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

Orange Background: European Commission Directives **Blue Background:** The Clinical Trials Regulations

These statutory instruments are secondary legislation to the Medicines Act and have transposed the European Directives into UK law.

EC Clinical Trials Directive (2001/20/EC)	**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). A brief description has been published by the MHRA: www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con2022633.pdf
EC Clinical Trials Directive (2005/28/EC)	**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) • Sharing of information between ethics committees and the MHRA
Amendments to the UK legislations	**The Medicines for Human Use (Clinical Trials) Amendment (No 2) Regulations SI 2006 2984**	• 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) Regulations SI 2008 941	• 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 trials occurring during a pandemic period. • Urgent safety measures are now reported ‘as soon as possible’ instead of ‘within 3 days’ which is the requirement for all other periods.