify.

4.0 CONSENT (Mandatory)

4.1 GENERAL CONSENT

4.1.1 Will informed consent be obtained and recorded?

Yes No

i) If Yes, please detail whether consent will be obtained for a) treatment b) sample collection c) data processing.

ii) If Yes, will consent be obtained for both participation in the study and for data processing associated with the study?

(e.g. Please comment on the extent to which consent is sought and captured for different elements of the study.)

iii) If No, please explain why it is not possible to seek consent from the research participant(s)

iv) In what way was consent from the research participant(s) formally considered at the design stage or any stage of the research?

(e.g. Was consent discussed with a research ethics committee, subject matter experts, collaborators etc.)

iv) If No, will consent from the research participant(s) be sought at any stage during the research study?

(e.g. If deferred consent is being obtained, please expand further. Please consider whether a Consent Declaration is required under Section 10.)

4.1.2 How will research participants be informed of their right to refuse to participate and their right to withdraw from this research study?

(Please comment as to whether this is outlined in the Patient Information Leaflet and Consent Form, and if not, why?)

4.1.3 i) Give details of the manner in which consent will be obtained.

(-Please provide detail if consent should be obtained from those with parental responsibility.

-Please attach copies of both the Patient Information Leaflet and Consent Form. If relevant to your study, attach Information Sheets for those with parental responsibility or next of kin, any relevant Assent Forms or Parental Consent Forms, or any additional documentation.

-Please comment on the time interval between providing the Information Leaflet and seeking consent.)

4.2 CAPACITY TO CONSENT

4.2.1 What arrangements have been made to assist research participants who might not adequately understand verbal or written information?

(-Please state clearly how capacity to participate in this research study will be determined.

-Please also state clearly how the issue of consent and assent will be managed for those research participants who are lacking decision-making capacity.

- Please justify and explain why there may be an urgency to seek consent without undue delay having regard to the rights of the prospective research participants and the risks of the study.)

4.2.2 If the person intended to be included in the study lacks decision-making capacity to consent,

i) please explain how it is intended to obtain the necessary consent for their participation in the study, and

ii) in relation to any personal data that may be processed, how will the required safeguard of explicit consent for processing their personal data be met (this may include seeking a Consent Declaration from the HRCDC under Section 10 of this form).

(NOTE: Where a research participant has a legally appointed representative, or enduring power of attorney who can lawfully provide consent for data processing on behalf of a research participant, a Consent Declaration is not appropriate in this scenario.

NOTE: A "legal representative" as defined in SI No 190/2004 is for the purposes of that legislation only and is not to be confused with a "legally appointed representative" as generally understood in law, including for the purposes of consent under the Health Research Regulations.)

4.2.3 If proxy assent (next-of-kin/friend/carer) is being sought as a suitable safeguard for data processing, please confirm that the participants have no legally appointed representative, or enduring power of attorney at the time of obtaining proxy (next-of-kin/friend/carer) assent.

(NOTE: proxy (next-of-kin relative, friend) assent for data processing on behalf of an individual that lacks decision making capacity has no lawful basis. However, it may be used as a suitable safeguard, in addition to seeking a Consent Declaration.)

- Not Applicable
- No legally appointed representative/enduring power of attorney available

Other comments:

5.0 CLINICAL TRIALS OF MEDICINAL PRODUCTS

5.1 Does this study involve a clinical trial of medicinal products for human use (as defined in SI No 190/2004)?

Yes No

If the answer is No, skip the rest of Section 5

*Please note that for all clinical trials, a site-specific assessment for each site in Ireland must be submitted before the committee can validate an application for ethical review.

5.2 Sponsor Details

("Sponsor" means, in relation to a clinical trial, the person who takes on responsibility for the initiation and management (or for arranging the initiation and management) of, and the financing (or arranging the financing) for that clinical trial.)

