

How to run clinical trials

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Objectives

The student will get a general understanding of

- What a clinical trial is
- GCP guidelines and EU directives
- Informed Consent
- How to recruit and keep patients
- Discuss case studies

Quick overview of clinical trials

In this section we will discuss what a clinical trial is, the types of clinical trials, the phases of clinical trials, reasons to do clinical trials and who is involved in trials.

Quick overview of GCP guidelines

We will do a brief overview of the basic principles of Good Clinical Practice and how they are implemented into clinical trials.

Quick overview of EU clinical trials directives

We will discuss the European directives and how they impact upon clinical trials.

- Two European Union Directives
- Purpose
- Overview
- What types of trials does it cover?

Overview of Informed Consent

We will overview the basic principles of the importance of Informed Consent and the practical implications.

- Informed Consent
- Principles
- Special considerations

How to recruit patients and keep study patients

We will discuss how you can find patients for studies and how to keep the patients in your studies.

Case studies

Recommended reading

Informed Consent

Royal College of Nurses (Nov 2006) Informed consent in health and social care research
RCN guidance for nurses [online] RCN publication London UK. Available from:
http://www.rcn.org.uk/_data/assets/pdf_file/0010/78607/002267.pdf

GCP guidelines

International Conference on Harmonisation (June 1996) International Conference on
Harmonisation of Technical Requirements for Registration of pharmaceuticals for Human
use. Guidance on good clinical practice E6 (R1) [online] Available from:
<http://www.ich.org/LOB/media/MEDIA482.pdf>

World Medical Association (1964) Declaration of Helsinki: Ethical Principles for Medical
Research Involving Human Subjects [online] Available from :
<http://www.wma.net/e/policy/pdf/17c.pdf>

The Nuremberg Code: Directives for Human Experimentation (1947)
[online] Available from: <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

Data protection

Editorial: Data protection, informed consent, and research *BMJ* 2004;328:1029-1030 (1 May)
[online] Available from: <http://www.bmj.com/cgi/content/full/328/7447/1029>

Audit and research

National Institute for Clinical Excellence (2002) Principles for Best Practice in
Clinical Audit [online] Radcliffe Medical Press Ltd, UK Available from:
<http://www.nice.org.uk/niceMedia/pdf/BestPracticeClinicalAudit.pdf>

Letters: Research discovers the right thing to do; audit ensures that it is done right *BMJ*
1997;315:1464 (29 November) [online] available from:
<http://bmj.bmjournals.com/cgi/content/full/315/7120/1464>

EU Directives

EU Clinical Trials Directive 2001/20/EC (April 2001)
[online] Available from:
<http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf>

EU Good Clinical Practice Directive 2005/28/EC (2005)
[online] Available from: http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf

European Parliament (2005)_Directive 95/46/EC of the European Parliament and of the
Council of 24 October 1995 on the protection of individuals with regard to the processing of
personal data and on the free movement of such data [online] Available from:
http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm