



STATUTORY INSTRUMENTS.

S.I. No. 726 of 2022

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEE
FOR CLINICAL INVESTIGATIONS OF MEDICAL DEVICES)
(AMENDMENT) REGULATIONS 2022

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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 2017 and Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) (Amendment) Regulations 2022.

(2) The Principal Regulations and these Regulations may be cited together as the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021 to 2022.

2. These Regulations shall come into operation on 1st January 2023.

3. In these Regulations “Principal Regulations” means the European Union (National Research Ethics Committee for Clinical Investigations of Medical Devices) Regulations 2021 (S.I. 260 of 2021).

4. The following Regulation is substituted for Regulation 20 of the Principal Regulations:

“Fees

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

- (a) €1,500 in respect of each application under Regulation 8(1),
- (b) €300 in respect of each application under Regulation 8(2), and
- (c) €1,200 in respect of each appeal under Regulation 17 (which fee shall be refundable if the appeal is successful).

(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 €150,

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 3rd January, 2023.*

- (b) the fee payable under paragraph (1)(b) may be reduced to €50, and
- (c) the fee payable under paragraph (1)(c) may be reduced to €100.

(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.”.



GIVEN under my Official Seal,
23 December, 2022.

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 Committee for Clinical Investigations of Medical Devices) Regulations 2021.

These Regulations amend the amount of fess payable in respect of applications for National Research Ethics Committee (“National REC”) review of a clinical investigation to be conducted in the State or for a National REC review of a substantial modification of a clinical investigation and appeals in respect of such applications.

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