

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

## Standard Operating Procedures

For ethical review of health research<sup>1</sup> studies directly related to COVID-19.

**Office for National Research Ethics Committees**  
Grattan House, 67-72 Lower Mount Street, D02 H838.

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<sup>1</sup> 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>

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These procedures have been informed by the '*Operational Procedures For Research Ethics Committees: Guidance 2004*' (Irish Bioethics Council) and the '*Galway University Hospitals Clinical Research Ethics Committee Standard Operating Procedures*' (Version 31)

## 1. Overview

A key objective outlined in the *National Action Plan for Ireland's Response to COVID-19*<sup>2</sup> is to harness the capacity of the research and evidence community in Ireland to support immediate decision making during the pandemic and to ensure Ireland is prepared for future threats. In accordance with the World Health Organization's *A Coordinated Global Research Roadmap*<sup>3</sup> and on recommendation from the National Public Health Emergency Team (NPHE), the Minister of Health established a temporary and dedicated national research ethics committee (NREC COVID-19) to deliver an expedited process for review for COVID-19-related health research .

The NREC COVID-19 is supported by the Office for National Research Ethics Committees (located in the Health Research Board). This Office is responsible for all administrative actions associated with the NREC COVID-19.

Committee members have been appointed by the Minister to the NREC COVID-19 based on the appropriate diversity of expertise, skills, knowledge and perspectives to ensure the highest standards of ethics review in line with international best practice. It has been constituted to ensure robust and independent ethics review, while accelerating the initiation and delivery of COVID-19 health research (Terms of Reference for the NREC COVID-19 can be found in the Appendix).

The temporary NREC COVID-19 is designed to include structured and coordinated interaction with other bodies involved in regulation of health research including the Health Products Regulatory Authority (HPRA) and the Health Research Consent Declaration Committee (HRCDC). In this way, researchers and sponsors can expect to receive all the necessary decisions from appropriate parties within the same expedited timelines. The ambition of the NREC COVID-19 is to relay decisions back to researchers within 7 days of confirmation of a validated application.

Impartial ethics review is designed to maintain the highest ethical standards of practice in research, to protect participants in research and research workers from harm or exploitation, to preserve participants' rights, including the right to privacy, and to provide reassurance to the public that these standards are being met. These standard operating procedures will support the NREC COVID-19 and the Office for National Research Ethics Committees in their delivery of an independent, comprehensive ethics review of COVID-19 research studies, which will serve investigators and the public alike.

The decisions from the NREC COVID-19 are aligned with international best practice and principles including the Declaration of Helsinki<sup>4</sup>. Deliberations by the NREC COVID-19 will be informed as appropriate by the Department of Health's *Ethical Framework for Decision-making in a Pandemic*<sup>5</sup> and

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<sup>2</sup> National Action Plan for Ireland's Response to COVID-19 (Department of the Taoiseach and the Department of Health, 2020) - <https://assets.gov.ie/71728/2b46989c737f4b689eb87842ce80325b.pdf>

<sup>3</sup> A Coordinated Global Research Roadmap: 2019 Novel Coronavirus (World Health Organization, March 2020) <https://www.who.int/who-documents-detail/a-coordinated-global-research-roadmap>

<sup>4</sup> Wma Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects - <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

<sup>5</sup> Ethical Framework for Decision-making in a Pandemic (Department of Health, 2020) <https://assets.gov.ie/72072/989943ddd0774e7aa1c01cc9d428b159.pdf>

other trusted sources of national and international guidance including from the European Network of Research Ethics Committees (EUREC) and the European Medicines Agency (EMA).

