



STATUTORY INSTRUMENTS.

S.I. No. 40 of 2022



EUROPEAN UNION (CLINICAL TRIALS ON MEDICINAL PRODUCTS
FOR HUMAN USE) REGULATIONS 2022

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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 (EC) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC¹, hereby makes the following regulations:

PART 1
GENERAL PROVISIONS

Citation

1. These Regulations may be cited as the European Union (Clinical Trials on Medicinal Products for Human Use) Regulations 2022.

Commencement

2. These Regulations shall come into operation on the 31st day of January 2022.

Application

3. (1) These Regulations apply to the authorisation and conduct of clinical trials.

(2) These Regulations shall not apply to non-interventional studies.

Interpretation

4. (1) In these Regulations—

“Advisory Committee for Human Medicines” means the committee established by section 9 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended;

“Assessment Report” has the meaning assigned to it in Article 6 of the Clinical Trials Regulation;

“Authority” means the Health Products Regulatory Authority established by section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended;

¹ OJ L 158, 27.05.2014, p.1

“Clinical Trials Regulation” means Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use;

“clinical study” has the same meaning as it has in the Clinical Trials Regulation;

“clinical trial” has the same meaning as it has in the Clinical Trials Regulation;

“Declaration of Helsinki” means the Declaration of Helsinki adopted by the General Assembly of the World Medical Association in June 1964, and as amended by the General Assembly of that Association from time to time;

“Directive” means Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

“ethics committee” means a committee established under Part 3 of the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (SI No. 41 of 2022) for the purposes of the Clinical Trials Regulation;

“EU database” means the database established under Article 81 of the Clinical Trials Regulation;

“EU portal” means the electronic portal established under Article 80 of the Clinical Trials Regulation;

“General Data Protection Regulation” means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC;

“incapacitated subject” has the same meaning as it has in the Clinical Trials Regulation;

“investigator” for the purposes of Article 49 of the Clinical Trials Regulation and these Regulations means –

- (a) a medical practitioner within the meaning of section 2 of the Medical Practitioners Act 2007 (No. 25 of 2007),
- (b) a visiting EEA practitioner within the meaning of section 2 of the Medical Practitioners Act 2007, or
- (c) a registered dentist within the meaning of section 2 of the Dentists Act 1985 (No. 9 of 1985);

“Joint Controllership Arrangement” means the arrangement agreed by the European Commission, European Medicines Agency, Member States, sponsors and marketing authorisation applicants or holders for the purpose of processing personal data captured in the EU portal;

“legally designated representative”, for the purposes of these Regulations and the Clinical Trials Regulation only, means—

- (a) in relation to an incapacitated subject who is, or is being considered as, a subject for a clinical trial—
 - (i) a person, other than a person connected with the conduct of the trial, who by virtue of his or her family or other personal relationship with the individual—
 - (aa) can provide the best interpretation of the will and preferences of the individual based on their knowledge of the individual,
 - (bb) is available and willing to act for that purpose, or
 - (ii) if there is no such person, the medical practitioner primarily responsible for the medical treatment provided to the individual where he or she—
 - (aa) can provide the best interpretation of the will and preferences of the individual based on their knowledge of the individual,
 - (bb) is not involved in the conduct of the trial,
 - (cc) is of the view that participation in the trial will not prejudice the health and wellbeing of the individual, and
 - (dd) is available and willing to act for that purpose, and
- (b) in relation to a minor who is, or is being considered as, a subject for a clinical trial, a guardian within the meaning of the Guardianship of Infants Act 1964 (No. 7 of 1964);

“legal representative” has the meaning assigned to it by Article 74 of the Clinical Trials Regulation;

“marketing authorisation” means an authorisation which is for the time being in force and which has been granted by the Authority under the Medicinal Products (Control of Placing on the Market) Regulations 2007 or by the Commission under Regulation (EC) No. 726/2004 and includes a marketing authorisation issued by the competent authority of an EEA State, other than the State, in accordance with Directive 2001/83/EC²;