Name of Sponsor:			
Status of Sponsor:			
Commercial:		Non-Commercial:	
Address:			
Tel:			
E-mail:			
Name and contact details of Sponsor representative:			
Name and contact details of Sponsor's legal representative (if sponsor has no presence in EEA):			

5.3 Please name the substance/medical device that you propose to administer during the clinical trial.

(Please include details of all medicinal products/medical devices including placebo.)

6.0 HUMAN BIOLOGICAL MATERIALS

6.1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

6.1.1 Does this study involve the use or collection of Human Biological Materials?

Yes No

If the answer is No, skip the rest of Section 6

6.2 BODILY TISSUE / BODILY FLUID SAMPLES PROSPECTIVELY COLLECTED

6.2.1 Does this study involve the prospective collection of human biological material?

Yes No

6.2.2 Please state the type of human biological material for prospective collection.

6.2.3 Who and what institution will be the custodian of the prospectively collected human biological material?

(Please note that for applications to set up a biobank, the custodian should be an institution as opposed to an individual e.g. a hospital / a university etc. For all other research applications, "the investigator responsible for collecting and maintaining the material (the custodian) should control access to this material for the duration of his/her studies." Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.)

6.2.4 a) Will the human biological material be collected as part of routine clinical care or specifically for the purposes of the study?

(Routine care: The participant may be undergoing surgery requiring the taking of a biopsy or may be giving blood samples as part of routine clinical care.

Purpose of the study: The participant may for example be undergoing a procedure that does not normally involve taking of a tissue sample and therefore a sample is being taken for the purposes of this study. Please consider whether consent is required for sample collection and/or data processing)

Routine care Purpose of study

6.2.4 (b) With reference to your responses to question 6.2.4 (a) please provide more detail, particularly will consent be obtained from participants to collect the sample , or for use of a sample (or part of a sample) being taken anyway for clinical reasons?

(Please ensure that the consent for either the taking of a sample for research or for the use of a sample that it is planned to take for clinical reasons is clearly separated from CONSENT FOR TREATMENT. A Study Information Leaflet and Consent Form specific to this research study is required. The Consent Form used for treatment is insufficient in this regard.)

6.2.5 a) With respect to prospectively collected human biological material, after the proposed laboratory analysis, will any human biological material remain?

Yes No

6.2.5 b) If Yes to above, will this remaining biological material be retained?

Yes No

i) If Yes, for how long and where will the samples be retained? For what purposes will the samples be retained? Comment on consent for retention of biological material.

6.2.5 c) If yes to above, will this human biological material and/or any data derived from it be used for any other purpose (including future research studies)?

(If you're processing personal data alongside human biological sample, please consider whether you require a Consent Declaration under Section 10.)

Yes No

i) If Yes, please comment on consent for future use of human biological material and/or any data derived from it.

6.2.6 Will the human biological material be collected specifically for the purposes of depositing it in a biobank?

(A 'biobank' is a collection or repository of human biological material. "While any biological sample archive can be termed a 'biobank', the term is normally applied to a centralised archive of material from which materials are made available for approved research." Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.)

Yes No

i) If Yes, please provide specific information in relation to this proposed biobank and confirm that the research participants will be informed in all Information Leaflets and Consent Forms that this is a biobank.

6.3 BODILY TISSUE / BODILY FLUID SAMPLES RETROSPECTIVELY COLLECTED

6.3.1 Does this study involve accessing retrospectively collected human biological material?

Yes No

i) If Yes, please state the type of human biological material that is being accessed, who will access the material, and who (or which institution) is the custodian of the material.

6.3.2 Please state for what purpose the human biological material was originally collected and please comment on the nature of consent for the collection of this material.

6.3.3 Do you intend to contact research participants to seek their consent to use stored human biological material?

Yes No

i) If Yes, will consent be obtained for the use of the biological sample OR the processing of the corresponding identifiable data OR both?

ii) If No, please justify why existing consent is considered sufficient, OR, whether you require a Consent Declaration under Section 10.)

