The UK Clinical Trials Regulations

An introduction to the regulations and guidelines that govern clinical trials in the UK

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DISCLAIMER

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The History Behind the UK Clinical Trials Law

The best way to understand what the UK Clinical Trials Regulations are and why we’ve seen them updated in recent years, is to take a step back and briefly study the historical events and core principles that form their foundation.

The Nuremberg Code (1947)

During the Second World War (1939 to 1945), the German Nazi’s performed many medical experiments on prisoners with a view to either ‘advancing science’ or aiding their soldiers in the battle.
Many of these experiments were terminal, none were in the best interests of those subjected to the experiments and none of the prisoners had a choice as to whether they would participate or not.

At the end of the Second World War some of the Nazi doctors who had performed human experiments were tried at a war crimes tribunal in Nuremburg. During the Nuremberg War Crime Trials, the ‘Nuremberg code’ was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype/foundation of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner (The Belmont Report).

The Declaration of Helsinki (1964)

The ethical principles set out in the Nuremberg Code have been further elaborated and clarified by the World Medical Association (WMA) through the document known as the ‘Declaration of Helsinki’, which has evolved since its inception in 1964 to its current form, which was published in 2008.

The Declaration of Helsinki is a very important document (in spite of recent controversies) because it provides the ethical foundation for ICH E6 (ICH GCP) (refer to Section 2.1 of ICH E6), the European Clinical Trial Directive (2001/20/EC) and GCP Directive (2005/28/EC) and national clinical research legislation. Everyone involved in clinical research should be encouraged to read this short document.

Thalidomide (1957-1961)

Thalidomide (alpha-phthalimido-glutarimide) was developed by the German firm Chemie Grunenthal as an anticonvulsant drug. Early trials showed it to be unsuitable for this purpose but indicated that it had sedative properties. Furthermore, it had one remarkable property: overdoses simply caused prolonged sleep, not death (Smithells & Newman, 1992).

In the mid-1950s there were no guidelines for the development, production and marketing of medicinal products, no uniform federal medicines act, and no licensing authority such as the present Federal Institute for Drugs and Medical Devices (BfArM), it was therefore possible to introduce thalidomide on the German market on 1st October 1957 without any governmental review of the documentation (The Thalidomide Tragedy – Grunenthal).

The drug was first marketed in Germany in 1957 under the name Contergan, and in the UK in April 1958 as Distaval. Later, compound preparations, which combined thalidomide with other drugs,
were marketed for a wide variety of indications: Asmaval for asthma, Tensival for hypertension, Valgraine for migraine, and so forth. The promotion of these products laid great stress on the safety of thalidomide, based on the remarkable property described above (Smithells & Newman, 1992).

Between 1958 and 1961, the drug thalidomide was used by expectant mothers to control the symptoms of morning sickness. Tragically, this led to many babies being born with often severe physical disabilities (Commons Hansard: Statement - Thalidomide survivors – 14th January 2010).

The suffering experienced by people who took thalidomide during the period from 1957 to 1961 is incalculable. The reported number of those harmed varies, but more recent scientific studies indicate that 10,000 people worldwide were affected (The Thalidomide Tragedy – Grunenthal).

The first European Community Pharmaceutical Directive (65/65/EEC) was issued in 1965. Much of the impetus behind Directive 65/65/EEC stemmed from a determination to prevent a recurrence of the thalidomide disaster in the early 1960. This experience,
which shook public health authorities and the general public, made it clear that to safeguard public health, no medicinal product must ever again be marketed without prior authorisation.


The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

The realisation that it was important to have an independent evaluation of medicinal products before they are allowed on the market was reached at different times in different regions. However in many cases the realisation was driven by tragedies, such as that with thalidomide in Europe in the 1960s (About the ICH).

For most countries, whether or not they had initiated product registration controls earlier, the 1960s and 1970s saw a rapid increase in laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new medicinal products. The industry, at the time, was becoming more international and seeking new global markets, however the divergence in technical requirements from country to country was such that industry found it necessary to duplicate many time-consuming and expensive test procedures, in order to market new products, internationally (About the ICH).

Harmonisation of regulatory requirements was pioneered by the European Community (EC), in the 1980s, as the EC (now the European Union) moved towards the development of a single market for pharmaceuticals. The success achieved in Europe demonstrated that harmonisation was feasible. At the same time there were bilateral discussions between Europe, Japan and the US on possibilities for harmonisation. It was, however, at the WHO Conference of Drug Regulatory Authorities (ICDRA), in Paris, in 1989, that specific plans for action began to materialise. Soon afterwards, the authorities approached IFPMA to discuss a joint regulatory-industry initiative on international harmonisation, and ICH was conceived (About the ICH).

