STATUTORY INSTRUMENTS.

S.I. No. 41 of 2022

EUROPEAN UNION (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) (NATIONAL RESEARCH ETHICS COMMITTEES) REGULATIONS 2022

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The Minister for Health, in exercise of the powers conferred on him by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Regulation (EC) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC[1], hereby makes the following regulations:

PART 1

PRELIMINARY AND GENERAL

Citation

1. These Regulations may be cited as the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022.

Commencement

2. These Regulations shall come into operation on the 31st day of January 2022.

Application

3. (1) These Regulations apply to the authorisation and conduct of clinical trials.

(2) These Regulations shall not apply to non-interventional studies.

Interpretation

4. (1) In these Regulations –

"Act of 2007" means the Medical Practitioners Act 2007 (No. 25 of 2007);

"application" means an application made by a sponsor for the authorisation of the conduct of a clinical trial under the Clinical Trials Regulation or for a substantial modification of such an authorisation;

"Authority" means the Health Products Regulatory Authority;

"clinical trial" has the same meaning as it has in the Clinical Trials Regulation;

[1] OJ L 158, 27.05.2014, p.1

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 4th *February,* 2022.

"Clinical Trials Regulation" means Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use[2];

"EU portal" means the electronic portal established in accordance with Article 80 of the Clinical Trials Regulation;

"expert member" means a member of a National REC who is -

(*a*) a practising or retired health practitioner,

(*b*) a person 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, or

(*c*) a person who is involved in the promotion, organisation or conduct of clinical research;

"Head of the National Office" has the meaning assigned to it by Regulation 5;

"health practitioner" has the same meaning as it has in the Health Identifiers Act 2014 (No. 15 of 2014);

"informed consent" has the same meaning as it has in the Clinical Trials Regulation;

"investigator" for the purposes of Article 49 of the Clinical Trials Regulation and these Regulations means -

(*a*) a medical practitioner within the meaning of section 2 of the Act of 2007,

(*b*) a visiting EEA practitioner within the meaning of section 2 of the Act of 2007, or

(*c*) a registered dentist within the meaning of section 2 of the Dentists Act 1985 (No. 9 of 1985);

"in writing" includes by electronics means;

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

"low-intervention clinical trial" has the same meaning as it has in the Clinical Trials Regulation;

"Minister" means the Minister for Health;

"minor" means a person who has not attained the age of 16 years;

"National Office" has the meaning assigned to it by Regulation 5;

"National REC" has the meaning assigned to it by Regulation 13;

"opinion" means an opinion of a National REC expressed for the purposes of these Regulations and the Clinical Trials Regulation;

"sponsor" has the same meaning as it has in the Clinical Trials Regulation;

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[2] OJ L 158, 27.05.2014, p.1

"substantial modification" has the same meaning as it has in the Clinical Trials Regulation;

"trial site" means a hospital, clinic, nursing home, health centre, surgery or other establishment or facility at or from which a clinical trial, or any part of such a trial, is conducted.

(2) Subject to paragraph (1), a word or expression which is used in these Regulations and which is also used in the Clinical Trials Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Clinical Trials Regulation.

PART 2

NATIONAL OFFICE FOR NATIONAL RESEARCH ETHICS COMMITTEES FOR CLINICAL TRIALS OF MEDICINAL PRODUCTS

Establishment of National Office

5. (1)(*a*) There shall be a unit within the Health Research Board which shall be known as the National Office for National Research Ethics Committees for Clinical Trials of Medicinal Products (in these Regulations referred to as the "National Office"), which shall, subject to subparagraph (b), be a constituent part of the Health Research Board.

(*b*) The National Office shall, subject to these Regulations, be independent in the performance of its functions.

(2) The National Office shall be headed by a person who shall, in these Regulations, be referred to as the "Head of the National Office".

(3) The Head of the National Office shall be appointed by the Health Research Board and he or she shall hold office and be paid such remuneration and any allowances for expenses that may, with the approval of the Minister, be determined by the Health Research Board, given with the consent of the Minister for Public Expenditure and Reform.