“manufacturer’s authorisation” means an authorisation for the manufacture or import of investigational medicinal products or auxiliary medicinal products, which is for the time being in force and which has been granted by the Authority;

“Minister” means the Minister for Health;

“minor” means a person under the age of 16 years;

“National Office” has the meaning assigned to it by Regulation 5 of the European Union Clinical Trials on Medicinal Products for Human Use (National Research Ethics Committees) Regulations 2022 (S.I. No. 41 of 2022);

² OJ No. L 311, 28.11.2001, p. 67.

“National Research Ethics Committee” has the meaning assigned to it by Regulation 13 of the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (S.I. No. 41 of 2022);

“nominated ethics committee” means the National Research Ethics Committee nominated by the National Office to assess and provide an opinion on a specific clinical trial application, or substantial modification to a clinical trial granted authorisation, pursuant to the Clinical Trials Regulation;

“non-commercial sponsor” means a sponsor which has no commercial or financial interest in the outcome of the clinical trial;

“non-commercial clinical trial” means a clinical trial conducted by a non-commercial sponsor which fulfils the following characteristics:

- (a) the ownership of the investigation data belongs to the non-commercial sponsor from the inception of the clinical trial, and
- (b) the design, conduct, recruitment, recording of data and reporting of the results of the investigation remains under the control of the non-commercial sponsor;

“registered nurse” means a person registered in the Register of Nurses and Midwives established under section 46(1)(a) of the Nurses and Midwives Act 2011 (No. 41 of 2011);

“registered pharmacist” means a person registered in the Register of Pharmacists established under section 13(1) of the Pharmacy Act 2007 (No. 20 of 2007);

“Regulation (EC) No 726/2004” means regulations of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

“Regulation (EU) 2017/556” means Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for good clinical practice inspection procedures pursuant to the Clinical Trials Regulation;

“subject” has the same meaning as it has in the Clinical Trials Regulation;

“trial site” means a hospital, clinic, nursing home, health centre, surgery or other establishment or facility at or from which a clinical trial, or any part of such a trial, is conducted.

(2) A word or expression which is used in these Regulations and which is also used in the Clinical Trials Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Clinical Trials Regulation.

Roles of Authority, National Office and Nominated Ethics Committee

5. (1) Subject to paragraph (2)—

- (a) the role of Member State, pursuant to the Clinical Trials Regulation, shall be carried out by the Authority and the National Office in conjunction with the Nominated Ethics Committee, each of which—
 - (i) may communicate information when carrying out their respective functions under the Clinical Trials Regulation, and
 - (ii) shall keep such communications confidential,
- (b) where the State is the reporting Member State under the Clinical Trials Regulation, the Authority and the National Office in conjunction with the Nominated Ethics Committee shall co-ordinate in the review of applications for the conduct of clinical trials and applications for substantial modifications to clinical trials granted authorisation, and perform the functions ascribed to the reporting Member State under the Clinical Trials Regulation,
- (c) where the State is a Member State concerned under the Clinical Trials Regulation, the Authority and the National Office in conjunction with the Nominated Ethics Committee shall perform the functions ascribed to the Member State concerned under the Clinical Trials Regulation,
- (d) where the State is an additional Member State concerned pursuant to Article 14 of the Clinical Trials Regulation, the Authority and the National Office in conjunction with the Nominated Ethics Committee shall perform the functions ascribed to additional Member States concerned under the Clinical Trials Regulation, and
- (e) notifications to the EU portal envisaged at Article 80 of the Clinical Trials Regulation and submissions to the EU database envisaged at Article 81 thereof shall be made by either the Authority or the National Office, as appropriate.
- (f) the Authority shall—
 - (i) perform the scientific review referred to in Article 4 of the Regulation,
 - (ii) validate the application dossier in accordance with Chapters II and III of the Clinical Trials Regulation;
 - (iii) be the national contact point for the purposes of Article 83 of the Clinical Trials Regulation,
 - (iv) perform the inspections envisaged by Articles 63 and 78 of the Clinical Trials Regulation,
 - (v) collect the fees envisaged by Chapter XVI of the Clinical Trials Regulation,
 - (vi) be responsible for the enforcement of these Regulations and the prosecution of any offences, thereunder