ICH E6 (GCP) Guidelines
ICH E6: Guideline for Good Clinical Practice, also known as ‘ICH GCP’. This is very much the ‘Clinical Trials Bible’, the contents of which have been implemented into the European clinical trial quality standards through the Clinical Trials Directive (2001/20/EC) and the GCP Directive (2005/28/EC). The content of these Directives has in turn been transposed into national law by each of the Member States e.g., The Medicines for Human Use (Clinical Trials) Regulations of 2004 (SI 2004/1031) in the UK.

ICH E6 is split into 8 sections:

1. Glossary
2. Principles of ICH GCP
3. Ethics Committee functions and responsibilities
4. Investigator responsibilities
5. Sponsor responsibilities
6. Clinical trial protocol and amendments
7. The Investigator’s Brochure (IB)
8. Essential documents for the conduct of a clinical trial and the Trial Master File

Particular attention is drawn to the following areas which are primarily and solely dealt with in ICH E6:

- The Investigators Brochure (Section 7)
- The Clinical Trial Protocol (Section 6)
- Monitoring (Section 5.18)
- The Trial Master File (TMF) and Essential Documents (Section 8)
What is GCP?

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible (as per ICH GCP).

The Principles of ICH GCP

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

(Section 2 of ICH GCP)
European Directives

ICH GCP was published in 1996 and most of the principles embodied in this 'Good Clinical Practice' guidance were captured in 2001 in a European-wide Directive that aimed to harmonise the regulatory requirements for clinical trials - The Clinical Trials Directive (2001/20/EC).

The European Commission has a very useful webpage summarising the clinical trial requirements and the impact of the Clinical Trials Directive in Europe:


The Clinical Trials Directive (2001/20/EC)
The clinical Trials Directive (2001/20/EC) (the 'CT Directive') laid the foundation for the minimum requirements for clinical trials that had to be laid down in the national law of each of the countries within Europe by May 2004.

These requirements included:

- Protection of trial participants (prior informed consent and respect for data privacy)*
- Competent Authority approval (one per member state)
- Research Ethics Committee approval (one per member state)
- Authorisation required to manufacture or import investigational drugs
- Investigational Medicinal Products (IMPs) to be manufactured to quality standards (Good Manufacturing Practice), as defined in Annex 13 and 2003/94/EC
- Safety Reporting Requirements (Reporting of Urgent Safety Measures, adverse events, serious adverse events and suspected unexpected serious adverse reactions)
- The need to register the clinical trial (EudraCT)
- Amendment and end of trial notification requirements

*a requirement stipulated by the clinical trials directive is that no clinical trial can commence without the prior informed consent of the trial subject or their legal representative (Articles 3.2, Article 4 & Article 5). In the majority of circumstances this makes practical sense. However, once transposed into national law this did mean that research in emergency situations became challenging if not impossible. It wasn’t until 2006, through SI 2006/2984 and in 2008, through SI 2008/941, that we rectified this in the UK for incapacitated adults and minors, respectively.

It was unrealistic to expect all of the information needed to conduct a clinical trial be included in the CT Directive itself as this would have made the document very long and would have detracted from the succinct summary of the requirements that it provides. Instead the CT Directive has allowed for ‘detailed guidance’ documents to be drawn up for all of the key areas. These are published in Eudralex Volume 10 and include:

- The information to be submitted to the competent authorities and to the ethics committees
- The requirements on safety monitoring and the reporting of adverse reactions
- The requirements regarding Good Clinical Practice, including the documentation, of the clinical trials
The specific requirements regarding the products and the clinical trials

The inspections of competent authorities and the applicable procedures


The Clinical Trials Directive was supplemented, not amended - the distinction is important, by the GCP Directive (2005/28/EC), which added detail and provide clarification on certain aspects of the framework set down by the Clinical Trials Directive.

This GCP Directive lays down the following provisions to be applied to investigational medicinal products for human use:
(a) the principles of good clinical practice and detailed guidelines in line with those principles, as referred to in Article 1(3) of Directive 2001/20/EC, for the design, conduct and reporting of clinical trials on human subjects involving such products;
(b) the requirements for authorisation of the manufacture or importation of such products, as provided for in Article 13(1) of Directive 2001/20/EC;
(c) the detailed guidelines, provided for in Article 15(5) of Directive 2001/20/EC, on the documentation relating to clinical trials, archiving, qualifications of inspectors and inspection procedures.