6.4 BODILY TISSUE / BODILY FLUID SAMPLES – SAMPLE MOVEMENT

6.4.1 Will human biological material at any stage leave the institution(s) of origin?

Yes No

i) If Yes, please specify the reason why, where the samples will be sent, and if the samples will be, irrevocably anonymised, pseudonymised, coded, identifiable etc. If 'coded', specify who will retain the key for reidentification.

(-It is recommended that the key to re-identify 'coded' samples remain at the site of origin of the samples. It is further recommended that the person who holds the 'key' to re-identify, be the Principal Investigator at the site or the custodian of the samples.

-If personal data associated with the sample is also is being transferred to a third party, Section 9 (Processing of personal Data & Safeguards) and Section 10 (Seeking a Consent Declaration), should be considered.)

6.4.2 If Yes to question 6.4.1, does a memorandum of understanding (or agreement / contract) exist between the institution(s) of origin and the institution(s) to which the samples will be sent? Please elaborate.

(Researchers should note the importance of putting such agreements in place in order to set out clear terms and conditions of use, and future use of the samples (and associated personal and clinical data). It is accepted that such arrangements between institutions may not be in place at the time of submission of the ethics application for review.)

If personal data associated with the sample is also is being transferred to a third party, Section 9 (Processing of personal Data & Safeguards) and Section 10 (Seeking a Consent Declaration), should be considered.

6.5 GENETIC TESTING

6.5.1 Does this research study involve 'genetic testing'?

Yes No

i) If Yes, please specify the nature and purpose of the genetic testing.

6.5.2 Will consent be obtained for genetic testing?

Yes No

i) If genetic testing is being undertaken, please set out the steps that will be taken and the information that will be provided to study participants prior to genetic testing and processing of genetic data.

Please clarify whether participants will be given the choice of receiving their individual research genetic result. If participants choose to receive their test results, they would need to be made aware of any potential implications for their health of, which may become known as a result of the genetic testing and the processing of genetic data.

Where genetic testing for research purposes gives rise to the processing of personal data, explicit consent is required as a safeguard (please indicate whether it is intended to seek a Consent Declaration under section 10 of this form).

(It is important that this information should be prominently placed in any Information Leaflets or Consent Forms. It is very important that the implications of any testing be stated clearly in any Information Leaflets, in particular, if there are implications for next of kin, offspring or future offspring.)

6.5.3 Please set out what arrangements will be in place to ensure the privacy and confidentiality of study participants' genetic data throughout the life cycle of the research.

6.5.4 Please set out any strategies or arrangements in place to address any significant results or information arising from the genetic testing or processing of genetic data with the study participant.

(This may require diagnostic confirmation of research results, and provision of genetic counselling by appropriately trained health professionals. Consent for disclosure of validated genetic test results should be given by either the participant, the next-of-kin or person with parental responsibility of for this disclosure. Please ensure that this is captured in the Information Leaflet(s) and Consent/Assent Form.)

6.6 COMMERCIAL VALUE

6.6.1 Will the human biological material in this research study, or the data derived from the analysis of the human biological material, be commercially valuable or is there the possibility that it will become commercially valuable?

("Researchers should discuss with research participants the potential commercial uses of their biological material, and also make clear that they will not be entitled to share in any profits that might ensue from their biological material. Research participants must be allowed to withhold their consent for commercial use of products developed from their biological material, as an exercise of control over the terms and conditions of their participation in the research. Disclosure of potential commercial applications is further indicated because of the practical consequences for research if people come to distrust doctors and researchers because they feel they were deceived or treated unjustly." Human Biological Material: Recommendations for Collection, Use and Storage in Research 2005.)