- (g) the National Office, in conjunction with the Nominated Ethics Committee, shall—
 - (i) perform the ethical review referred to in Article 4 of the Clinical Trials Regulation,
 - (ii) validate the aspects covered by the Part II assessment, pursuant to Chapters II and III of the Clinical Trials Regulation.
- (h) the National Office shall have the additional functions described in the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022.
- (i) a National Research Ethics Committee shall have the additional functions described in the European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022.

(2) The Minister may publish guidelines as to the appropriate division of tasks prescribed by the Clinical Trials Regulation, between the Authority, the National Office and the nominated ethics committee, as appropriate.

PART 2

DETERMINATION OF ROLE AS REPORTING MEMBER STATE AND SCOPE OF APPLICATION

6. (1) Subject to paragraph (2), the Authority shall determine whether the State is willing to be the reporting Member State pursuant to Article 5(1) of the Clinical Trials Regulation, or not, and shall notify any decision to all Member States concerned through the EU Portal.

(2) Before making its determination under paragraph (1), the Authority shall consult with the National Office.

Determination on scope of application

7. The Authority shall assess whether the application for authorisation is within the scope of the Clinical Trials Regulation as envisaged by Article 5(3)(a) thereof.

PART 3
CONDUCT OF CLINICAL TRIALS

Conduct of clinical trials within the State

8. (1) Without prejudice to the Clinical Trials Regulation, in particular Articles 17 to 19, 21 to 23 and 47 thereof, a person shall not—

- (a) conduct a clinical trial,
- (b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor), or
- (c) perform the functions of the investigator of a clinical trial,

in the State, otherwise than in accordance with paragraph (2).

(2) The activities at paragraph 1(a) to (c) shall be conducted in accordance with—

- (a) the Clinical Trials Regulation,
- (b) these Regulations,
- (c) the Declaration of Helsinki,
- (d) the authorisation to conduct that clinical trial as notified to the sponsor through the EU portal,
- (e) any clinical trial protocol relating to a particular clinical trial,
- (f) any particulars or documents, other than the clinical trial protocol, accompanying a clinical trial application, as may be modified from time to time in accordance with Articles 17 to 23 of the Clinical Trials Regulation, and
- (g) the conditions and principles of good clinical practice.

Compliance with obligations where the sponsor is not established in European Union

9. Where a natural or legal person is established in the Union as the legal representative of a sponsor not established in the European Union in accordance with Article 74(1) of the Clinical Trials Regulation, that representative shall be responsible for ensuring compliance with the sponsor's obligations in the State, pursuant to the Clinical Trials Regulation and these Regulations.

Provision of medicinal products, including devices, to trial participants

10. (1) In accordance with Article 92 of the Clinical Trials Regulation, the sponsor of a clinical trial shall ensure that: -

- (a) the investigational medicinal products and the auxiliary medicinal products used in the clinical trial, and

- (b) any medical devices used for the administration of such products,

are made available free of charge.

(2) Paragraph (1) shall not apply to a non-commercial clinical trial that is conducted by a non-commercial sponsor, except in circumstances where the sponsor has obtained the products or devices referred to in paragraph (1) free of charge, in which case clinical trial subjects shall not bear any cost relating to such products or devices.

Damage compensation

11. A clinical trial shall not be authorised under these Regulations, or conducted in the State, unless there is in place a policy of insurance or indemnity scheme to provide compensation for any damage suffered by a subject resulting from participation in the clinical trial, which policy or scheme shall be appropriate to the nature and the extent of the risk.