The following list some excerpts from the GCP Directive...

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**Good Clinical Practice**

The rights, safety and well being of the trial subjects shall prevail over the interests of science and society.

Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks.

Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

The necessary procedures to secure the quality of every aspect of the trials shall be complied with.

The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

(Articles 2 & 3 of 2005/28/EC)
Good Clinical Practice

Clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996).

The protocol referred to in point (h) of Article 2 of Directive 2001/20/EC shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

(Articles 3, 4 & 5 of 2005/28/EC)

The Trial Master File (TMF) and Archiving

The documentation referred to Article 15(5) of Directive 2001/20/EC as the trial master file shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated. Those documents shall show whether the investigator and the sponsor have complied with the principles and guidelines of good clinical practice and with the applicable requirements and, in particular, with Annex I to Directive 2001/83/EC (Article 16 of 2005/28/EC)

The Clinical Trial Sponsor

A sponsor may delegate any or all of his trial-related functions to an individual, a company, an institution or an organisation.

However, in such cases, the sponsor shall remain responsible for ensuring that the conduct of the trials and the final data generated by those trials comply with Directive 2001/20/EC as well as this Directive.

The investigator and the sponsor may be the same person (Article 7 of 2005/28/EC)
The Investigator's Brochure (IB)

The investigator's brochure shall be validated and updated by the sponsor at least once a year (Article 8.3 of 2005/28/EC)

The Ethics Committee

The Ethics Committees shall, in every case, retain the essential documents relating to a clinical trial, as referred to in Article 15(5) of Directive 2001/20/EC, for at least three years after completion of that trial. They shall retain the documents for a longer period, where required under other applicable requirements (Article 6.2 of 2005/28/EC)
The Clinical Trials Directive (2001/20/EC) was transposed into UK law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), which have been amended 8 times since their enforcement in 2004 (see below).

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), are the ‘principal’ regulations and these are amended over time. What this means is that any amendments aren’t stand alone documents, they amend specific aspects of the principle regulations so they make no sense whatsoever if read in isolation. This is why we
always talk about the ‘Medicines form Human Use (Clinical Trials) Regulations 2004 (as amended)’.

Refer to the MHRA guidance: Clinical trials for medicines - implementation of the Clinical Trials Directive in the UK

http://www.mhra.gov.uk/Howwereregulate/Medicines/Licensingofmedicines/Clinicaltrials/Legislation/ImplementationofClinicalTrialsDirectiveintheUK/index.htm#5

Canary Limited provide a fantastic resource, it’s a consolidated version of all the UK clinical trials regulations and takes all the effort out of having to do it for yourself, which believe me isn’t as easy as you might imagine!
The UK Clinical Trial Regulations: indexed and consolidated
3rd edition
ISBN 978-1-903712-84-9


The book also has a useful subject index to help the reader find the appropriate sections.
The book also comes with a CD containing the official Statutory Instruments as PDFs.

Can be purchased from Canary Ltd
The Integrated Research Application (IRAS)

The Integrated Research Application System (IRAS):

• Is a single system for applying for the permissions and approvals for health and social care / community care research in the UK
• Enables you to enter the information about your project once instead of duplicating information in separate application forms
• Uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
• Helps you to meet regulatory and governance requirements
• Retains familiar aspects of the NRES form system
• IRAS captures the information needed for the relevant approvals from the following review bodies:
  • Administration of Radioactive Substances Advisory Committee (ARSAC)
  • Gene Therapy Advisory Committee (GTAC)
  • Medicines and Healthcare products Regulatory Agency (MHRA)
  • Ministry of Justice
  • NHS / HSC R&D offices
  • NRES/ NHS / HSC Research Ethics Committees

• National Information Governance Board (NIGB)
• National Offender Management Service (NOMS)
• Social Care Research Ethics Committee

UK Clinical Trials Competent Authority (MHRA)

Refer to: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/index.htm

National research Ethics Service (NRES)

For guidance on all aspects of the UK ethics committee requirements, refer to: http://www.nres.npsa.nhs.uk/

GCP Considerations
Conditions and Principles which apply to all Clinical Trials in the UK

The conditions and principles listed below apply to all clinical trials (as per Part 1.1 of Schedule 1 of SI 2004/1031 as amended)

Principles based on Articles 2 to 5 of the GCP Directive (2005/28/EC)

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.
2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.
3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.
6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.
7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.
8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.
9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.
**Conditions based on Article 3 of the Directive (2005/28/EC)**

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.