Yes No

i) If Yes, please elaborate

7.0 MEDICAL DEVICES

7.1 Is the focus of this study/trial to investigate/evaluate a medical device?

(The term 'medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. It includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames or other assistive technology products; pregnancy tests, blood glucose monitors and pacemakers - many thousands of items used each and every day by healthcare providers and patients. Medical devices do not include ambulance vehicles, general workshop equipment such as power or machine tools, or general-purpose laboratory equipment. Pre-filled devices, for example, drug inhalers, syringes and certain other drug / device combinations are classed as medicines, not medical devices. This is according to HPRA definitions.)

Yes No

i) If Yes, provide the name of device (or device nomenclature) and provide a general description of the medical device.

If answer is No, skip remaining questions in Section 7.

7.2 i) Does the device have a CE Mark?

(CE stands for 'Conformité Européene' and is a mandatory conformity mark on many products placed on the single market in the European Economic Area. If the device has a CE Mark, please ensure to enclose the relevant certificate for review.)

Yes No

7.2 ii) If the device has a CE Mark, is it proposed to use the device within its stated intended use for CE marking?

Yes No

7.2 iii) If No, please describe:

7.2 iv) CE Mark Number OR Notified body:

7.2 v) If the device does not have a CE Mark or is being used outside its intended use, is this study being undertaken for the purposes of obtaining a CE Mark?

Yes No

7.3 Is this an application to conduct a clinical investigation of a medical device?

Yes No

7.4 If Yes, will the Medical Devices section of the Health Products Regulatory Authority (HPRA) be reviewing this study?

(Please note that review by the HPRA will be required if you completed 7.2 (c) or stated 'yes' in response to 7.2 (e) above. Please refer to the Medical Devices Section of the HPRA website.)

Yes No

8.0 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

8.1 Does this study involve a medicinal product?

(Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.)

Yes No

i) If Yes, provide the trade name of the product, the active substance, and the formulation.

If the answer is No, skip remaining questions in section 8

8.2 Is this an application to conduct a non-interventional trial of a medicinal product?

("Non-interventional trial': a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation, where the assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice, where the prescription of the medicine is clearly separated from the decision to include the patient in the study and where no additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.)

Yes No

8.3 Is this trial a post-authorisation safety study?

(A pharmaco-epidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product. Post-authorisation safety studies fall under the definition of non-interventional trials and should be conducted in accordance with the requirements outlined in Volume 9A of the Rules Governing Medicinal Products in the European Union, Guidelines on Pharmacovigilance for Medicinal Products for Human Use available from the European Commission website.)

Yes No

9.0 PROCESSING OF PERSONAL DATA FOR THE PURPOSES OF THE HEALTH RESEARCH

(Mandatory section where the study involves the processing of personal data)

(PLEASE CONSULT WITH YOUR INSTITUTION'S DATA PROTECTION OFFICER AS NEEDED*)

9.1 DATA PROCESSING & SAFEGUARDS

9.1.1 i) Describe the personal data that will be obtained and used for the research.

(e.g. names, date of birth, age, gender, clinical data, phenotype data, addresses, economic data, ethnicity, (Ref Art 4/GDPR, Ref Art 9/GDPR) (Regulation 5(4)(c)(i).)

ii) Identify the data sources from which the personal data will be obtained.

(e.g. Medical records, Hospitals, Health Service providers, Registries, databases, questionnaires, social media etc.)

iii) If data is pseudonymised, please confirm what organisation, and with whom the 'master key' or equivalent will be stored.

* Health Research Regulations.
All references to Articles herein, are those cited in General Data Protection Regulation (GDPR); Regulation (EU) 2016/679.

9.1.2 Explain why the research requires that personal data be obtained and processed rather than fully anonymised data (Regulation 5(4)(c)(i))

(**NOTE**: pseudonymised or de-identified data may also be considered personal data (Ref Recital 26/GDPR.)