PART 4

PROTECTION OF CLINICAL TRIAL SUBJECTS AND INFORMED CONSENT

12. (1) A clinical trial shall not be conducted in the State unless the conditions specified in Article 28 of the Clinical Trials Regulation are met.

(2) The requirements of Article 28 (1) (b) and (c), Article 31(1) (a) and (b), and Article 32(1)(a) and (b) of the Clinical Trials Regulation do not apply in the case of clinical trials in emergency situations, provided that the decision to include a subject in a trial is taken at the time of the first intervention on the subject, in accordance with the protocol for that clinical trial, and that the additional requirements of Article 35 are met.

13. (1) The provisions of Chapter V of the Clinical Trials Regulation shall apply to the giving and obtaining of informed consent for all clinical trials conducted in the State.

(2) The interview required to be conducted with the subject or his or her legally designated representative, in accordance with Article 29(2)(c) of the Clinical Trials Regulation, shall be conducted by the investigator or by –

- (a) a registered medical practitioner,
- (b) a registered dentist, or
- (c) a registered nurse

whose training, experience and qualifications have been assessed by the investigator and determined to be appropriate to qualify him or her to conduct the interview.

(3) In addition to the informed consent given by a guardian, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical trial.

14. A clinical trial shall not be conducted in the State unless there are adequate safeguards relating to the rights of trial subjects to physical and mental integrity, to privacy and to the protection of the data concerning them in accordance with the General Data Protection Regulation, the Data Protection Acts 1988 to 2018 and all laws of the State giving further effect to the General Data Protection Regulation.

15. Where a clinical trial is to be conducted exclusively in the State, an investigator or a person specified at Regulation 13(2) may obtain informed consent by the simplified means set out in Article 30(2) of the Clinical Trials Regulation, provided that all of the conditions set out in Article 30(3) of the Clinical Trials Regulation are fulfilled.

PART 5 ARCHIVING

Archiving

16. Without prejudice to the general obligations on sponsors and investigators under Article 58 of the Clinical Trials Regulation in relation to archiving, the clinical trial master file shall be archived in a manner which ensures that it can be made available for inspection by the Authority.

17. The medical files of trial subjects shall be retained for the maximum period of time permitted or required by the trial site.

PART 6 SUPERVISION AND CONTROL

18. The Authority and the National Office, in conjunction with the nominated ethics committee, shall supervise clinical trials authorised for conduct in the State and may communicate with each other in regard to same. All such communications shall be confidential.

19. The Authority is designated as the competent authority for inspections pursuant to Article 78 of the Clinical Trials Regulation and shall carry out the functions of the competent authority in that regard under this Regulation.

20. (1) Where the State is a Member State concerned and the Authority has justified grounds for considering that the requirements set out in the Clinical Trials Regulation are no longer met, the Authority may notify the sponsor and/or the investigator, forthwith or from a date specified in the notice of its intention to:

- (a) revoke the authorisation of a clinical trial;
- (b) suspend a clinical trial;
- (c) require the sponsor to modify any aspect of the clinical trial.

(2) Pursuant to Article 77(2) of the Clinical Trials Regulation, before the Authority takes any of the measures referred to in paragraph (1), it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion must be delivered within a period of seven days.

(3) The Authority may consult with:

- (i) the National Office, and/or
- (ii) the nominated ethics committee and/or
- (iii) other Member States concerned,

when considering whether the requirements set out in the Clinical Trials Regulation are no longer met before taking any of the measures referred to in paragraph (1).

PART 7

SAFETY REPORTING

21. (1) The Authority may consult with the National Office in accordance with Article 44 (3) of the Clinical Trials Regulation.

22. The Authority may, by notifying the sponsor, require him or her to send the records referred to in 41(3) of the Clinical Trials Regulation, or copies of such records, to the Authority.