(Source: Part 2 of Schedule 1 of SI 2004/1031 as amended by SI 2006/1928)

**Informed Consent in Clinical Trials**

A person gives informed consent to take part, or that a subject is to take part, in a clinical trial only if his decision—

(a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and

(b) either—

(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.
This include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.

(Source: Part 1.3 of Schedule 1 of SI 2004/1031 as amended)
Amendments to the Medicines for Human Use (Clinical Trials) Regulations 2004

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

- Implements the GCP Directive (2005/28/EC) into UK law
- Additionally, requires the sponsor to notify the MHRA within 7 days of any occurrence of a serious breach of GCP or the protocol (Regulation 29A)

Enforces a form of ‘self-regulation’, which keeps trial Sponsors and Investigators ‘on their toes’!

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

Amends the principal regulations (SI 2004/1031) to allow incapacitated adults into a clinical trial without the prior consent of their legal representative assuming certain conditions are met

Amends Schedule 1, Part I of SI 2004/1031

Research in emergency situations is now once again possible!

Implements Section 4.8.15 of ICH GCP into UK law

“In emergency situation, when prior consent of the subject is not possible, the consent of the subjects legally acceptable representative, if present should be requested. When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the IRB/IIEC, to protect the rights, safety and well-being of the subject and to ensure compliance with the applicable regulatory requirements. The subject or the subject’s legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested”
SI 2008/941
The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

Amends the principal regulations (SI 2004/1031) to allow minors into a clinical trial without the prior consent of their legal representative assuming certain conditions are met.

Research in emergency situations is now once again possible!

Implements Section 4.8.15 of ICH GCP into UK law

“In emergency situation, when prior consent of the subject is not possible, the consent of the subjects legally acceptable representative, if present should be requested. When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with the applicable regulatory requirements. The subject or the subject’s legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.”

SI 2008/941
The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

Amends the principal regulations (SI 2004/1031)

Allows the Gene Therapy Advisory Committee (GTAC) to notify UKECA that its advice is not required for routine gene therapy trials and allows such applications to be transferred to another EC for an opinion.

(amends Regulation 15 of SI 2004/1031)

Modifies the procedures for operation of ethics committees (ECs) to widen the available expertise, reduce administrative burden and rationalise the documents an applicant must submit for an opinion.

( amends Regulation 15 and Schedules 2 & 3 of SI 2004/1031)

Amends the definition for “the Directive”, “Directive 2001/83/EC” and “the Gene Therapy Advisory Committee” (amends Regulation 2 of SI 2004/1031)
SI 2009/1164
The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009

Amends the principal regulations (SI 2004/1031)

Allows Urgent Safety Measures to be notified to the Ethics Committees and MHRA ‘as soon as possible’ rather than the usual restrictive 3 days during any period when a disease is pandemic and is a serious risk, or potentially a serious risk, to human health

(ammends Regulation 30 of SI 2004/1031)
Refer to the MHRA's website for further guidance on Advanced Therapy Medicinal Products:

http://www.mhra.gov.uk/Howweregulate/Advancedtherapymedicinalproducts/index.htm
Citing Statutory Instruments... the Statutory Instruments or ‘SIs’ are referenced by year of publication and ascend numerically i.e., each year they begin at 1. So the first SI of 2011 would be SI 2011/1. Therefore, when you cite the SIs you need to make sure you cite the year and number e.g., ‘SI 2004/1031’. Just citing ‘SI 1031’ is non-sensical.

For more information about Statutory Instruments refer to: http://www.parliament.uk/business/bills-and-legislation/secondary-legislation/statutory-instruments/
Which version of the Declaration of Helsinki should I use?

According to the harmonised edition of ‘Governance arrangements for research ethics committees’ (May 2011):

The latest version of the Declaration should normally be used, insofar as it is compatible with UK law. NB:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the October 1996 version.

