



STATUTORY INSTRUMENTS.

**S.I. No. 725 of 2022**

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EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES  
FOR PERFORMANCE STUDIES OF IN VITRO DIAGNOSTIC MEDICAL  
DEVICES) (AMENDMENT) REGULATIONS 2022

S.I. No. 725 of 2022

EUROPEAN UNION (NATIONAL RESEARCH ETHICS COMMITTEES  
FOR PERFORMANCE STUDIES OF IN VITRO DIAGNOSTIC MEDICAL  
DEVICES) (AMENDMENT) REGULATIONS 2022

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, as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022, hereby makes the following regulations:

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 2022.

2. These Regulations shall come into operation on 1<sup>st</sup> January 2023.

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 following Regulation is substituted for Regulation 35 of the Principal Regulations:

*“Fees*

35. (1) 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,
- (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) Where the National Office is satisfied that an application relates to a non-commercial performance study, at the discretion of the National Office—

- (a) the fee payable under paragraph (1)(a) may be reduced to €150,
- (b) the fee payable under paragraph (1)(b) may be reduced to €50, and

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

(c) the fee payable under paragraph (1)(c) may be reduced to €100”.

(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.”.



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 Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations 2022.

These amend the amount of fess 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.

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