## 2. Composition, function and operations

- a) The NREC for COVID-19-related research (NREC COVID-19) is constituted in accordance with European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No 190 of 2004).
- b) The NREC COVID-19 will ensure that its membership will equip the Committee to address all relevant considerations arising from the categories of COVID-19-related research to be submitted for review. This may from time to time necessitate the co-opting of additional members with specific expertise.
- c) The NREC COVID-19 comprises a maximum of 21 members, one third of which are independent “lay” members as outlined in Schedule 2 of the Regulations (S.I. No 190 of 2004).
- d) A Chairperson, Vice Chairperson and Alternate Vice Chairperson are appointed for an initial period of three months from the date of the establishment of the Committee by the Minister irrespective of the date of his or her appointment. Decisions on membership beyond that initial period will be made by the Minister at the appropriate time and all members will be so advised.
- e) A quorum consists of seven members one of whom must be the Chairperson and / or Vice Chair, one expert member and one layperson.
- f) If the Chairperson, Vice-Chairperson and alternate-Vice-Chairperson are simultaneously absent from a meeting, another member of the NREC COVID-19 will be nominated as Chairperson for the purposes of the meeting.
- g) Committee members will be appointed for an initial period of three months from the date of the establishment of the Committee by the Minister irrespective of the date of his or her appointment. Decisions on membership beyond that initial period will be made by the Minister at the appropriate time and all members will be so advised.
- h) All members are appointed for their independent expertise and not in a representative capacity.
- i) All members are expected to maintain confidentiality regarding meeting deliberations, applications, information on research participants and all related matters. Each member will adhere to and sign a Confidentiality Agreement in relation to their work on the NREC COVID-19.
- j) The NREC COVID-19 will produce a report at the end of the Committee’ tenure in accordance with Regulation 12 (S.I. No 190 of 2004).
- a) Members will attend all meetings using video conferencing in the interest of public health, until a time in which it is deemed safe to meet in person.

### **3. Meeting procedures**

- a. Meetings of the NREC COVID-19 will be held with sufficient frequency to meet the national demand from COVID-19 research studies requiring ethics review and to comply with the Regulations (S.I. No 190 of 2004). Initially, the Committee will meet on a weekly basis.
- b. For workflow management purposes, the Chairperson of the NREC COVID-19, in consultation with the Office may, at their discretion, limit the number of applications to be reviewed at any given meeting.
- c. Members of the NREC COVID-19 who have any conflict of interest in relation to an application under consideration will declare that fact at the earliest point of becoming aware of the conflict. They will desist from discussion of that project and, depending on the nature of the conflict of interest, may be asked to leave the meeting during the discussion.
- d. The minutes of the meetings of the NREC COVID-19 will be prepared by the Office of National Research Ethics Committees in consultation with the Chairperson.
- e. The Minutes will be submitted to the following meeting of the NREC COVID-19 for approval by the Committee.
- f. Minutes will be made publicly available on the webpage of the Office of National Research Ethics Committees shortly after Committee approval.

#### 4. Review procedures

- a) Valid applications submitted for review will be included on the agenda for the next meeting of the NREC COVID-19 (subject to 3b).
- b) Application forms and associated documentation will be circulated to the Committee at a minimum two working days ahead of the meeting.
- a) The NREC COVID-19 will require that clinical trials are conducted in accordance with International Conference on Harmonisation Good Clinical Practice Consensus Guidelines (ICHGCP) (<https://ichgcp.net/>).
- c) The NREC COVID-19 must be satisfied before approving a clinical trial that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of participation in the trial.
- d) The NREC COVID-19 will require that arrangements are present for indemnity/insurance to cover the liability of the Sponsor and/or Investigator for any potential claim made against them and that applicants comply with all Data Protection legislation.
- e) The NREC COVID-19 will examine whether informed consent is appropriate to the research study and complies with recognised ethics standards paying particular regard to persons whose autonomy is compromised. Particular attention will be paid to the methods of obtaining consent and the documentation used to inform participants.

## 5. Decision making process

- a) The NREC COVID-19 will endeavour to reach decisions by consensus. If consensus cannot be reached, the Chair will decide the course of action to derive a decision, which may include voting by majority.
- b) The NREC COVID-19 will return one of the following decisions on each application submitted for its review:
  - i. **Approved**, the applicant may conduct the research as outlined in the research proposal submitted to the NREC.
  - ii. **Provisionally approved**, subject to revisions required to the proposal or answers to questions posed to the applicant. The revisions and/or answers must be submitted to the NREC to support consideration for final approval. Addressing the revisions or questions to the satisfaction of the Chair or designate is a condition of approval. No research may be conducted prior to receiving final approval.
  - iii. **Approval declined** detailed reasons for declining approval should be forwarded to the applicant, with or without an invitation to resubmit a substantially altered proposal for reconsideration.
- c) The NREC COVID-19 decision will be communicated to the applicant in writing within two days of the meeting at which the decision was taken. All decisions taken by the NREC COVID-19 on applications will be recorded in the meeting minutes, which will be made publicly available on the webpage of the Office of National Research Ethics Committees.
- d) Should an application receive *Provisional Approval* from NREC COVID-19, the applicant will have 7 days to respond to the Committee's queries; requests to extend this duration will be considered on a case-by-case basis and should be made in correspondence with the Office.
- e) Should an application receive *Approval* from NREC COVID-19, the applicant should accept the approval, including provisions, within 7 days and confirm study start date. Approval from the Committee will be subject to the Standard Conditions of Research Ethics Approval by the NREC COVID-19 as detailed in the decision letter.
- f) Should an application receive an outcome of *Approval Declined* from NREC COVID-19, the applicant should confirm receipt of the outcome. Any intended resubmission of a declined application should be first discussed with the Office.

