Regulation Flowchart

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The Clinical Trial Regulations

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The Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031), as amended (The Clinical Trial Regulations)

The Medicines for Human Use (Clinical Trials) Regulations SI 2004 1031

The principal Regulations (the main statutory instrument) governing the conduct and management of clinical trials of investigational medicinal products (CTIMPs).

The Medicines for Human Use (Clinical Trials) Amendment Regulations SI 2006 1928

- Amended the wording of the GCP conditions and principles
- Clarified the sponsor can delegate functions but not responsibility
- Introduced the reporting of serious breaches of GCP/protocol
- Introduced Investigator Brochure update/validation requirements
- Introduced Trial Master File & archiving requirements (named individual).

The Medicines for Human Use (Clinical Trials) Amendment (No 2) Regulations SI 2006 2984 (.PDF)

Amended the requirements for consent in the emergency setting for incapacitated adults. Inclusion, prior to consent being obtained by a legal representative, is now possible under defined circumstances.

The Medicines for Human Use (Clinical Trials) and Blood & Safety Quality (Amendment) Regs. SI 2008 941 (.PDF)

Amended the requirements for consent in the emergency setting for minors. Inclusion, prior to consent being obtained by a parent or legal representative, is now possible under defined circumstances.

The Medicines for Human Use (Miscellaneous Amendments) Regulations SI 2009 1164

Amended the timelines for reporting urgent safety measures to competent authorities/ethics committees for pandemic trials. Urgent safety measures are now reported ‘as soon as possible’ instead of ‘within 3 day’ which is the requirement for all other CTIMPs.

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations (SI 2019 744)

Came into force on 1st January 2021 (exit day) to enable the MHRA to operate as a regulator outside the EU.