Links are provided below to cited versions of the Declaration of Helsinki:

- 1989 version
- 1996 version (Clinical Trials Version!!)
- 2008 version
# References

All of the references listed below were last accessed on the 1st September 2011

## Global Clinical Trial-related References

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**GCP Considerations: Informed Consent**
Guidance on Informed Consent in Clinical Trials: UK (March 2011)

http://www.chcuk.co.uk/gcpinformedconsent.html
http://www.chcuk.co.uk/gcpicreport.html

**GCP Consideration: Regulatory Maps**
CHCUK 'Regulatory Maps' aim to provide the user with a pictorial overview of how the various regulations and guidelines fit together. Each map provides hyperlinks to all of the listed regulations and guidelines.

http://www.chcuk.co.uk/gcpmaps.html

**GCP Considerations: Investigators Brochure (IB)**
Questions are often raised by clinical study team members regarding the use of an Investigator's Brochure (IB), an IB supplemented by a Summary of Product Characteristics (SmPC), or an SmPC to support products that are already registered. This requires further elaboration and discussion in order to provide meaningful and specific guidance.

This short report was produced in response to such questions and provides Guidance on the purpose, design and management of an Investigator’s Brochure (IB) with particular emphasis on the UK requirements.

http://www.chcuk.co.uk/investigatorsbrochure.html
**GCP Considerations: Contraception**

We routinely include statements in the clinical trial protocol and patient information leaflet/subject information sheet about potential harm to the unborn child and the need for use of a ‘reliable form of contraception’ during the clinical trial, but what do we mean by a ‘reliable form of contraception’?

The following short report walks you through the recommended precautions when including men and women of child bearing potential in clinical trials, as well as a consideration of the recommended birth control methods.

[http://www.chcuk.co.uk/contraception.html](http://www.chcuk.co.uk/contraception.html)

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**GCP Considerations: Pharmacy GCP Checklist**

This checklist aims to provide R&D Departments and Pharmacy Clinical Trial Teams with a simple tool to assess the GCP compliance of the clinical trial/IMP management services provided by NHS Pharmacy Departments and focuses on the policies, procedures and operational aspects of these services with particular attention paid to compliance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) and the Department of Health Research Governance Framework for Health and Social Care (2005).

GCP Considerations: Useful Links

We are very fortunate to live in age when information is so abundantly and readily available. However, we increasingly find that we are faced with the challenge of sifting through this abundance to find the nuggets of useful and relevant information.

This document provides hyperlinks to many of the resources I have found useful whilst looking for GCP-related information and it is hoped that these resources will also be helpful to you.


A more up to date document (June 2011) can be found on the NIHR GCP Resources website. This document was created by CHCUK for the NIHR:


http://www.crncc.nihr.ac.uk/training/courses/gcp/gcp_resources
The Mengele Twins and Human Experimentation: A Personal Account
Eva Mozes-Kor

To look back at my childhood is to remember my experiences as a human guinea pig in the Birkenau laboratory of Dr. Joseph Mengele. To recount such painful memories is to relive the horrors of human experimentation, where people were used as merely objects or means to a scientific end. I envision the chimneys, the smell of burning flesh, the medical injections, the endless blood taking, the tests, the dead bodies all around us, the hunger, and the rats. Nothing that is close to human existence existed in that place.

I hope that what was done to me will never happen again to another human being. This is the reason I have told my painful story. Those who do research must be compelled to obey international law. Scientists should continue to do research. But if a human being is ever used in the experiments, the scientist must make a moral commitment never to violate a person’s human rights and dignity. The scientist must respect the wishes of the subjects. Every time scientists are involved in human experimentation, they should try to put themselves in the place of the subject and see how they would feel. The scientists of the world must remember that the research is being done for the sake of mankind and not for the sake of science; scientists must never detach themselves from the humans they serve. I hope with all my heart that our sad stories will in some way impel the international community to devise laws and rules to govern human experimentation. The dignity of all human beings must be respected, preserved and protected at all costs; life without dignity is mere existence. I experienced such loss of dignity every day as a guinea pig in Dr. Mengele’s laboratory. Forty-five years later, I still feel deep pain and anger for the way I was treated by the doctors. These same doctors had taken an oath to help and to save human life.

Read more of Eva’s personal account...

http://www.chcuk.co.uk/mengeletwins.html
http://www.candlesholocaustmuseum.org/
CHCUK provide bespoke GCP training for clients as well as providing a complimentary ‘GCP Refresher’ slide set that is available to download from our website:

http://www.chcuk.co.uk/2010-10-22_GCP%20Refresher.pdf

GCP Compliance Healthcheck

CHCUK provides process-related services which range from performing a GCP compliance gap analysis on your current procedures (SOPs), through to process engineering e.g., addressing identified gaps in your SOPs or QMS and/or developing new SOPs.

• What clinical research are you doing/planning to do?
• What are the applicable regulations and guidelines?
• What processes will you need/do you have in place?
• Do they match?

We have example gap analysis reports available on request (info@chcuk.co.uk)