## 6. Application procedures

- a) The NREC COVID-19 will require that:
  - i. The application for ethics review is submitted on the prescribed application form.
  - ii. The application for review is submitted at least 7 days prior to the intended Committee meeting date for review.
- b) If an application is deemed invalid, the Office for National Research Ethics Committees will notify the applicant.
- c) An application will be regarded as valid if it meets all the following criteria:
  - i. Applications are within scope for review by the NREC COVID-19 and meet the criterion for expedited review on public health grounds;
  - ii. All documents have been submitted as outlined on the application checklist;
  - iii. The application form(s) has been completed with all questions sufficiently and comprehensively answered;
  - iv. The application form(s) has been signed by the Principal Investigator;
  - v. A short curriculum vitae for the Principal Investigator has been submitted;
  - vi. Supporting documents have version numbers and dates in the case of the research Protocol, Patient Information Sheet and Consent / Assent Form, Letters to participants or others with an interest in the research, and any other documentation to be used in the research that is not already scientifically validated and referenced;
  - vii. Evidence of funding or conditional funding is provided where funding is required;
  - viii. Evidence of insurance / indemnity cover for both research participants and researchers is provided (*please note, studies and research team members covered by the Clinical Indemnity Scheme are required to notify the State Claims Agency of the proposed study*).
- d) The opinion of the Chair of the Committee will be sought where there is any doubt that an application is within scope for review by the NREC COVID-19.
- e) In the case of clinical trials, evidence from any additional sites where the trial is proposed to take place, of the institution's agreement in principle to allow the research to take place at their site is highly desirable and but is not a criterion for validation. Site Specific Assessment Forms should be included with the application. It is not necessary for these to have been signed by site CEOs for review to take place. It is the responsibility of the Principal Investigator to advise the NREC COVID-19 in writing that no objection has been raised at the each of the additional sites.

## 7. Office of National Research Ethics Committees procedures

- a) The Office for National Research Ethics Committees endeavours to support the NREC COVID-19 at each point of the ethics review process.
- b) The Office will issue a receipt of application and tracking number to all submissions for ethics review.
- c) Ahead of being submitted to the NREC COVID-19 for review, the Office will review all submissions to ensure applications are deemed valid. This validation process assesses whether:
  - i. Applications are within scope for review by the NREC COVID-19 and meet the criterion for expedited review on public health grounds;
  - ii. All documents have been submitted as outlined on the application checklist;
  - iii. The application form(s) has been completed with all questions sufficiently and comprehensively answered;
  - iv. The application form(s) has been signed by the Principal Investigator;
  - v. A short curriculum vitae for the Principal Investigator has been submitted;
  - vi. Supporting documents have version numbers and dates in the case of the research Protocol, Patient Information Sheet and Consent / Assent Form, Letters to participants or others with an interest in the research, and any other documentation to be used in the research that is not already scientifically validated and referenced;
  - vii. Evidence of funding or conditional funding is provided where funding is required;
  - viii. Evidence of insurance / indemnity cover for both research participants and researchers is provided (*please note, studies and research team members covered by the Clinical Indemnity Scheme are required to notify the State Claims Agency of the proposed study*).
- d) If the Office does not deem a submission valid, they may request further information or additional documentation, or request that the applicant resubmit their application for ethics review to a local Research Ethics Committee.
- e) Applicants will be notified by the Office if their application is deemed valid and is scheduled for a NREC COVID-19 meeting a minimum of three working days ahead of the Committee meeting.
- f) If a submission is related to a clinical trial of a medicinal product under S.I. No 190 of 2004, the Office will notify the Health Products Research Authority and provide them with any relevant details of the study.
- g) If a submission requires a Consent Declaration in addition to ethics approval, the Office will notify the HRCDC secretariat and share the relevant documentation with them. Both Committee review processes will run in parallel.

