



STATUTORY INSTRUMENTS.

S.I. No. 29 of 2023

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION
AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO
IONISING RADIATION) (AMENDMENT) REGULATIONS 2023

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AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO
IONISING RADIATION) (AMENDMENT) REGULATIONS 2023

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), for the purpose of giving further effect to Council Directive 2013/59/EURATOM of 5 December 2013¹, as affected by Corrigendum of 17 March 2016² and Corrigendum of 11 June 2019³, insofar as it relates to medical exposures, hereby make the following regulations:

Citation and Commencement

1. These Regulations may be cited as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) (Amendment) Regulations 2023.
2. These Regulations shall be construed as one with the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018) and the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) (Amendment) Regulations 2022 (S.I. No. 528 of 2022) and may be cited together with those Regulations as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 to 2023.
3. These Regulations shall come into operation on 1st February 2023.

Interpretation

4. In these Regulations “Principal Regulations” means the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018).

Amendments to the Principal Regulations

5. Regulation 2(1) of the Principal Regulations is amended –
 - (a) by inserting before the definition of “Authority” the following:

¹ OJ No. L 13, 17.1.2014, p. 1.

² OJ No. L 72, 17.3.2016, p. 69.

³ OJ No. L 152, 11.6.2019, p.128.

“‘appointing authority’ means the institution on whose behalf application for recognition of an ethics committee in accordance with Regulation 37(1) is made and for the purposes of this definition ‘institution’ means a hospital, a University or other similar body involved in higher education or in the award of post-graduate specialist medical or dental qualifications or in the provision of continuing medical or dental education;”, and

(b) by substituting for the definition of “ethics committee” the following:

“‘ethics committee’ means an ethics committee recognised in accordance with Part 8 of these Regulations;”.

The Principal Regulations are amended by inserting after Part 7 the following:

“PART 8 ETHICS COMMITTEES

Establishing, recognising and monitoring of ethics committees

36. (1) The Minister shall be the Ethics Committees Supervisory Body (hereinafter in these Regulations referred to as the Supervisory Body) which shall be the body responsible in the State for recognising and monitoring ethics committees in accordance with these Regulations.

(2) Ethics committees shall be established by an appointing authority in accordance with the provisions of Schedule 1, and subject to such committees being recognised pursuant to Regulation 37, such committees shall have authority to act for the purposes of these Regulations.

(3) Ethics committees may also be established by the Supervisory Body to act –

- (a) for the whole state or part thereof, and
- (b) in relation to such descriptions or classes of ionising radiation, as it considers appropriate and such ethics committees shall be deemed to have been recognised pursuant to Regulation 37.

(4) The Supervisory Body may –

vary the area for which any committee it has established acts or, as the case may be, the descriptions or classes of medical or biomedical research in relation to which such a committee acts, or

abolish any such committee.

(5) The Supervisory Body shall monitor the extent to which ethics committees adequately perform their functions under these Regulations and may provide advice and assistance to such committees in relation to the performance of their functions.

(6) Where an ethics committee is established by the Supervisory body –
the provisions of these Regulations applicable to appointing authorities shall apply to the Supervisory Body in respect of such establishment, and
the provision of these Regulations applicable to ethics committees, shall apply to such committees, save where otherwise indicated.

Recognition of ethics committees

37. (1) Subject to the provisions of this Regulation, the Supervisory Body shall recognise a committee as an ethics committee for the purposes of these Regulations if –

- (a) an application in relation to that committee has been made by an appointing authority, and
- (b) it is satisfied that the proposed arrangements for the membership and operation of the committee would –
 - (i) enable the committee to adequately perform the functions of an ethics committee, and
 - (ii) comply with the provisions of Schedule 1.

(2) An application for recognition of an ethics committee shall be made in writing and be accompanied by such information, documentation and particulars as are necessary to enable the Supervisory Body to determine the application.

(3) In granting recognition in respect of a committee as an ethics committee, the Supervisory Body shall specify in writing -

- (a) whether the committee may act for the whole State or part of the State,
- (b) that the committee may act as an ethics committee for the purposes of Regulation 8(2) of these Regulations, and
- (c) any other conditions or limitations that apply to that committee.

(4) In granting recognition to an ethics committee for the purposes of Regulation 8(2) of these Regulations the Supervisory Authority shall specify any other conditions or limitations that apply to that committee in areas outside of the definition of biomedical research in relation to these Regulations or in relation to ionising radiation.

Revocation of recognition for ethics committee

38. The Supervisory Body may revoke a recognition of an ethics committee, granted pursuant to Regulation 37, if it is satisfied that –

- (a) the provisions of Schedule 1 are not being complied with by that committee,
- (b) the committee is failing to perform its functions under these Regulations adequately or at all, or
- (c) it is otherwise necessary or expedient to do so.

Membership and operation of ethics committee

39. (1) The provisions of Schedule 1 shall have effect in respect of all recognised ethics committees.

(2) Membership and operation of ethics committees shall be determined by the Chairperson of each recognised ethics committee.

Recognition of Existing Ethics Committees

40. (1) For the purposes of these Regulations, the Supervisory Body recognises research ethics committees established by a state body linked to national legislation. Such bodies include bodies operating under the Health Service Executive and higher education institutions.

