The Joint Clinical Trials Office

A partnership for clinical research

Quality Policy

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Prepared by	Jackie Pullen, Quality Manager
Approved by	Medical Director KCH NHS Foundation Trust Medical Director GSTFT NHS Foundation Trust Vice Principal (Health Schools) KCL
Superseded documents	n/a
Related documents	ICH Topic E6, the ICH Note for Guidance on Good Clinical Practice 1996
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928 Research Governance Framework for Health & Social Care 2005 version 2

Change History			
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GLOSSARY

EU Clinical Trials Directives – 2001/20/EC issued on the 4th April 2004 to all EEA member states. The aims of the Directive is to protect the rights, safety and well being of trial participants, to simplify and harmonise the administrative provisions governing clinical trials and to establish transparent procedure that will harmonise trial conduct in the EU and ensure the credibility of results. Directive **2005/28/EC** issued on the 8th April 2005 lays down principles and detailed guidance for good clinical practice.

The Regulations - Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Good Clinical Practice (GCP) – Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects, ICH Topic E6, the ICH Note for Guidance on Good Clinical Practice is an international standard for GCP and became operational in the EU in January 1997.

The Joint Clinical Trials Office (JCTO) – was established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust to provide a streamlined approach for all aspects of trial administration.

Clinical Trial - A Clinical Trial means any investigation in human subjects, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one of more such products with the object of ascertaining the safety or efficacy of those products

Partner Organisations – King's College London, Guy's & St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust

Sponsor - The organization(s) who takes responsibility for the initiation, management and financing (or arranging the financing) of a medicinal clinical trial.

Standard Operating Procedures (SOPs) -, defined by the ICH GCP guideline as "detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the base on which Quality Systems and Processes are conducted and monitored against.

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INTRODUCTION

The EU Clinical Trials Directive was transposed into UK legislation as the Medicines for Human Use (Clinical Trial) Regulations 2004 (the Regulations) and subsequent Amended Regulations 2006.
The aim of these Regulations is to ensure that the rights, safety and well-being of clinical trial subjects are protected by requiring sponsors of trials to be responsible for designing, conducting, recording and reporting clinical trials according to internationally recognised principles of Good Clinical Practice (GCP).
The Regulations provide a statutory basis for:

- standardisation of procedures for ethical and competent authority consideration and authorisation
- GCP standards for commencing and conducting clinical trials
- Good Manufacturing Practice (GMP) standards for medicines used in clinical trials
- inspections against internationally accepted principles and standards of GCP and GMP, supported by enforcement powers.

The Partner Organisations all conduct clinical trials that fall within the above Regulations therefore a policy and systems are required to govern these trials to ensure compliance with the Regulations.

The JCTO, initially set up to oversee the management of commercial clinical trials across the three partner organisations; has now been allocated resource to set up a Quality Team to develop and implement this Policy and resulting quality systems and processes for all clinical trials conducted by the Partner Organisations.

OBJECTIVE

The JCTO Quality Policy describes the Quality system required to ensure that clinical trials conducted across the Partner Organisations fulfil the statutory requirements laid down in the current and any future clinical Trial Regulations.

The aim of the policy is to maintain a quality management process that not only meets the criteria of the Regulations, but also adds value to the Partner Organisations reputations as providers of high quality robust research.

SCOPE

All relevant clinical research activity conducted or managed by/at Kings College London, Guy's & St Thomas' NHS Foundation Trust and/or King's College Hospital NHS Foundation Trust will be bound by the terms of this policy.

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STANDARD OPERATING PROCEDURES

Clinical trials will be conducted according to approved Good Clinical Practice (GCP) compliant Standard Operating Procedures (SOPs). Trials sponsored by one or more of the Partner Organisations will adhere to the JCTO Standard Operating Procedures. These SOPs will cover all aspects of trial set up, conduct and management.

Trials sponsored by organisations other than the Partner Organisations may be conducted according to the individual trial SOPs as described in the trial protocol if available; however, if no Sponsor SOPs are available the trial will be conducted according to JCTO Standard Operating Procedures.

Training will be provided to staff involved in the conduct of clinical trials by the JCTO Quality Team. A training database will be held. All Clinical trials sponsored by one or more of the Partner Organisations will be monitored for GCP compliance and adherence to the JCTO SOPs using a risk based approach.

STANDARD OPERATING PROCEDURE APPROVAL

JCTO CT SOP1 – Production, Review and Approval of Standard Operating Procedures will be approved and reviewed by JCTO Board and signed by the Board Chairperson.

All subsequent SOPs will be reviewed by the R&D Directors of each Trust and College Vice Principal (Health Schools) and once the review process is complete will be approved by the Director of the JCTO.

POLICY DISSEMINATION

This Quality Policy will be actively disseminated to all triallists and interested parties and will be published on the JCTO website, GSTFT R&D and KCH R&D websites.

POLICY REVIEW

This policy will be reviewed annually or sooner if required.

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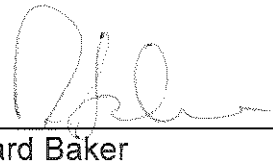
APPROVAL and SIGNATURES

Professor Robert Lechler
Vice Principal Health Schools,
King's College London

5.1.08
Date



Dr Edward Baker
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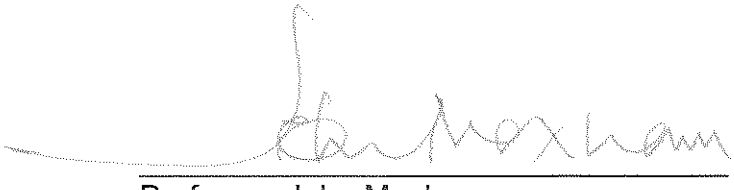
1/02/08
Date



Professor John Moxham
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14/2/08
Date