PART 8

MANUFACTURING AND IMPORTATION OF MEDICINAL PRODUCTS USED IN CLINICAL TRIALS

23. The provisions of Chapters IX and X of the Clinical Trials Regulation shall apply to the manufacturing, importation, and labelling of investigational medicinal products and auxiliary medicinal products for use in clinical trials.

24. Commission Delegated Regulation (EU) 2017/1569 and the complementary detailed Commission guideline on good manufacturing

practice for investigational medicinal products, shall apply from the 31st of January 2022, the date on which the Clinical Trials Regulation applies.

25. (1) The requirement under Article 61(1) of the Clinical Trials Regulation shall not apply to the processes specified in Article 61(5) thereof, where those processes are carried out by or under the personal supervision of a registered pharmacist, a registered medical practitioner, or a registered dentist in hospitals, health centres or clinics, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the State.

PART 9

FEES

26. (1) In accordance with Article 86 of the Clinical Trials Regulation, the Authority may charge fees to a sponsor for activities set out in the Clinical Trials Regulation.

(2) The amount of the fee, or fees under paragraph (1) shall be—

- (a) reviewed on an annual basis by the Authority and the National Office and approved by the Minister, and
- (b) published on the websites of the Authority and the National Office.

(3) The fees under paragraph (1) shall be—

- (a) payable immediately upon submission of a clinical trial application through the EU portal in accordance with Article 5 and Article 14 of the Clinical Trials Regulation,
- (b) where applicable, payable immediately upon submission of a substantial modification through the EU portal in accordance with Article 16 of the Clinical Trials Regulation,
- (c) non-refundable once the clinical trial application has been validated in accordance with Article 5, Article 17 or Article 20 of the Clinical Trials Regulation.

PART 10

APPEALS

27. (1) A sponsor may, within 28 days of receipt of a decision, give notice to the Authority of his or her wish to submit an appeal pursuant to Article 8(4), 14(10), 19(2), 20(7), or 23(4) of the Clinical Trials Regulation.

(2) The Authority shall publish guidelines setting out the procedures applicable to appeals under paragraph (1).

PART 11
LANGUAGE

28. For clinical trials to be conducted in the State and for the purposes of Article 26 of the Clinical Trials Regulation, the

- (a) application dossier described under Article 25 of the Clinical Trials Regulation, and
 - (b) any documentation addressed to subjects,
- shall be in English

PART 12
OFFENCES, PENALTIES, AND ENFORCEMENT

Offences and penalties

29. (1) A person who -
- (a) commences a trial in the State without-
 - (i) notification of authorisation in accordance with Article 8 of the Clinical Trials Regulation, or
 - (ii) having in place a scheme to provide compensation for any damage suffered by a subject resulting from a clinical trial in accordance with Regulation 11,
 - (b) commences a substantial modification to a clinical trial without notification of authorisation in accordance with Articles 19, 20, and 23 of the Clinical Trials Regulation,
 - (c) conducts a clinical trial, other than in accordance with the requirements of Article 47 of the Clinical Trials Regulation,
 - (d) performs the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor) other than in accordance with the requirements of the Clinical Trials Regulation and Regulation 8(2),
 - (e) performs the functions of the investigator of a clinical trial, other than in accordance with the requirements of the Clinical Trials Regulation and Regulation 8(2),
 - (f) charges a fee to a subject of a clinical trial other than in accordance with Regulation 10,
 - (g) fails to maintain a trial master file in accordance with the requirements of Article 57 of the Clinical Trials Regulation,
 - (h) fails to meet their obligations in relation to archiving under Article 58 of the Clinical Trials Regulation,

