The University of Manchester

**The University of Manchester Clinical Trials Management Group**

**TERMS OF REFERENCE**

The Clinical Trials Management Group (CTMG) undertakes all sponsorship responsibilities to ensure the University meets its obligations to comply with the Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments) for regulated trials. The CTMG also oversees the fulfillment of the sponsor role for unregulated, high risk trials on behalf of the University of Manchester. The CTMG has the power to suspend and/or terminate a trial where it is deemed necessary and/or appropriate and reports up to the Research Compliance Committee (RCC).

## 1. SCOPE AND DUTIES

The CTMG is the ultimate authority empowered by the University of Manchester to decide if the University can or cannot sponsor a Clinical Trial of an Investigational Medicinal Product (CTIMP), and other high risk trials including device trials.

The primary roles of the CTMG are to ensure that:

(i) the rights, safety, dignity and well-being of subjects are protected and take priority over all other interests*

(ii) the data generated are reliable and robust.

The CTMG works (i) to ensure that the University meets its obligations and comply with The Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments) and (ii) to oversee all University-sponsored CTIMPs and other high risk trials.

The duties of the CTMG include but are not limited to the following:

I. To develop and oversee a suite of Standard Operating Procedures (SOPs) which serve as guidelines, and set minimum standards, for any study-specific SOPs.

II. To conduct and review risk assessments of proposed trials for sponsorship in order to:
   a. make, on behalf of the University, the decision whether to sponsor a trial;
   b. determine the suitability of proposed sponsorship arrangements;
   c. determine at the outset the frequency and type of monitoring and audit

III. To provide guidance to potential Chief Investigators on ways in which their protocol may be adapted to make it suitable for sponsorship; for example, by making appropriate arrangements with a Clinical Trials Unit (CTU) for monitoring

and pharmacovigilance.

IV. To ensure appropriate members have seen and signed off major documents including the protocol and delegation of responsibilities.

V. To review and approve the primary submission to the relevant competent authorities.

VI. To review protocol amendments prior to submission to the relevant competent authorities. The CTMG will consider whether any protocol amendments affect the contractual arrangements.

VII. To receive and review copies of the annual reports submitted to the funding body and competent authorities.

VIII. To receive and review study reports from Chief Investigators (the frequency of which will usually be every three months but this may vary per trial).

IX. To receive and review regular reports to and from Data Monitoring Committees (DMECs) (where present) and Trial Steering Committees (TSCs), or where there is no DMEC for the TSC to fulfill this role.

X. To approve the monitoring plan and audit schedule based on the sponsor risk assessment for each trial and to assess compliance.

## 2. MEMBERSHIP

The CTMG comprises the following membership:

Person Responsible for Clinical Trials (Chair)
Deputy Chair(s) with experience of running a CTIMP or Device trial
Head of the Contracts Team or deputy
PSS Senior Representative (FBMH) or deputy
Research Support Services Implementation Manager or delegate (FBMH Costings)
Head of Research Governance, Ethics and Integrity Team
Sponsor Pharmacist
Research Governance, Ethics and Integrity Officer (Clinical Trials)
Research Governance, Ethics and Integrity Assistant

Co-opted membership of the CTMG will include (but not limited to) representation from:
Manchester Academic Heath Science Centre CTU (MAHSC-CTU)
University Insurance Office
Records Management
IT
Costing/Finance
Statistician – Richard Emsley or delegate

In addition other co-opted members from other Faculties may also be invited if a trial from that Faculty is being considered for sponsorship or if there is an ongoing sponsored trial in that Faculty.

All members of CTMG are required to have up to date Good Clinical Practice (GCP) training.

## 3. ATTENDANCE AT MEETINGS

Meetings require 4 members to be present in order to be *quorate* .This must include a chair and a representative of the Research Governance, Ethics and Integrity Team. All other members will have the opportunity to comment.

## 4. FREQUENCY OF MEETINGS

Meetings will be held as required, but at least bi-monthly.

## 5. REPORTING

The CTMG will provide quarterly compliance reports to the University RCC meetings. Minutes of CTMG meetings will be retained by the Research Governance, Ethics and Integrity Team and will be circulated to all members of CTMG.

## 6. REVIEW OF TERMS OF REFERENCE

The Terms of Reference for CTMG will be reviewed annually and amended when necessary; all such changes will be version control and dated.

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* REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536