



STATUTORY INSTRUMENTS.

S.I. No. 260 of 2021

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEE
FOR CLINICAL INVESTIGATIONS OF MEDICAL DEVICES)
REGULATIONS 2021

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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017¹ and Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020², hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021.

Commencement

2. These Regulations come into operation on 26 May 2021.

Interpretation

3. (1) In these Regulations—

“Authority” means the Health Products Regulatory Authority;

“EU Regulation” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017¹, as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020²;

“expert member” means a member of a National REC who—

- (a) is a practising or retired health practitioner,
- (b) has qualifications in, or experience directly relating to, the conduct of health research (other than as a member of a research ethics committee), or
- (c) has qualifications or experience in the area of ethics;

“lay member” means a member of a National REC who is not an expert member;

“Minister” means the Minister for Health;

“National REC” means a committee established under Regulation 4;

“opinion” means a decision issued under Regulation 13(1).

¹ OJ No. L 117, 5.5.2017, p. 1.

² OJ No. L 130, 24.4.2020, p. 18.

(2) A word or expression which is used in these Regulations and which is also used in the EU Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the EU Regulation.

Establishment and functions of national research ethics committee

4. (1) The Minister may, from time to time, establish one or more than one, committee to perform ethical review, and give opinions, valid for the entire State, of clinical investigations under the EU Regulation, and a committee so established is, in these Regulations, referred to as a “National REC”.

(2) The functions of a National REC are those set out in these Regulations and include such incidental, supplementary and consequential actions as are necessary or expedient for the purposes of carrying out those functions.

Membership and operation of National RECs

5. (1) The Minister shall, subject to this Regulation and the Schedule, appoint the members of a National REC.

(2) A National REC shall consist of expert members and lay members who, having regard to the functions of the National REC concerned, are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on applications likely to be made to the National REC, and in relation to lay members particular regard should be given to individuals who are patients or representatives of patient organisations.

(3) The Minister shall not appoint a person to be a member of a National REC unless the Minister is satisfied that the person is a fit and proper person to be so appointed.

(4) The rules and procedures set out in the Schedule shall apply to the membership and operation of a National REC.

Prohibition on seeking or receiving payments or benefits

6. (1) Subject to paragraph (2) of this Regulation and paragraph (7) of the Schedule, a member of a National REC or an appeal panel may not seek or receive any payment, fee or financial or other benefit in respect of any application or appeal under these Regulations.

(2) Where a member of a National REC or appeal panel receives any payment, fee or financial or other benefit from a person in respect of any application or appeal under these Regulations as appropriate, he or she shall return it to the person concerned and shall, as soon as practicable, advise the National REC accordingly.

Sub-committees of National RECs

7. (1) A National REC may establish one or more sub-committees to provide advice and assistance to the National REC.

(2) Each member of a sub-committee established under paragraph (1) shall be a member of the National REC concerned.

(3) The acts of a sub-committee are subject to confirmation by the National REC concerned unless the National REC dispenses with the necessity for such confirmation.

(4) A National REC may, at any time, dissolve a sub-committee established under paragraph (1).

(5) A decision on an application made under Regulation 8(1) may not be made by a sub-committee established under paragraph (1).

Applications for ethical review

8. (1) A sponsor proposing to carry out a clinical investigation in the State for the purpose of the EU Regulation shall apply to the relevant National REC for review of the ethical aspects of the proposed research.

(2) A sponsor of a clinical investigation which is being or to be conducted in the State, who intends to introduce modifications to which Article 75 of the EU Regulation applies, shall apply to the relevant National REC for approval pursuant to that Article.

(3) The National REC may, as appropriate, coordinate with the Authority, including in relation to—

- (a) the initial and ongoing assessment of applications under paragraphs (1) and (2),
- (b) the follow-up on authorised clinical investigations, including in relation to any modifications, and
- (c) the execution of tasks pursuant to the EU Regulation.

(4) An application under paragraph (1) shall be—

- (a) submitted no later than the time of submission of the application to the Authority for authorisation or notification of the clinical investigation,
- (b) made in the form and manner specified by the National REC, and
- (c) accompanied by the specified fee, if any.