- (i) fails to retain the medical files of subjects of clinical trials in accordance with Regulation 17,
- (j) fails to pay a fee due under Part 9,
- (k) fails to comply with the requirements for the manufacture and import of investigational medicinal products and auxiliary medicinal products in accordance with Part 8,
- (l) labels, sells or supplies a medicinal product or auxiliary medicinal product other than in accordance with Regulation 23,
- (m) sells or supplies an investigational medicinal product for the purposes of a clinical trial knowing or having reasonable cause to suspect that it was manufactured, labelled, packaged or imported in contravention of Regulation 23,
- (n) otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under these Regulations, is in possession of an investigational medicinal product knowing or having reasonable cause to suspect that it was imported in contravention of Regulation 23,
- (o) fails to comply with a notice of suspension or termination served under Regulation 20, unless same has been withdrawn or revoked by the Authority,
- (p) fails to comply with the requirements for notifications and submissions laid down in Article 34 and 35 of the Clinical Trials Regulation,
- (q) wilfully obstructs or interferes with the exercise of a power by an authorised officer pursuant to Regulation 34,
- (r) without reasonable excuse, fails to comply with any request made by an authorised officer under Regulation 34,
- (s) fails to comply with the provisions laid down in the Clinical Trials Regulation on the submission of information intended to be made publicly available to the EU database,
- (t) fails to comply with safety reporting requirements as laid down in Articles 41, 42 and 43 of the Clinical Trials Regulation,
- (u) fails to provide records requested by the Authority in accordance with Regulation 22,
- (v) fails to meet the requirements of Article 54 of the Clinical Trials Regulation in relation to Urgent Safety measures,
- (w) fails to establish a legal representative in accordance with Article 74 (1) of the Clinical Trials Regulation when required,
- (x) fails to meet the requirements of Part 4 of these Regulations in relation to the protection of clinical trial subjects and informed consent,
- (y) fails to meet the requirements of Regulation 14,

shall be guilty of an offence.

(2) The offences listed in paragraph (1) also apply to a legal representative of a sponsor responsible for ensuring compliance with the sponsor's obligations in the State pursuant to Article 74(1) of the Clinical Trials Regulation.

- (3) (a) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €3,000 or to imprisonment for a term not exceeding six months or both.
- (b) A person guilty of an offence under these Regulations shall be liable on conviction on indictment to a fine not exceeding €300,000 or to imprisonment for a term not exceeding 5 years or both.

(4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent, connivance or approval of or to have been attributable to the wilful neglect on the part of any person, being a director, manager, qualified person, secretary or other officer of the body corporate or a person who was purporting to act in any such capacity, that person, as well as the body corporate shall be guilty of an offence and shall be liable to be proceeded against and punished as if he or she was guilty of the first mentioned offence.

(5) Summary proceedings for an offence under these Regulations may be instituted from the date of the offence.

Separate contraventions

30. For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation of these Regulations.

Infringement notices

31. (1) If the Authority has objective grounds for considering that any person has contravened any provision to which this Regulation applies, it may serve upon that person a notice in writing (in these Regulations referred to as an "*infringement notice*") –

- (a) informing him or her of the Authority's grounds for considering that the person has contravened one or more of those provisions;
- (b) specifying the relevant provision of these Regulations;
- (c) specifying the measures which the person must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;
- (d) requiring the person to take those measures, within such period as may be specified in the notice;

- (e) warning the person that unless the requirements of subparagraph (d) are met, further action may be taken in respect of the contravention.

(2) An infringement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(3) If the Authority serves an infringement notice in accordance with paragraph (1), it shall forthwith inform the nominated ethics committee.

(4) This Regulation applies to Articles 35, 37, 41-43, and 54 of the Clinical Trials Regulation.

False or misleading information

32. (1) A person who in the course of-

- (a) submitting an application for authorisation to conduct a clinical trial;
- (b) giving notice of a substantial modification to the clinical trial;
- (c) submitting an application for the grant or variation of a manufacturing authorisation,
- (d) submitting information in relation to an appeal under Part 10 of these Regulations;

provides to the Authority, to a nominated ethics committee, to the National Office or to the Advisory Committee for Human Medicines any relevant information which is false or misleading in a material particular, shall be guilty of an offence.

