STATUTORY INSTRUMENTS.

S.I. No. 25 of 2026

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES FOR CLINICAL INVESTIGATIONS OF MEDICAL DEVICES (AMENDMENT) REGULATIONS 2026

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EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES FOR CLINICAL INVESTIGATIONS OF MEDICAL DEVICES (AMENDMENT) REGULATIONS 2026

I, JENNIFER CARROLL MACNEILL, 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 2017, Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 and Regulation (EU) 607/2023 of the European Parliament and of the Council of 15 March 2023, hereby make the following regulations:

1. These Regulations may be cited as the European Union (National Research Ethics Committees for Clinical Investigation of Medical Devices) (Amendment) Regulations 2026.

2. These Regulations shall come into operation on 1 February 2026.

3. In these Regulations "Principal Regulations" means the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2023 (S.I. No. 671/2023).

4. The Principal Regulations are amended by deleting Regulation 35, and substituting it with the following:

'Fees

35. (1) Subject to paragraph (2), the following fees shall be payable by a sponsor to the relevant National Office:

(a) €1,650 in respect of each application for National REC review relating to the conduct of a clinical investigation in the State,

(b) €440 in respect of each application for National REC review of a substantial modification of a clinical investigation, and

(c) €2000 in respect of each appeal under Regulation 24 (which fee shall be refundable if the appeal is successful).

(2) Paragraph (1) does not apply to applications relating to a non-commercial clinical investigations.

(3) The National Office 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.'

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3*rd February,* 2026.

L.S.

GIVEN under my Official Seal,
29 January, 2026.

JENNIFER CARROLL MACNEILL,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations amend the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2023 (S.I. No. 671/2023).

The purpose of these Regulations is to provide for the revision of fees payable to the National Office by a sponsor associated with the conduction of clinical investigations in the State and applications for national research ethics committee reviews and appeals in respect of such applications.

These Regulations may be cited as the European Union (National Research Ethics Committees for Clinical Investigation of Medical Devices) (Amendment) Regulations 2026.

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