(5) The National REC shall, as a preliminary matter, and in consultation with the Authority as appropriate, decide whether an application under paragraph (1) or (2) is—

- (a) one to which the EU Regulation applies, or
- (b) one to which the EU Regulation does not apply,

and shall notify the applicant accordingly.

Consultation by National REC

9. (1) In considering an application under Regulation 8(1) or (2), a National REC may consult with a person who is not a member of the National REC where it considers that that person has an expertise required by the National REC.

(2) The views of a person consulted under paragraph (1) shall be recorded by the National REC in the minutes of the meeting at which the proposal concerned is considered.

(3) A person who is consulted under paragraph (1) shall, as soon as he or she becomes aware of it, advise the National REC of any interest or association he or she may have in or with the proposal being considered.

Ethical considerations and timelines on applications

10. (1) A National REC to which an application is made under Regulation 8(1) or (2) shall consider the ethics of the proposed clinical investigation and, subject to paragraphs (2) and (3), shall within the specified period following receipt of the application give an opinion in relation to the clinical investigation to which the application relates.

(2) Where, following receipt of an application under Regulation 8(1) or (2), it appears to the National REC that further information is required in order to give an opinion, the National REC may, within the specified period and before giving its opinion, send a notice in writing to the applicant, that he or she provides such information to the National REC.

(3) Where the National REC sends a request in accordance with paragraph (2), the specified period shall be suspended pending receipt of the information requested.

(4) The National REC may, as deemed necessary, consult a specialist sub-committee, or a person referred to in Regulation 9, before giving its opinion.

(5) In preparing its opinion, the National REC shall consider, in particular and where applicable, the following matters:

- (a) whether there is compliance with the requirements of Article 62 of the EU Regulation as they apply to ethical considerations;
- (b) the relevance of the clinical investigation and its design;
- (c) whether the evaluation of the anticipated benefits and risks is satisfactory and whether the conclusions are justified;
- (d) the clinical investigation protocol;
- (e) the suitability of the investigator and supporting staff;
- (f) the investigator's brochure;
- (g) the quality and adequacy of the facilities for the clinical investigation;
- (h) whether the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the

degree of distress are specifically defined in the clinical investigation plan and constantly monitored;

- (i) whether any undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the clinical investigation;
- (j) whether vulnerable population subjects are appropriately protected in accordance with Articles 64 to 68 of the EU Regulation;
- (k) the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent to participation in the clinical investigation;
- (l) if the subjects are to include persons who because they are minors are incapable of giving informed consent, whether the research is justified having regard to Article 65 of the EU Regulation;
- (m) if the subjects are to include persons who are adults and who are incapable by reason of physical or mental incapacity of giving informed consent, whether the research is justified having regard to Article 64 of the EU Regulation;
- (n) the arrangements for the recruitment of subjects;
- (o) the provision made for indemnity or compensation in the event of injury or death attributable to the clinical investigation in accordance with Regulation 11;
- (p) the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and investigation subjects; and
- (q) the terms of any agreement between the sponsor and the owner or occupier of the investigation site which are relevant to the arrangements referred to in subparagraph (p).

(6) If any subject participating in a clinical investigation is to be a minor and the National REC does not have a member with professional expertise in paediatrics, it shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial concerns specific to the field of paediatrics which may arise in relation to that investigation.

(7) If any subject participating in a clinical investigation is to be an adult incapable by reason of physical or mental incapacity of giving informed consent to participation in the investigation and the National REC does not have a member with professional expertise in the treatment of—

- (a) the disease to which the investigation relates, and
- (b) the patient population suffering that disease,

it shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial concerns, in the field of that disease and the patient population concerned, which may arise in relation to that investigation.

(8) In this Regulation, “specified period” means—

- (a) in the case of an application under Regulation 8(1), 55 days or such extended period as may be required by the National REC where consultation is required, and
- (b) in the case of an application under Regulation 8(2), 38 days, or 45 days where consultation is required.

Damage compensation in clinical investigations

11. A clinical investigation shall not be approved under these Regulations or conducted unless there is in place a policy of insurance or indemnity scheme to provide compensation for any damage suffered by a subject resulting from participation in the clinical investigation, which policy or scheme shall be appropriate to the nature and the extent of the risk.

