STATUTORY INSTRUMENTS

# 2004 No. 1031

# MEDICINES

## The Medicines for Human Use (Clinical Trials) Regulations 2004

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| *Made - - - -* | *31st March 2004* |
| *Laid before Parliament* | *1st April 2004* |
| *Coming into force* | *1st May 2004* |

## THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004

PART 3 — CONDITIONS WHICH APPLY IN RELATION TO AN ADULT ABLE TO CONSENT OR WHO HAS GIVEN CONSENT PRIOR TO THE ONSET OF INCAPACITY

1. The subject has had an interview with the investigator, or...
2. The subject has been informed of his right to withdraw...
3. The subject has given his informed consent to taking part...
4. The subject may, without being subject to any resulting detriment,...
5. The subject has been provided with a contact point where...

PART 4 — CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO A MINOR

1. Conditions
2. That person or legal representative has been provided with a...
3. That person or legal representative has been informed of the...
4. That person or legal representative has given his informed consent...
5. That person with parental responsibility or the legal representative may,...
6. The minor has received information according to his capacity of...
7. The explicit wish of a minor who is capable of...
8. No incentives or financial inducements are given—
9. The clinical trial relates directly to a clinical condition from...
10. Some direct benefit for the group of patients involved in...
11. The clinical trial is necessary to validate data obtained—
12. The corresponding scientific guidelines of the European Medicines Agency are...
13. Principles
14. The clinical trial has been designed to minimise pain, discomfort,...
15. The risk threshold and the degree of distress have to...
16. The interests of the patient always prevail over those of...

PART 5 — CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO AN INCAPACITATED ADULT

1. Conditions
2. The legal representative has been provided with a contact point...
3. The legal representative has been informed of the right to...
4. The legal representative has given his informed consent to the...
5. The legal representative may, without the subject being subject to...
6. The subject has received information according to his capacity of...
7. The explicit wish of a subject who is capable of...
8. No incentives or financial inducements are given to the subject...
9. There are grounds for expecting that administering the medicinal product...
10. The clinical trial is essential to validate data obtained—
11. The clinical trial relates directly to a life-threatening or debilitating...
12. Principles
13. The clinical trial has been designed to minimise pain, discomfort,...
14. The risk threshold and the degree of distress have to...
15. The interests of the patient always prevail over those of...

SCHEDULE 2 — ADDITIONAL PROVISIONS RELATING TO ETHICS COMMITTEES

1. In this Schedule— “appointing authority” means— in relation to an...
2. (1) The provisions of this Schedule shall not apply in...
3. Membership
4. A member of an ethics committee shall hold and vacate...
5. (1) The appointing authority shall appoint— (a) one of the...
6. (1) An ethics committee may— (a) appoint sub-committees consisting of...

**Status:**
Point in time view as at 02/12/2019.

**Changes to legislation:**
The Medicines for Human Use (Clinical Trials) Regulations 2004 is up to date with all changes known to be in force on or before 18 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.