- h) Decision letters from the NREC COVID-19 will be issued to applicants by email from the Office within two days of the committee meeting.
- i) If a submission requires a Consent Declaration in addition to ethics approval, applicants will be notified of the outcomes of both Committees by the Office.
- j) Applicants receiving ethics approval for their research study should complete the annual reporting requirements of the NREC COVID-19.
- k) Any questions in relation to applications, processes or the NREC COVID-19 should be directed to Office and not to members of the Committee.
- l) The Office may share summary information on research studies receiving ethics approval from the NREC COVID-19 with other research ethics committees and other relevant stakeholders in health research with a view to contributing to coordination of the national response to the COVID-19 pandemic.

## **National Research Ethics Committee for COVID-19 research (NREC COVID-19) Terms of Reference**

### **1. Background Information**

The National Action Plan for Ireland's response to COVID-19 was published on 16 March 2020. A key objective outlined in the plan is to harness the capacity of the research and evidence community in Ireland to support immediate decision making and to ensure Ireland is prepared for future threats. Researchers in Ireland are mobilising in response to rapid-response research calls at national and European level to accelerate the conduct of COVID-19-related research studies and trials in Ireland.

The World Health Organisation and other respected bodies have highlighted that, even in emergency situations, independent ethical approval and oversight of such research at a national level is necessary to protect the rights of participants and ensure high quality research. They have called on member states to explore expedited and coordinated evaluation procedures that accelerate delivery of COVID-19 research but comply with best international practice and ethical standards.

To that end, the National Public Health Emergency Team have determined that the optimum way to achieve the required ethical approval and oversight in Ireland is by the Minister establishing, on a temporary basis, a dedicated national research ethics committee (REC) for all COVID-19 human health research.

The committee will be supported in its work by the National Office for Research Ethics Committees (located in the Health Research Board). The National Office will be responsible for all administrative actions associated with the committee.

Any person with a query in relation to the committee either generally or in relation to an application (already made or intended to be made) must communicate with the National Office and not directly with the committee. The email address for the National Office is [nationaloffice@nrec.ie](mailto:nationaloffice@nrec.ie) and the weblink is <https://www.hrb.ie/covid-19-ethical-review/nrec-covid-19-overview/>

## 2. Purpose

The purpose of the National Research Ethics Committee (**NREC COVID-19**) is to review all COVID-19-related studies that fall under the definition of health research as set out in the Health Research Regulations 2018 –for convenience this can be found at the end of the Terms of Reference.

**NREC COVID-19** will review proposals for clinical trials (of medicinal products and devices) as well as all other research considered to be COVID-19-related. The opinion of the Chair of the committee will be sought where there is any doubt that an application meets the criterion of COVID-19-related research.

Importantly, the temporary **NREC COVID-19** is designed to include structured and coordinated interaction with other bodies involved in regulation of health research including the Health Products Regulatory Authority (HPRA) and the Health Research Consent Declaration Committee (HRCDC). In this way, researchers and sponsors can expect to receive all the necessary decisions from appropriate parties within the same expedited timelines.

## 3. Composition

The National Research Ethics Committee (**NREC COVID-19**) will comprise:

- A Chairperson
- at least 2 Deputy Chairpersons
- no more than 21 members of which at least one third shall be lay members (see 5 below).

A decision on an application can only be made at a meeting where there are no less than 7 members present (at least, one of whom must be a lay member and another must be an expert member) and one of the 7 must also be the chairperson or deputy chairperson.

Members shall not be paid for their work on the committee but shall be re-imbursed for all reasonable expenses incurred by them in connection with the work of the committee.

Members will enjoy legal indemnity in relation to their work on the committee where any action taken or decision made is taken or made in good faith.

## 4. Tenure

A person appointed as Chairperson, Deputy Chairperson or Ordinary Member shall hold office for an initial period of 3 months from the date of the establishment of the committee by the Minister irrespective of the date of his or her appointment.

Decisions on membership beyond that initial period will be made by the Minister at the appropriate time and all members will be so advised.

Any member of the committee may resign his or her membership by letter to the Minister which should be forwarded through the National Office for Research Ethics Committees

## **5. Composition**

The committee shall be composed of expert and lay members as described immediately below:

“expert member” means a member of an ethics committee who is a health care professional or who has professional qualifications or experience relating to the conduct of, or use of statistics in, clinical research, unless the said qualifications or experience relate only to the ethics of clinical research or medical treatment;

“lay member” means a member of an ethics committee who is not an expert member and who is not and never has been a registered medical practitioner or registered dentist and who does not in the course of his or her employment or business provide medical, dental or nursing care or participate in the promotion or conduct of clinical research.

The actual membership of the committee will be framed having regard to background, experience, qualifications, knowledge and interests of individual members so as to ensure that collectively there is a membership suitably constituted to make informed decisions on applications likely to be received.