Consideration of proposals by divisions of National REC

12. For the purposes of the effective and efficient consideration of applications under Regulation 8(1) or (2), the Chairperson of the National REC, after consulting with the Deputy Chairpersons, may determine that the National REC shall sit in divisions of not less than seven members.

Opinions on applications

13. (1) Where the National REC has considered the relevant matters in an application under Regulation 8(1) or (2) in accordance with the EU Regulation and these Regulations, the National REC shall issue a decision (in these Regulations referred to as an “opinion”—

- (a) refusing to give its ethical approval if it is satisfied that one or more of those matters has not been met, or
- (b) giving its ethical approval to the proposal if it is satisfied that those matters have been met.

(2) The National REC shall notify—

- (a) the applicant, and
- (b) the Authority

in writing of its opinion under paragraph (1).

(3) If the opinion of the National REC is that the application is approved (with or without conditions), the notification under paragraph (2) shall include a statement of—

- (a) conditions, if any, to which the clinical investigation or modification is to be subject, and
- (b) matters identified as possible adverse events that must be reported by the sponsor to the National REC should they occur in the carrying out of the clinical investigation.

(4) If the opinion of the National REC is that the application is refused, the notification under paragraph (2) shall include—

- (a) the reasons for the refusal, and
- (b) a statement that the person may appeal the refusal.

Notification of acceptance of opinion or intention to appeal opinion

14. Where a sponsor has been notified of an opinion, he or she shall notify the National REC that issued the opinion, in writing, not later than 10 days after the notification is sent, that he or she—

- (a) accepts the opinion,
- (b) does not accept the opinion but does not intend to appeal, or
- (c) does not accept the opinion and intends to appeal it.

Effect of approval

15. (1) Where an application or appeal is approved under these Regulations that approval shall have effect in every investigation site specified in the application.

(2) No institution that is in receipt of any funding from the State, or research ethics committee established or jointly established by such an institution, shall request or require, as a condition of research associated with a clinical investigation approved under these Regulations being carried out in that institution, that any examination of the matters referred to in Regulation 10 be done.

(3) Where an institution or research ethics committee referred to in paragraph (2) makes a request or imposes a requirement of the nature specified in that paragraph, the sponsor whose clinical investigation has been approved under these Regulations shall notify the National REC that issued the opinion containing such approval of the request or requirement.

(4) Upon receipt of a notification under paragraph (3), the National REC shall write to the institution or research ethics committee concerned and the institution or research ethics committee shall co-operate with any request for information made by the National REC under this paragraph.

Application for consent declaration

16. A sponsor making an application under Regulation 8(1) or (2) shall indicate, as part of the application, whether it is intended to make an application for a consent declaration to the Health Research Consent Declaration Committee established by the Minister under the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

Appeals from opinions

17. (1) A sponsor may, within 28 days of receipt of notification under Regulation 13(2), bring an appeal against an opinion issued by a National REC under these Regulations to an appeal panel established by the National REC.

(2) A National REC shall publish guidelines setting out the procedures applicable to procedures under paragraph (1).

Offences

18. (1) A person who—

- (a) conducts a clinical investigation to which the EU Regulation applies contrary to an opinion or appeal decision under these Regulations refusing ethical approval for such clinical investigation,
- (b) introduces a modification to a clinical investigation to which Article 75 of the EU Regulation applies without applying for and being granted approval for such modification under these Regulations,
- (c) conducts a clinical investigation approved under these Regulations without there being in place a policy of insurance or indemnity scheme to provide compensation for any damage suffered by a subject resulting from participation in such clinical investigation in accordance with Regulation 11,
- (d) in the course of an application or appeal under these Regulations, or the monitoring of a clinical investigation approved under these Regulations, makes any statement or representation, whether oral or written, that he or she knows to be false or misleading in any material respect to a National REC, or
- (e) knowingly makes any statement or representation, whether oral or written, that a clinical investigation that he or she is carrying out, or is planning to carry out or has carried out, has been approved by a National REC or an appeal panel if he or she knows the statement or representation to be false or misleading,

is guilty of an offence.

Penalties and prosecution of offences

19. (1) A person who commits an offence under these Regulations is liable—

- (a) on a summary conviction, to a class B fine or imprisonment for a term not exceeding 6 months, or both, or
- (b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 3 years, or both.