(4) The Health Research Board may dismiss the Head of the National Office where it is satisfied that the Head of the National Office –

(*a*) has become incapable through ill health of effectively performing the functions of the office,

(*b*) is adjudicated bankrupt,

(*c*) is convicted of a criminal offence,

(*d*) has, without reasonable excuse, failed to discharge his or her functions for a continuous period of 3 months beginning not earlier than 6 months before the day of dismissal, or

(*e*) should be dismissed for any other stated reason.

(5) The Head of the National Office and the officers of the National Office shall be employees of the Health Research Board which shall determine their conditions of employment and duties, and the officers of the National Office shall report to the Head of the National Office in relation to the performance of those duties.

Governance of National Office

6. (1) The Health Research Board shall, to the extent that it is necessary and appropriate in order to assist the National Office in performing its functions efficiently and effectively, provide administrative and operational support to the National Office.

(2) The Health Research Board shall, not later than the 30th day of June each year, submit a statement to the Minister setting out the funding required for the following financial year to provide the administrative and operational support referred to in paragraph (1).

Information on the internet in relation to National Office

7. The National Office shall maintain, and update in a timely manner, a website containing the following -

(*a*) contact details for the National Office,

(*b*) contact details for each National REC,

(*c*) the names of the members of each National REC and their identification as expert members or lay members,

(*d*) information on the National Office's operational processes and procedures,

(*e*) minutes of the meetings of each National REC,

(*f*) the decisions given under Regulation 21 by a National REC in relation to proposals referred to it by the National Office,

(*g*) information on appeals and complaints procedures,

(*h*) any other matters that the National Office considers appropriate.

Development and support of National RECs

8. The Head of the National Office shall, subject to any general directions by the Minister –

(*a*) take such actions and initiatives as he or she considers appropriate in order to assist in the development of high performing National RECs,

(*b*) provide such administrative and other support as he or she considers necessary to enable National RECs to perform their functions efficiently and effectively.

Engagement by National Office with National RECs to ensure efficient and effective National REC system

9. The National Office shall engage with National RECs to ensure an effective National REC system and may, where it considers it appropriate to do so, develop best practice procedures for the purpose of assisting National RECs in performing their functions.

Supervision of clinical trials granted authorisation in the State

10. The Authority and the National Office shall co-operate in the supervision of clinical trials authorised for conduct in the State including, where appropriate, by consultation with a National REC.

Advice, educational outreach and training for National RECs

11. The National Office shall provide such advice and training as it considers appropriate for National RECs in relation to the performance of their functions.

Annual Report

12. (1) The National Office shall make an Annual Report to the Minister on or before such date as he or she may determine and the report shall include such matters related to the National Office and National RECs as the Minister may determine.

(2) The National Office shall make available a copy of each annual report on its website.

PART 3

ESTABLISHMENT OF NATIONAL RESEARCH ETHICS COMMITTEES FOR CLINICAL TRIALS OF MEDICINAL PRODUCTS

Establishment of National Research Ethics Committees

13. The Minister may, from time to time, establish one or more than one National Research Ethics Committees (each of which shall, in these Regulations, be referred to as a National REC) to perform ethical reviews and provide opinions on clinical trials on medicinal products under the Clinical Trials Regulation.

Membership and operation of National RECs

14. (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 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 form opinions on applications likely to be made to the National REC under Part 4 and, in relation to lay members, particular regard shall be given to individuals who are patients or representatives of patient organisations.

(3) The Schedule shall apply to the membership and operation of a National REC.

(4) The Minister may –

(*a*) direct the Head of the National Office to publicly invite expressions of interest from persons who may be interested in being appointed as a member of a National REC,

(*b*) set a deadline for the receipt of expression of interests under subparagraph (a), and

(*c*) issue such guidance to the Head of the National Office as the Minister considers appropriate relating to the matters provided for in this Regulation.

(5) Where, after consideration of any expressions of interest made under paragraph (4), the Head of the National Office is of the view that it is necessary, in order to ensure that a National REC has an appropriate membership composition, to invite one or more other persons (including, where appropriate, persons residing outside the State) having particular skills, qualifications, interests or backgrounds to be considered by the Minister for membership of the National REC, the Head of the National Office shall invite such persons as he or she considers appropriate to make an expression of interest within such period as he or she considers appropriate.

