



STATUTORY INSTRUMENTS.

S.I. No. 670 of 2023

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES
FOR PERFORMANCE STUDIES OF IN VITRO DIAGNOSTIC MEDICAL
DEVICES) (AMENDMENT) REGULATIONS 2023

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES FOR PERFORMANCE STUDIES OF IN VITRO DIAGNOSTIC MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2023

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 EU 2017/746 of the European Parliament and of the Council of 5 April 2017,¹ as amended Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023,² hereby makes the following regulations:

1. (1) These Regulations may be cited as the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2023.

(2) The European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 (S.I. 257 of 2022) and these Regulations may be cited together as the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 and 2023.

2. These Regulations shall come into operation on 1 January 2024.

3. In these Regulations “Principal Regulations” means the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022 (S.I. 257 of 2022).

4. The Principal Regulations are amended by substituting for Regulation 35 (as amended by the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2022 (S.I. No. 725 of 2022)) the following:

“Fees

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

- (a) €1,500 in respect of each application for National REC review relating to the conduct of a performance study in the State,

¹ OJ No. L 117, 5.5.2017, p. 176.

² OJ L 80, 20.3.2023, p. 24.

- (b) €300 in respect of each application for National REC review of a substantial modification of a performance study, and
 - (c) €1,200 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 performance studies.
- (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.”.

5. The European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2022 (S.I. No. 725 of 2022) are revoked.



L.S.

GIVEN under my Official Seal,
20 December, 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.)

These Regulations amend the European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022.

These Regulations also revoke European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2022 (S.I. No. 725 of 2022).

They amend the amount of fees payable in respect of applications for National Research Ethics Committee (“National REC”) review of a performance study to be conducted in the State or for a National REC review of a substantial modification of a performance study and appeals in respect of such applications. In particular, these Regulations remove fees for applications relating to non-commercial performance studies.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Tel: 046 942 3100
r-phost: publications@opw.ie

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