(2) Proceedings in relation to a summary offence under these Regulations may be prosecuted by the Minister.

Fees

20. (1) The following fees shall be payable by a sponsor to the relevant National REC:

- (a) €500 in respect of each application under Regulation 8(1), and €80 in respect of each trial site to which the application relates;
- (b) €125 in respect of each application under Regulation 8(2); and
- (c) €400 in respect of each appeal under Regulation 17 (which fee shall be refundable if the opinion appealed against is reversed or varied).

(2) Where a National REC is satisfied that an application relates to a non-commercial clinical investigation, at the discretion of the National REC—

- (a) the fee payable under paragraph (1)(a) may be reduced to a single fee of €75,
- (b) the fee payable under paragraph (1)(b) may be reduced to €25, and
- (c) the fee payable under paragraph (1)(c) may be reduced to €60.

(3) The National REC may recover, as a simple contract debt in any court of competent jurisdiction, from the person by whom it is payable, any amount due and owing to it as a fee payable under this Regulation.

Transitional arrangements

21. (1) Where, at the date of the coming into operation of these Regulations, an application for an ethics opinion is pending for consideration or under consideration by an ethics committee in accordance with the provisions of the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994) or the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. No. 253 of 1994), that committee shall not give any further consideration to the application and shall forward all papers and information relating to the application to the relevant National REC, and the application shall be treated as an application under these Regulations.

(2) The National REC shall, in relation to an application forwarded under paragraph (1), notify the applicant, in writing, that the application is being treated as if it was an application made under these Regulations and considered accordingly.

*Schedule**Regulation 5***Membership and Procedural Matters relating to National RECs****Membership**

1. (1) A National REC shall have no fewer than 15 members and no more than 28 members, including a chairperson, and 3 deputy chairpersons.
 - (2) The chairperson, deputy chairpersons and ordinary members of a National REC shall be appointed by the Minister.
 - (3) A National REC shall consist of persons who in the opinion of the Minister, having regard to the functions of the National REC concerned, are suitably qualified to serve as lay or expert members, as appropriate.
 - (4) One quarter of the total members of a National REC shall be lay members.
 - (5) The chairperson and the deputy chairpersons of a National REC shall each hold office for the period of 2 years from the date of his or her appointment, which period may be extended by one year.
 - (6) An ordinary member of a National REC shall hold office for the period of 3 years from the date of his or her appointment.
 - (7) Subject to subparagraph (8), a member of a National REC whose term of office expires by the efflux of time shall be eligible for reappointment to the National REC.
 - (8) A person who has served 2 consecutive terms of office as a member of a National REC is not eligible for re-appointment to that National REC.
 - (9) A person may not be a member of more than one National REC, at the same time.
2. (1) A member of a National REC may resign by written notice signed by him or her to the Minister and the resignation shall take effect on the date of the meeting of the National REC concerned next held after written notice of resignation is received by the Minister.
 - (2) The Minister may at any time remove from office a member of a National REC if, in the Minister's opinion—
 - (a) the member has become incapable through ill-health of performing his or her functions,
 - (b) the member has committed stated misbehaviour of a type that would make him or her unsuitable for membership of the National REC, or
 - (c) the removal of the member appears to the Minister to be necessary for the National REC to perform its functions effectively and with public confidence.
 - (3) If a member of a National REC dies, resigns, ceases to be qualified for office and ceases to hold office, or is removed from office, the Minister may appoint a person to be a member to fill the casual vacancy so occasioned.

(4) A person appointed to be a member of a national REC under paragraph (3) holds office for that period of the term of office of the member who occasioned the casual vacancy that remains unexpired at the date of his or her appointment and is eligible for reappointment as a member of the National REC for one term of office on the expiry of that period or such longer term, not exceeding 3 years, as the Minister may determine.

Meetings

3. (1) The quorum for a meeting of the National REC (other than a sub-committee thereof) shall be 7, and at least one of those present shall be the chairperson or a deputy chairperson.

(2) Subject to subparagraph (1), the proceedings of a National REC shall not be invalidated by any vacancy among its members.