(6) The Head of the National Office shall forward the Minister for consideration for appointment to a National REC the relevant details of persons who –

(*a*) expressed an interest under paragraph (4), or

(*b*) expressed an interest following an invitation under paragraph (5), and who, in the opinion of the Head of the National Office, are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to form opinions on applications likely to be made to the National REC under Part 4.

(7) 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.

Prohibition on seeking or receiving payments or benefits

15. (1) Subject to paragraph (2) of this Regulation and paragraph 7 of the Schedule, a member of a National REC may not seek or receive any payment, fee, financial or other benefit from a person in respect of any application made under Part 4 and considered by that National REC.

(2) Where a member of a National REC receives any payment, fee, financial or other benefit from a person in respect of any application made under Part 4 and considered by the National REC of which he or she is a member, the member shall return it to the person concerned and shall, as soon as practicable, advise the National Office accordingly.

Sub-committees of National RECs

16. (1) The Head of the National Office may, after consulting with the chairperson of a National REC, convene one or more sub-committees of a National REC (in this Regulation referred to as a National REC sub-committee) to provide advice and assistance to the National REC in the carrying out of its work.

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

(3) The Head of the National Office may, after consulting the chairperson of the National REC concerned, at any time, dissolve a National REC sub-committee.

(4) A National REC sub-committee may not consider an application made under these Regulations for the authorisation of the conduct of a clinical trial under the Clinical Trials Regulation.

(5) Subject to paragraph (6), a National REC sub-committee may consider and make a decision on a proposal referred to the National REC under Regulation 17(2) for an ethical opinion on a substantial modification of a clinical trial under the Clinical Trials Regulation.

(6) A National REC sub-committee may consider and make a decision referred to in paragraph (5) only where the sub-committee concerned is chaired for such consideration by –

(*a*) the chairperson or, in his or her absence, a deputy chairperson of the National REC concerned, or

(*b*) where neither the chairperson nor the deputy chairperson is available, another member of the National REC concerned who is designated by the chairperson to chair that meeting.

PART 4

APPLICATIONS TO AND DECISIONS OF NATIONAL RESEARCH ETHICS COMMITTEES

Referral of a proposal to a National REC

17. (1) Where an application, including such fees as are payable, has been made through the EU portal either the National Office or the Authority or, when required, both the National Office and the Authority shall validate the application in accordance with Article 5, 17, or 20 of the Clinical Trials Regulation, as appropriate.

(2) When an application has been validated under paragraph (1), the National Office shall refer the application to a nominated National REC for a decision on the ethical aspects of the proposed clinical trial or the ethical aspects of the proposed substantial modification of a trial.

(3) A National REC may consider only applications referred to it under paragraph (2) and any matters relating to, or arising from, such applications.

(4) The National Office shall put in place such procedures, including electronic procedures, as it considers appropriate to facilitate the referral of a proposal for consideration by a National REC under paragraph (2).

Consultation by a National REC

18. (1) For the purposes of considering a proposal referred to it under Regulation 17 (in particular in respect of a proposal concerning vulnerable populations where specific consideration is required pursuant to Article 10 of the Clinical Trials Regulation), a National REC may, where it considers that the members of the National REC do not have the necessary expertise required to advise on the proposal concerned, consult a person who is not a member of the National REC where it is satisfied that the person has the relevant expertise to consider the proposal.

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

(3) Where a person who is consulted under paragraph (1) has an interest in, or association with, the proposal being considered he or she shall, as soon as he or she becomes aware of the interest or association, advise the National REC of the interest.

(4) A person who is consulted under paragraph (1) may, subject to the agreement of the National Office, be paid a fee by the National REC.

Ethical matters to be considered by National REC

19. (1) A National REC to which a proposal is referred for consideration under Regulation 17 shall consider the ethical aspects of the clinical trial and, subject to paragraphs (2) and (3), shall give an opinion on the ethical aspects of the clinical trial or substantial modification to which the proposal relates.

(2) Where, following receipt of a proposal referred under Regulation 17**,** it appears to the National REC that additional information is required in order for it to give an opinion on the ethical aspects of the proposal, the National REC shall advise the National Office to request such additional information as it may specify from the sponsor.