(2) A person who –

- (a) is conducting a clinical trial authorised in accordance with these Regulations;
- (b) is a sponsor of such a clinical trial; or
- (c) while acting under arrangements made with a sponsor of such a clinical trial, performs the functions of that sponsor;
- (d) is engaged as a qualified person in accordance with Article 61 of the Clinical Trials Regulation;
- (e) holds a manufacturing authorisation.
- (f) is on the Article 61(5) Register

and who, for the purposes of these Regulations, provides to the Authority or to a nominated ethics committee or the National Office any relevant information which is false or misleading in a material particular, shall be guilty of an offence.

Defence of due diligence

33. In any proceedings for an offence under any of the preceding provisions of these Regulations, it shall be a good defence for a person charged to show that he or she reasonably believed that the said provisions had been complied with.

Enforcement

34. (1) The Chief Executive of the Authority may appoint such and so many officers as he or she thinks fit to be authorised officers for the purposes of the enforcement of these Regulations and the Clinical Trials Regulation.

- (2) (a) An authorised officer shall be furnished with a warrant of his or her appointment and when exercising a power conferred on him or her under this Regulation, he or she shall, if required by a person thereby affected, produce the warrant to that person for inspection.
- (b) Without prejudice to subparagraph (a), good clinical practice inspections may be carried out on any of the following occasions:
- (i) before, during or after the conduct of clinical trials;
 - (ii) as part of the verification of applications for a manufacturing or marketing authorisation;
 - (iii) as a follow-up to the granting of authorisation;
 - (iv) where services are provided for the support of clinical trials.

(3) Subject to paragraphs (4) and (5) an authorised officer may, for the purpose of ensuring that these Regulations are being complied with, carry out all or any of the following acts –

- (a) at all reasonable times, enter (if necessary, by the use of reasonable force) and search a premises of any class or description,
- (b) inspect any medicinal product, substance, article or product which is manufactured, processed, disposed of, stored, distributed, imported, exported, labelled, packaged, sold or supplied,
- (c) require the production of, inspect and, if he or she thinks fit, take copies of any book, invoice, order, record, register, or other document or of any entry in any such book, invoice, order, record, register, or other document at such premises,
- (d) inspect and copy or extract information from any data source (including personal data) within the meaning of the General Data Protection Regulation and the Data Protection Acts 1988 to 2018,

- (e) take (without payment) samples of any medicinal product or substance stored, or kept for supply at such premises for test, examination or analysis,
- (f) detain, and if necessary seize any medicinal product, substance or article,
- (g) take any document which he or she has reasonable cause to believe to be a document which may be required as evidence in proceedings under these Regulations,
- (h) inspect and take copies, or samples of, labels used, or intended to be used on an investigational medicinal product,
- (i) require any person carrying on, or who has carried on, an activity to which these Regulations relate, or any person currently or previously employed in connection with such an activity, to give to the authorised officer such information as the authorised officer may reasonably require for the purposes of these Regulations,
- (j) take photographs of premises and equipment,
- (k) contact the subject of a clinical trial directly, in accordance with Article 10(6) of Regulation (EU) 2017/556, and
- (l) ask any representative or member of staff of the inspected entity and any party involved in the clinical trial for explanations relating to the subject matter and purpose of the inspection and record the answer.

(4) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (10) authorising such entry.

(5) Any expert who accompanies an authorised officer may:

- (a) ask any representative or member of staff of the inspected entity and any party involved in the clinical trial for explanations relating to the subject matter and purpose of the inspection and record the answer,
- (b) review, record, and extract information from any data (including personal data) within the meaning of the General Data Protection Regulation and the Data Protection Acts 1988 to 2018.

(6) When exercising a power under this Regulation, an authorised officer may, subject to any warrant under paragraph (10), be accompanied by such number of:

- (a) other authorised officers,
- (b) inspectors from the competent authority of another Member State, or
- (c) persons with expertise relevant to the aspects being examined,

- (d) members of An Garda Síochána or Customs and Excise Officers,

as he or she considers appropriate in the circumstances of the case.