9.1.3 Describe how you will ensure that personal data will not be processed in such a way that damage or distress is, or is likely to be, caused to the participant. (Regulation 5(4)(c)(ii))

9.1.4 Confirm that there will be no disclosure of the personal data, unless that disclosure is required by law or the participant has given his or her explicit consent to the disclosure. (Regulation 5(4)(c)(iv))

9.1.5 Describe how you will ensure that only the minimal amount of personal data will be collected and used, and the personal data will go no further than is necessary for the purpose of attaining the research objective. (Regulation 3(1)(c)(iii))

This question relates specifically to the data minimisation principle (Ref Art 5(1)(c)/GDPR)

9.1.6 i) Jurisdiction of data processing for the research.

(Ref: https://www.dataprotection.ie/en/organisations/international-transfers, Ref Chapter V/GDPR)

- Ireland
- European Economic Area
- Non-EEA

ii) If Non-EEA please identify the legal basis for the transfer of personal data below:

- Transfer on the basis of an Adequacy Decision,
- Transfer using the safeguard of Standard Data Protection clauses,
- Transfer using the safeguard of Binding Corporate Rules,
- Transfer on the basis of Approved Codes of Conduct,
- Transfer on the basis of Approved Certification Mechanisms,
- Transfer on the basis of A legally binding and enforceable instrument between public authorities or bodies,
- Transfer on the basis of a Derogation,

ii) If a legal basis for transfer of personal data outside the EEA has been identified above, please outline what arrangements are in place governing the transfer.

9.2 LEGAL BASIS

9.2.1 Identify the legal basis under Article 6 and the relevant condition under Article 9 for the proposed processing of the personal data. (Regulation 5(4)(a)(i), Regulation 5(4)(a)(ii))

Please consult with the Data Controller's Data Protection Officer as necessary. (Ref Art 6/GDPR & Art 9/GDPR)

9.3 DATA PROTECTION RISK ASSESSMENT *(Regulation 3(1)(c)(i)&(ii), Regulation 5(4)(c)(vi), Regulation 5(4)(d))*

9.3.1 i) Please outline or attach the advice of the Data Protection Officer(s) (DPO) regarding the data protection risks of the research study.

(Please outline any specific risks highlighted by the DPO, and advice provided to mitigate any risks. Where there are joint data controllers the advice of each data controller's DPO must be attached.)

Name of DPO #1:

Advice of DPO#1:

ii) If the data protection risks have been deemed 'high risk', please confirm a Data Protection Impact Assessment (DPIA) has been completed.

(Please attached a copy of the DPIA, which should be completed if the risk is deemed 'high'. Where there are joint data controllers, a single DPIA will suffice, but the advice of each data controller's DPO must be attached.)

Copy of DPIA attached

Status:

iii) Indicate the steps taken to address any risks identified, and/or action taken in relation to advice provided by the DPO.

(Please specifically reference any data protection risks identified if data linkage is being carried out and where possible provide details of any consultations undertaken with research participants whose data is being linked.)

9.4 INFORMATION, SECURITY, TRAINING

9.4.1 Specify the transparency arrangements that are/will be in place to ensure that personal data are processed in a transparent manner (Ref Art 5(1)(a)/GDPR) (Regulation 3(1)(d))

(Please provide supporting documentation/evidence where possible. Consider for example, data protection policies, public notices, publicity campaigns, information leaflets, websites etc.)

9.4.2 Identify the technical and organisational measures/arrangements in place to; (Regulation 3(1)(c)(iv)-(viii))

i) limit access and prevent unauthorised alteration, disclosure or erasure of personal data.

ii) log persons who access and process the personal data.

iii) protect the security of the personal data concerned.

(e.g. encryption techniques, passwords, pseudonymisation techniques, firewalls etc.)

iv) anonymise, archive or destroy personal data once the research study has been completed.