(3) When considering a proposal referred to it, a National REC –

(*a*) shall have regard to:

(i) the matters specified in subparagraphs (a) to (d) of paragraph (4) to the extent that they are considered relevant by the National REC to the proposal being considered, and

(ii) the matters specified at subparagraphs (e) to (l) of paragraph (4), when considering a proposal involving Part II of an assessment report provided for in accordance with Article 7 of the Clinical Trials Regulation,

and

(*b*) may have regard to any other ethical matter that the National REC wishes to consider, in accordance with international best practice in ethical reviews of clinical trials.

(4) The following matters are specified for the purposes of paragraph (3)(a):

(*a*) the relevance of the clinical trial and its design;

(*b*) whether the evaluation of the anticipated benefits and risks is satisfactory and whether the conclusions are justified;

(*c*) the clinical trial protocol;

(*d*) the investigator's brochure;

(*e*) the suitability of the investigator and his or her supporting staff;

(*f*) the quality and adequacy of the facilities for the trial;

(*g*) compliance with the provisions for protection of subjects and informed consent specified in Chapter V of the Clinical Trials Regulation;

(*h*) the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects;

(*i*) the arrangements for the recruitment of trial subjects;

(*j*) the arrangements for the protection of research participants' privacy and confidentiality;

(*k*) compliance with Article 76 of the Clinical Trials Regulation;

(*l*) compliance with the applicable rules for the collection, storage and future use of biological samples of clinical trial subjects.

Consideration of proposals by National REC

20. For the purposes of the effective and efficient consideration of proposals referred to it under Regulation 17 the chairperson of a National REC, following consultation with the deputy chairpersons and the Head of the National Office shall, with a view to maximising the efficiency of the operation of the National REC determine procedures for the organisation and prioritisation of the work of the National REC.

Decisions on applications

21. (1) A National REC, having had regard to such matters referred to in paragraph (4) of Regulation 19 as are appropriate to the proposal being considered, shall make a decision –

(*a*) to give a favourable opinion in relation to the proposal,

(*b*) to give a favourable opinion in relation to the proposal, subject to certain conditions, or

(*c*) to refuse to give a favourable opinion in relation to the proposal.

(2) The National Office shall record the decision of the National REC made under paragraph (1) and shall notify the decision, including the reasons for the decisions, to the Authority or directly to the EU portal, as appropriate.

Effect of a favourable opinion under Regulation 21

22. (1) Where an application has received authorisation in accordance with the Clinical Trials Regulation and a decision to give a favourable opinion has been given under Regulation 21(1)(a) or (b) that decision shall have effect in every trial site in the State specified in the application.

(2) An institution or a research ethics committee established or jointly established by such an institution shall not request or require, as a condition of the research being carried out in that institution, that an examination of the matters referred to in Regulation 19 be carried out.

(3) Where an institution or research ethics committee referred to in paragraph (2) makes a request or imposes a requirement specified in paragraph (2), the sponsor whose research has been the subject of a decision under Regulation 21(1) (a) or (b) shall notify the National Office of such request or requirement.

(4) Upon receipt of a notification under paragraph (3), the National Office shall contact the institution or research ethics committee concerned and request such information as it considers appropriate and the institution or research ethics committee shall co-operate with any such request.

(5) An institution or a research ethics committee established or jointly established by such an institution shall not give or purport to give an ethical opinion for the purposes of the Clinical Trials Regulation.

(6) A decision under Regulation 21(1) (a) or (b) shall not be construed as authorising the conduct of a clinical trial under the Clinical Trials Regulation in any trial site without the approval of the institution in which the trial site is located.

Application for Consent Declaration

23. A sponsor making an application under this Part shall indicate, as part of the application, whether or not it is intended to make an application for a consent declaration to the Committee appointed by the Minister under Regulation 7 of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

PART 5

APPEALS

Appealing a decision made under Regulation 21

24. A sponsor (in this Part referred to as the "appellant") may submit an appeal to the Authority against a decision not to grant authorisation under the Clinical Trials Regulation, and where some or all of that appeal relates to a decision of a National REC under Regulation 21(1)(c), the Authority shall refer those aspects of the appeal to the National Office.

Establishment of appeal panel

25. (1) Where an appeal relating to the decision of a National REC under Regulation 21(1)(c) is submitted under Regulation 24, the National Office shall establish a panel (in this Part referred to as an "appeal panel") of persons who are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to form opinions for the purposes of hearing and determining such an appeal.