(7) The Authority shall ensure that confidentiality is respected by authorised officers and other experts engaged in inspections and, with regard to personal data, that the requirements of the General Data Protection Regulation and Data Protection Acts 1988 to 2018 are respected.

(8) An authorised officer, for the purpose of exercising any of the powers conferred on him or her by paragraph (3), may require any other person, having authority to do so, to break open any container or package or to permit him or her to do so.

(9) Where an authorised officer detains or seizes any medicinal product, substance, article or document in the exercise of a power conferred on him or her by paragraph (3), he or she shall inform the person from whom it is detained or seized.

(10) If a judge of the District Court is satisfied, on the sworn information of an authorised officer, that there are reasonable grounds to authorise entry into any premises referred to in paragraph (4), the judge may issue a warrant authorising such an authorised officer, accompanied, if appropriate, by other authorised officers or by a member or members of the Garda Síochána, or both, at any time or times within one month from the date of issue of the warrant, on production of the warrant if requested, to enter those premises or part thereof and to exercise any of the powers conferred on such an authorised officer under this Regulation.

(11) A person shall not wilfully obstruct or interfere with the exercise of a power by an authorised officer pursuant to this Regulation.

(12) A person shall not, without reasonable excuse, fail to comply with any request made by an authorised officer under this Regulation.

(13) Any material taken away by an authorised officer under this Regulation may be retained by him or her for use as evidence in any proceedings.

Prosecution of offences

35. Proceedings in relation to a summary offence under these Regulations may be brought and prosecuted by the Authority.

PART 13

JOINT CONTROLLERSHIP ARRANGEMENT

36. For the purposes of the Joint Controllership Arrangement, the Authority and the National Office shall be the State's joint controllers in relation to the processing of personal data captured in the EU portal.

PART 14
REVOCATIONS

Revocations

37. Subject to Regulation 39, the following are revoked:
- (a) European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004);
 - (b) European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2004 (S.I. No. 878 of 2004);
 - (c) European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006 (S.I. No. 374 of 2006);
 - (d) European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2009 (S.I. No. 1 of 2009).

PART 15
ENTRY INTO FORCE AND TRANSITIONAL ARRANGEMENTS

38. (1) These Regulations will come into operation on the 31st day of January 2022 and shall only apply to clinical trial applications submitted under the Clinical Trials Regulation.

Transitional arrangements

39. Notwithstanding the revocation, by Regulation 37, of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. 190 of 2004) -

- (a) those Regulations shall continue to apply until the 30th day of January 2025
 - (i) in respect of an application submitted in accordance with those Regulations before the 31st day of January 2022, and
 - (ii) in respect of an application made on or before the 31st day of January 2023, where the sponsor opted to make the application in accordance with those Regulations, and
- (b) a sponsor of a clinical trial that received a favourable opinion from an ethics committee recognised by the Minister in accordance with Part 2 of those Regulations and, in relation to which trial the Authority granted an authorisation, shall continue to comply with his or her reporting obligations under those Regulations until the 31st day of January 2025.



GIVEN under the Official Seal of the Minister for Health,
31 January, 2022.

MUIRIS O'CONNOR,

A person authorised under section 15 of the Ministers and
Secretaries Act 1924 to authenticate the seal of the Minister
for Health.

EXPLANATORY NOTE

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

These Regulations give further effect to Regulation (EC) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (“Clinical Trials Regulation”) which applied from the 31st of January 2022.

The Clinical Trials Regulation replaces and repeals Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

The Regulations provide that the Health Products Regulatory Authority will exercise the functions of the competent “Authority” for the purposes of the Clinical Trials Regulation and for the purposes of supervision and enforcement as required by the Regulations.

The National Office and National Research Ethics Committees, as provided for in the Clinical Trials Regulation, have been defined in separate Regulations, the European Union Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (S.I. No. 41 of 2022).

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