(2) Research ethics committees currently recognised for the purposes of these Regulations include Tallaght University Hospital / St. James's University Hospital REC, Clinical Research Ethics Committee of the Cork Teaching Hospitals, Galway University Hospitals, Mater Misericordiae University Hospital / Mater Private Hospital, St. Vincent's Healthcare Group, University of Limerick Hospitals, Beaumont Hospital REC, HSE South Eastern Area, HSE North East, National Maternity Hospital (Holles Street), Irish College of General Practitioners and St. Luke's Radiation Oncology REC.

Schedule 1

PROVISIONS FOR ETHICS COMMITTEES

1. (1) In this Schedule -

'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.

- (2) Ethics committees shall be established by appointing authorities in accordance with the provisions of this Schedule.
2. (1) The members of an ethics committee shall be appointed by the appointing authority and shall consist of expert members and lay members.
- (2) An ethics committee shall consist of no more than twenty one members of which at least one third shall be lay members and at least one half of those lay members shall be persons who are not and never have been health care professionals.
- (3) A member of an ethics committee shall hold and vacate office as a member in accordance with the terms of the instrument appointing him or her as a member.

Chairperson, vice-chairperson and alternate vice-chairperson

3. (1) The appointing authority shall appoint—
 - (a) one of the members of each ethics committee to be chairperson of the committee;
 - (b) another member to be vice-chairperson; and
40. another member to be alternate vice-chairperson.
- (2) The members appointed as chairperson, vice-chairperson and alternate vice-chairperson shall each be appointed for such period, not exceeding the remainder of his or her term as a member, as the appointing authority may specify on appointing him or her.
- (3) Any member so appointed may at any time resign from the office of chairperson, vice-chairperson or alternate vice-chairperson.
- (4) Where the chairperson has died or has ceased to hold office, or where he or she is unable to perform his or her duties as chairperson owing to illness, absence or any other cause, references to the chairperson in this Schedule shall, so long as there is no chairperson available to perform his or her duties, be taken to include references to the vice-chairperson; or if the vice-chairperson is also unable to perform his or her duties, the alternate vice-chairperson.

Committees, meetings and proceedings

4. (1) An ethics committee may -
 - (a) appoint sub-committees consisting of members of the committee; and
 - (b) make arrangements for the exercise, on behalf of the committee, of any of its functions by such a sub-committee, in accordance with the standing orders and operating procedures adopted under subparagraph (3).
- (2) Subject to subparagraph (4), the meetings and proceedings of an ethics committee and its sub-committees shall be conducted in accordance with the standing orders made, and standing operating procedures adopted, under subparagraph (3).
- (3) An ethics committee -
 - (a) shall, subject to approval by the Supervisory Body, make standing orders, and adopt standing operating procedures, for the Regulation of its proceedings and business; and
 - (b) may, subject to approval by the Supervisory Body, vary or revoke such orders or procedures, including provision for the suspension of the standing orders or operating procedures or any of them.
- (4) No business shall be transacted at a meeting of an ethics committee to determine, in accordance with Regulation 13, the opinion of an ethics committee in relation to a clinical trial, unless the chairperson and least

six other members (including any members co-opted under paragraph 6) are present, including at least -

- (a) one lay member who is not and never has been -
 - (i) a health care professional, or
 - (ii) a chairperson, member, director, officer or employee of a health service body; and
- (b) one expert member.

Deputies and co-opted members

5. (1) An ethics committee may appoint a person to act as the deputy of an expert member or a lay member provided that the person would be eligible for appointment as an expert member or, as the case may be, a lay member.

- (2) A deputy shall hold and vacate office as a deputy member in accordance with the terms of the instrument appointing him or her as a deputy.
- (3) A deputy may attend meetings and vote as a member of the committee only if the member for whom he or she acts as deputy is absent.
- (4) A deputy member and the member for whom he or she is deputy shall count as one member for the purposes of paragraphs 2(2) and 4(4).

6. (1) At any meeting of an ethics committee, the committee may co-opt up to 2 additional members for the purposes of that meeting.

- (2) At any meeting of a sub-committee of an ethics committee, the sub-committee may co-opt an additional member for the purposes of that meeting.
- (3) A person shall be eligible to be co-opted as a member only if he or she is or has been a member of an ethics committee.
- (4) A co-opted member shall hold office only in relation to the meeting for which he or she is co-opted.
- (5) A member co-opted under this paragraph shall not count as a member for any of the purposes of paragraph 2(2).

Staff, premises and facilities

7. (1) The appointing authority shall make arrangements for the appointment of such administrative and other staff for an ethics committee as it considers necessary to enable the committee to perform its functions.

- (2) The appointing authority shall -
 - (a) secure the provision to an ethics committee of such accommodation and facilities as it considers necessary to enable the committee to perform its functions; and

- (b) secure that arrangements are made for such administration, maintenance, cleaning and other services as may, in its opinion, be necessary for such accommodation and facilities.”



GIVEN under my Official Seal,
3 February, 2023.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

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

The main purpose of these Regulations is to give further effect to Council Directive 2013/59/EURATOM of 5 December 2013⁴, as affected by Corrigendum of 17 March 2016⁵ and Corrigendum of 11 June 2019⁶, insofar as it relates to medical exposures.

⁴ OJ No. L 13, 17.1.2014, p. 1.

⁵ OJ No. L 72, 17.3.2016, p. 69.

⁶ OJ No. L 152, 11.6.2019, p.128.

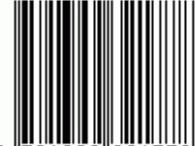
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