(2) Where the National Office considers it appropriate, in all the circumstances, an appeal panel may hear and determine more than one appeal.

(3) (*a*) An appeal panel established under paragraph (1) shall consist of not less than 7 and not more than 11 members each of whom, in the opinion of the Head of the National Office having regard to the functions of the appeal panel, is suitably qualified to hear the appeal.

(*b*) The Head of the National Office shall appoint one of the members of the appeal panel to be its chairperson.

(*c*) None of the members appointed to an appeal panel shall be a member of the National REC that was involved in considering the application which is the subject of the appeal.

(*d*) An appeal panel shall determine its own procedure.

(*e*) An appellant shall provide, through the portal, such written information (including any documentation) relevant to the appeal that the appeal panel requests within the period specified by the appeal panel.

(*f*) an appeal panel –

(i) shall request the National REC that made the decision to forward observations, if any, in relation to an appeal before it, including on any documentation or other written information provided to the appeal panel by the appellant that was not provided to the National REC when it was considering the application the subject of the appeal concerned,

(ii) may invite submissions from any person whom it considers appropriate, and

(iii) may consult any person whom it believes could assist in the consideration of the appeal.

(*g*) The National Office shall provide such administrative and secretarial support to the appeal panel as it requires to discharge its role efficiently and effectively.

Hearing an appeal

26. (1) An appeal under Regulation 24 shall be considered by the appeal panel as soon as practicable following the establishment of the appeal panel under paragraph (1) of that Regulation.

(2) (*a*) The appeal panel shall, in hearing an appeal, have regard to some or all of the matters set out in Regulation 19(4) to the extent that the appeal panel consider them appropriate to the particular appeal being heard.

(*b*) Having considered an appeal, the appeal panel shall –

(i) confirm the decision under Regulation 21(1)(c), or

(ii) allow the appeal,

and shall as soon as practicable notify the National Office.

(*c*) After receiving a notification under subparagraph (b), the National Office shall notify the Authority of the outcome of the appeal and the Authority shall notify the sponsor of the outcome of the appeal.

Dissolution of appeal panel

27. An appeal panel, having considered the appeal or appeals in relation to which it has been established under Regulation 25 and having made a decision or decisions and notified the National Office under Regulation 26, shall stand dissolved 30 working days after it has made such notifications.

Allowances for reasonable expenses

28. There may be paid by the Minister to the members of an appeal panel such allowances in respect of reasonable expenses properly incurred by them in the performance of their functions as the Minister may, with the consent of the Minister for Public Expenditure and Reform, determine.

PART 6

CO-OPERATION BETWEEN NATIONAL OFFICE, NATIONAL REC AND AUTHORITY

Co-operation: general

29. The National Office, the Authority and each National REC shall co-operate with each other and assist each other in the performance of their respective functions in order to give full effect to the Clinical Trials Regulation in the State.

Co-operation on specific matters

30. Without prejudice to the generality of Regulation 29, the National Office, on behalf of National RECs, and the Authority shall –

(*a*) co-ordinate the review of applications, including timelines, for the conduct of clinical trials and substantial modifications to clinical trials,

(*b*) co-operate in relation to the performance of tasks relating to a clinical trial in accordance with timelines and procedures provided for in the Clinical Trials Regulation,

(*c*) submit notifications through the EU portal and the EU database to which reference is made in Articles 80 and 81 of the Clinical Trials Regulation, and

(*d*) co-operate, where appropriate, in the supervision of clinical trials granted authorisation in the State.

Co-operation: Memorandum of Understanding

31. (1) For the purposes of giving effect to Regulations 29 and 30, the National Office and the Authority may, from time to time, enter into a Memorandum of Understanding.

(2) A Memorandum of Understanding that has been entered into under paragraph (1) may, from time to time, be amended by the National Office and the Authority.

(3) A Memorandum of Understanding that has been entered into under paragraph (1) or amended under paragraph (2) shall be made available on the website of the National Office and the website of the Authority.