(Please consider how the data will be further safeguarded by for example, destroying the master list/key, deleting or returning personal data etc.)

v) Outline any other technical and organisational measures in place, together with processes for testing and evaluating the effectiveness of such measures, to ensure data processing is in accordance with the data protection legislation. (Ref Recital 78/GDPR, Art 32/GDPR)

9.4.3 Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the research. (Regulation 3(1)(b)(vii))

9.4.4 Please specify any third party (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed. (Regulation 3(1)(b)(vi))

Not Applicable

Name of Organisation:

Principal Business:

Purpose of Sharing:

Country:

Data being shared:

Anonymised Pseudonymised

Other; please specify

10.0 SEEKING A CONSENT DELARATION FROM THE HRCDC

HRCDC
Health Research Consent Declaration Committee

10.1 GENERAL

10.1.1 Do you require a Consent Declaration for the processing personal data

(NOTE: Explicit consent (informed consent that is recorded) to process personal data for research purposes is specified as one of the necessary safeguards under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations.)

○ Yes ○ No

You should give careful consideration to whether you need a Consent Declaration for the data processing parts of the research study. It can only be granted by the Health Research Consent Declaration Committee where there is a substantial public interest and obtaining informed consent is not feasible.

If you DO NOT require a 'Consent Declaration' for your study, please move to section 11 on Financial Arrangement.

If you DO require a Consent Declaration, please complete all questions in the sections below. The consideration process of the HRCDC will run in parallel with the NREC COVID19 to ensure a streamlined process.

10.2 PUBLIC INTEREST

10.2.1 Describe fully why you believe that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the participant and provide any supporting evidence for your case. (Max 500 words).

(Please provide supporting documentation where appropriate.)

10.3 PUBLIC/PATIENT INVOLVEMENT

10.3.1 What consultations or engagement, if any, have been undertaken with focus groups, advocacy groups, patient and/or representatives regarding;

i) The feasibility of obtaining consent?

ii) The development of the research?

10.4 SCOPE OF DECLARATION

10.4.1 i) To establish the scope of the Consent Declaration being sought, please outline what specific data processing activities will be carried out, without the explicit consent of the research participants.

(Consider activities such as: accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction (Ref Art 4(2)/GDPR))

ii) If the research involves data linkage between different sources of information, please describe what is involved and its purpose. (Regulation 5(4)(d))

10.5 EXIT STRATEGY

10.5.1 Describe your exit strategy whereby the research study will no longer require a Consent Declaration.

(e.g. Please consider at what stage during the research study personal data will be rendered irrevocably anonymised to the Data Controller(s), returned or destroyed, or when future consent may be obtained etc. Where relevant, consider at what point the master list/key that codifies the personal data, will be destroyed. If you require a Consent Declaration over several years, or indefinitely, please set out the reasons why.)

11.0 FINANCIAL ARRANGEMENTS (Mandatory)

11.1 What arrangements have been made for compensation in the event of a claim made by or on behalf of a participant?

11.2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.

(Please submit a copy to the NREC COVID19.)

11.3 Has funding for the study been secured?

(Only applications that have secured funding, or conditional offers of funding, will be reviewed by NREC COVID19. Non-disclosure of any sources of funding will result in revocation of ethical approval)

Yes No

i) If Yes, give details of funding organisation(s) and amount secured and duration:

Organisation(s):	
Contact name:	
Address:	
Tel:	
E-mail:	
Amount:	

11.4 Does the Principal Investigator or any of the investigators have any direct/indirect involvement in the outcome of the study that could in anyway be regarded as a possible conflict of interest?

Yes No

i) If Yes, explain why.

12.0 ANY ADDITIONAL ETHICAL REQUIREMENTS

12.1 Does this study raise any additional ethical issues?

Yes No

i) If yes, please identify any additional ethical issues that this study raises and discuss how you have addressed them.

13.0 DECLARATION OF THE PRINCIPAL INVESTIGATOR (Mandatory)

DECLARATION OF THE PRINCIPAL INVESTIGATOR

This declaration must be signed and sent to the NREC.
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 study 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.
- In completing Section 10 'Seeking a consent declaration from the HRCDC', I confirm that I am the Data Controller, or that I am duly authorised by the Data Controller to submit this information for review by the HRCDC.
- 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)