## **6. Responsibilities**

The committee collectively and its individual members shall act in good faith as regards the business of the committee and conduct the affairs of the committee with due regard to accepted principles of good governance. This is particularly so where any conflict of interest arises in relation to an application. In such a case, the member must immediately declare the conflict of interest and remove himself or herself from any further consideration of the application.

The committee shall prepare and forward a report for the Minister on its activities at the end of the initial 3 month period of establishment or at any other time before that date that the Minister so requests

## **7. Requirement to provide public information**

The committee shall publish on a website maintained by the National Office for Research Ethics Committees the following information in relation to the committee:

- the names of its members and their professional details, where appropriate,
- information on its processes and procedures,
- summary information about applications made to it and scheduled for consideration by the committee,
- minutes of its meetings,
- decisions on applications made,
- guidance and other material that relates to its work, and
- such other information that the chairperson considers appropriate.

## 8. Decisions

In relation to any application that it considers to fall under its terms of reference, the committee may make any of the following decisions:

- give approval,
- refuse to give approval,
- give approval with conditions,
- refer the application back to the applicant for re-submission,

The committee may request additional information from the applicant to enable it make its decision or consult with any person who it believes can assist it in its deliberations on an application. Where any of the above decisions are made by the committee, it will inform the applicant, in writing (which includes by electronic means), and give reasons.

## 9. Application process

All applications for ethical review should be submitted to the National Office at [nationaloffice@nrec.ie](mailto:nationaloffice@nrec.ie).

Should a study include a clinical trial of an investigational medicinal product (CTIMP), or a clinical investigation of a medical device, an application should be submitted to the HPRA ([clinicaltrials@hpra.ie](mailto:clinicaltrials@hpra.ie) or [devices@hpra.ie](mailto:devices@hpra.ie)) for review as usual and the HPRA and NREC will work in close coordination to facilitate expedited and common timelines for decisions.

Applicants submitting proposals to the **NREC COVID-19** should consider whether their study requires a consent declaration from the HRCDC under the Health Research Regulations for data processing for health research, where it is not feasible to obtain explicit consent and the research represents a substantial public interest. If applicants are planning to submit an application to the **NREC COVID-19** and to the HRCDC, it is important to note that the HRCDC has included additional sections in the **NREC COVID-19** form in order to minimise duplication of effort for applicants and to streamline the application and decision making process. This section of the **NREC COVID-19** form should be completed if appropriate and the HRCDC will concurrently consider the application for a consent declaration.

<b>10. Applications and timeline for decisions</b>	The committee, with the administrative support of the National Office, will expedite procedures, while maintaining the integrity of the ethics approval system, to ensure that decisions on fully completed applications are made as quickly as possible and, in that regard, applications shall only be submitted to <b>NREC COVID-19</b> where peer reviewed has been completed and where funding is in place or has been definitively secured.
<b>11. Meetings, organisation of work and proceedings</b>	<p>Meetings of the committee shall be convened, as deemed necessary by the chairperson, in order that the committee can discharge its functions efficiently and effectively, particularly as regards making decisions on applications.</p> <p>Subject to these Terms of Reference, the chairperson of the committee may organise the work of the committee and its proceedings as he or she thinks appropriate. The chairperson of the committee may establish such sub-committees to help with the work of the committee as he or she thinks necessary.</p>
<b>12. Administrative support</b>	<p>The National Office for National Research Ethics Committees will provide support (as indicated in these Terms of Reference) to the committee and may advise an applicant on matters relating to an application but it cannot offer legal advice on applications and the responsibility for any application submitted lies with the applicant. None (and where a fee in relation to ethical approval would have been payable under Regulation 52(2) of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended) (SI 190 of 2004) the Minister has decided to waive such fee for applications to this committee).</p>
<b>13. Fees</b>	
<b>14. Legal framework</b>	<p>The establishment of this committee is in accordance with law and the Minister's powers.</p> <p>For the purposes of the ethical consideration of clinical trials on medicinal products for human use governed by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, the Minister as Supervisory Body for Ethics Committees under those Regulations has established this committee under and for the purposes of those Regulations. Notice of so doing will appear in Iris Oifgiuil.</p> <p>The establishment of a committee of this type is recognised in and for the purposes of the Health Research Regulations 2018.</p>

### **Definition of Health Research for the purposes of these Terms of Reference (NREC COVID-19)**

“health research” means any of the following scientific research for the purpose of human health:

- (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels;
- (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;

(iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;

(iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;

(v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status