PART 7

AMENDMENT OF THE HEALTH RESEARCH BOARD (ESTABLISHMENT) ORDER 1986

32. Article 4 of the Health Research Board (Establishment) Order 1986 (SI No. 279 of 1986) is amended, in paragraph (1), by the insertion of the following subparagraph after subparagraph (d):

"(*e*) to carry out the functions conferred on the Board (including the functions conferred on the unit within the Board known as the National Office for National Research Ethics Committees for Clinical Trials of Medicinal Products) by the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (S.I. No. 41 of 2022).".

SCHEDULE

Regulation 14

Membership and Procedural Matters relating to National RECs

Membership

1. (1) A National REC shall have not fewer than 15 members and not more than 28 members, including a chairperson, and 2 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) The members of a National REC shall be appointed by the Minister and of the members not fewer than one quarter shall be lay members.

(5) (*a*) The chairperson and the deputy chairpersons of a National REC shall each hold office for a period of 4 years from the date of his or her appointment, or such shorter period as may be determined by the Minister.

(*b*) An ordinary member of a National REC shall hold office for a period of 3 years from the date of his or her appointment, or such shorter period as may be determined by the Minister.

(*c*) in determining the duration of any appointment under this subparagraph, the Minister shall seek to ensure that not more than one third of the membership is due to expire during any particular period.

(6) 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.

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,

(*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 subparagraph (3) holds office for such period as the Minister may determine.

Meetings

3. (1) The quorum for a meeting of a National REC shall be 7, and at least one of those present shall be the chairperson or a deputy chairperson or, subject to paragraph 4(3)(b), where neither of the aforementioned are available, another member of the National REC who is designated by the chairperson to chair that meeting.

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

4. (1)(*a*) The chairperson or, in the absence of the chairperson, a deputy chairperson of a National REC, shall convene a meeting of the National REC, not later than 20 working days after being advised by the National Office that he or she should do so.

(*b*) The chairperson or, in the absence of the chairperson, a deputy chairperson of a National REC may, at any time, inform the National Office, of his or her intention to convene a meeting of the National REC.

(2) At least 5 working days before a meeting of a National REC, the agenda approved 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 by the National Office to every member of the National REC scheduled to attend the meeting.

(3) 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 office of chairperson of the National REC is vacant, the Head of the National Office shall nominate a deputy chairperson to be the chairperson of the meeting or, where a deputy chairperson is not available, another member of the National REC shall be designated by the Head of the National Office to chair that meeting.

(4) For the purposes of the effective and efficient consideration of applications referred to it by the National Office, the chairperson of a National REC, after consulting with the deputy chairpersons and the Head of the National Office, shall determine the best way to organise the work of the REC concerned.

Decision Making

5. (1) 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 chairperson of the National REC and the National Office 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.

(2) For the purposes of this paragraph, but without prejudice to the generality of subparagraph (1), 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.

(3) 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 (2) 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.

(4) Where a material interest is disclosed under subparagraph (1), 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.

(5) 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 (1), the question may, subject to subparagraph (6), 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.

(6) Where, at a meeting of the National REC the chairperson of the meeting is the person in respect of whom a matter to which subparagraph (1) 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 (5).

(7) Where the Minister is satisfied that a member of a National REC has not complied with subparagraph (1), the Minister may remove that member from office and that person shall then be disqualified from being a member of the National REC concerned or any other National REC.

(8) 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) An officer of the National Office shall attend each meeting of a National REC and he or she shall cause proper minutes of the meeting to be prepared, which shall, subject to any agreed amendments, be approved by the National REC at the next meeting of the National REC concerned and, after they are approved, the minutes shall be published on the website of the National Office.

(2) The National Office shall, when compiling minutes, have regard to matters of commercial sensitivity and shall ensure that minutes published on its website comply with the Data Protection Acts 1998 to 2018.

(3) 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, following consultation with the National Office, shall determine its own procedures, including that its members may attend a meeting of the National REC by remote means and how decisions under Regulation 21 are to be made.

GIVEN under the Official Seal of the Minister for Health,
31 January, 2022.

MUIRIS O'CONNOR,
A person authorised under section 15 of the Ministers and Secretaries Act 1924 to authenticate the seal of the 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 National Research Ethics Committees for Clinical Trials of Medicinal Products for Human Use and for a National Office to administratively support the work of the National RECs."

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