4. (1) At least 5 working days before a meeting of a National REC, a notice in writing, signed by or on behalf of the chairperson of the National REC concerned, or in the absence of the chairperson, by or on behalf of a deputy chairperson, shall be sent to every member of the National REC scheduled to attend the meeting and shall specify the agenda for that meeting.

(2) At a meeting of the National REC—

(a) the chairperson of the National REC shall, if present, be the chairperson of the meeting,

(b) if and so long as the chairperson of the National REC is not present, or if that office is vacant, a deputy chairperson shall be the chairperson of the meeting.

Decision Making

5. (1) Every question arising at a meeting of a National REC duly convened shall be determined by a majority of the votes of the members of the National REC present and voting on the question at a meeting of the National REC.

(2) In the case of an equal division of votes on any question arising at a meeting of the National REC, the chairperson of the meeting shall have a second or casting vote.

(3) Where a member of a National REC has a material interest in any matter which falls to be considered by the National REC he or she shall-

(a) disclose to the chairman of the National REC the nature of the interest in advance of any consideration of the matter,

(b) neither influence nor seek to influence a decision relating to the matter,

(c) withdraw from a meeting or that part of a meeting at which the matter is being discussed or considered, and

(d) take no part in any deliberation or decision relating to the matter.

(4) For the purposes of this paragraph, but without prejudice to the generality of subparagraph (3), a person is regarded as having a material interest if—

- (a) the person, a connected relative of the person or a nominee of either of them is a member of a company or any other body which has a beneficial interest in, or material to, any matter to be considered under that subparagraph,
- (b) the person or a connected relative of the person is in partnership with or is in the employment of a person who has a beneficial interest in, or material to, any such matter,
- (c) the person or a connected relative is a party to any arrangement or agreement (whether or not enforceable) concerning land to which any such matter relates, or
- (d) a connected relative has a beneficial interest in, or material to, any such matter.

(5) For the purposes of this paragraph, a person is not regarded as having a material interest in any matter by reason only that he or she, or any company or other body or person mentioned in subparagraph (4), has an interest which is so remote or insignificant that it cannot reasonably be regarded as likely to influence a person in considering or discussing, or in voting on, any question in respect of the matter or in performing any function in relation to the matter.

(6) Where a material interest is disclosed under subparagraph (3), the disclosure shall be recorded in the minutes of the meeting concerned and, for so long as the matter to which the disclosure relates is being dealt with by the meeting, the member of the National REC by whom the disclosure is made shall not be counted in the quorum for the meeting.

(7) Where, at a meeting of a National REC, a question arises as to whether or not a course of conduct, if pursued by a member of the National REC, would constitute a failure by him or her to comply with the requirements of subparagraph (3), the question may, subject to subparagraph (8), be determined by the chairperson of the meeting, whose decision shall be final, and where such a question is so determined, particulars of the determination shall be recorded in the minutes of the meeting.

(8) Where, at a meeting of a National REC, the chairperson of the meeting is the person in respect of whom a matter to which subparagraph (3) applies falls to be determined, the other members of the National REC attending the meeting shall choose one of their number to be chairperson of the meeting for the purposes of subparagraph (7).

(9) Where the Minister is satisfied that a member of a National REC has not complied with subparagraph (3), the Minister may remove that member from office and that person shall then be disqualified from being a member of that National REC or any other National REC.

(10) In this paragraph, “connected relative” in relation to a person, means a spouse, civil partner, parent, brother, sister, child or the spouse or civil partner of a child of the person.

Minutes

6. (1) The chairperson of a meeting of the National REC shall cause proper minutes of the meeting to be prepared which shall be approved by the National REC at the next meeting of the National REC.

(2) The names of all members present at a meeting of a National REC shall be recorded in the minutes of the meeting.

Expenses

7. A member of a National REC may be paid such allowances in respect of reasonable expenses as the Minister, with the consent of the Minister for Public Expenditure and Reform, determines.

Procedures

8. Subject to these Regulations, a National REC shall determine its own procedures, including that a member of a National REC may attend a meeting of a National REC by remote means.



GIVEN under my Official Seal,
25 May, 2021.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations provide for the establishment of national research ethics committees for the purpose of ethical approval of clinical investigations of medical devices, and lay down procedures and rules that apply to applications to such committees.

These Regulations may be cited as the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021.

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