

University of Glasgow Sponsorship and Co-Sponsorship Arrangements with NHS Greater Glasgow & Clyde

Introduction

This document confirms the University of Glasgow's commitment to undertaking sponsorship or co-sponsorship with NHS GG&C for clinical activity and describes the circumstances under which this will occur.

Definitions

Sponsor: The organisation responsible for ensuring appropriate arrangements are in place for the governance, initiation, management and financing of clinical research projects. In this context, the term refers to projects that fall within the Scottish Executive's Research Governance Framework for Health and Community Care (2006).

Co-sponsorship: For projects that fall under the Medicines for Human Use (Clinical Trials) Act 2004 (as amended 2010), the University and NHSGG&C have signed a Memorandum of Understanding to agree to act as co-sponsors in specified non-commercial clinical trials of medicinal products for human use. Under the co-sponsorship arrangement one party may agree to perform certain elements of the study activity for which the other is responsible, this does not constitute a delegation of this responsibility.

Chief Investigator (CI): The person with overall responsibility for the running of a clinical research project, including development of the protocol.

Principal Investigator (PI): Where a study involves more than one research location, the PI is responsible for the running of the trial at their local site.

NHS Patient: For the purposes of this policy an NHS patient is anyone with an NHS diagnosed condition or illness whether they are recruited specifically through NHS clinics or not. Please note: this includes people who are recruited through association with NHS patients (relatives etc.) and/or if they are recruited via NHS facilities or NHS-based advertising.

Healthy Volunteer: For the purposes of this policy a healthy volunteer is anyone who is recruited for a research study without reference to a medical, illness or condition and without making use of NHS facilities.

1. Clinical Trials - Co-sponsorship

1.1 The University and NHS GG&C signed a Memorandum of Understanding (MoU) in August 2004 to the effect that they would co-sponsor non-commercial clinical trials where the **CI is substantively employed by the University of Glasgow**. This MoU sets out the respective responsibilities of each organisation under this arrangement.

In 2007 the University of Glasgow and NHS GG&C developed single and multi-site co-sponsorship agreements which must be put in place before a clinical trial can commence. These agreements clearly define the roles and responsibilities of the co-sponsors under the Medicines for Human Use Act (Clinical Trials) 2004 (as amended 2010).

1.2 The University of Glasgow may consider third party co-sponsorship of trials with NHS GG&C. Consideration is on a case by case basis following a detailed risk assessment of each trial by the Research Governance Manager. Sponsorship decisions of this nature lie ultimately with the

Head of the College of Medical, Veterinary and Life Sciences. A third party co-sponsorship agreement must be put in place before any third party CI trial can commence.

The University of Glasgow may consider international co-sponsorship of clinical trials with NHS GG&C in the European Union and other territories (excluding the USA and Canada).

In all cases appropriate insurance cover must be obtained, and be in place, before a trial can commence. In addition, all relevant contracts must in place before a trial can commence.

1.3 Insurance / Indemnity arrangements: The NHS provides cover for clinical negligence through its indemnity scheme (CNORIS). The University of Glasgow is responsible for ensuring indemnity is in place in respect of the actions of its employees, including insurance for risks associated with the protocol, where it is developed by University staff.

2. Clinical Research - Sponsorship under the Research Governance Framework

The Research Governance Framework encompasses all research that involves NHS staff, patients, their samples tissue or data. Within the University of Glasgow and NHS GG&C, this definition is key to determining which organisation should act as sponsor for a research study.

2.1 When the NHS will sponsor: Under most circumstances, the NHS will sponsor research that involves NHSGG&C patients (please note the definition of NHS patient above). This is in line with the duty of care for these individuals.

This definition includes:

- Studies that make use of data provided by the NHS regardless of where the work is undertaken, as the NHS retains responsibility for safe-guarding their patients,
- Studies involving people recruited outside the NHS due to a pre-existing medical illness or condition,
- Studies that are undertaken at NHS facilities including Clinical Research Facilities,
- Studies that involve tissue from NHS patients, including if it is processed at University facilities provided that it is returned to the NHS for further processing or disposal.

Confirmation of sponsorship: Where the NHS is sponsor, the research is assessed by an NHS Research Ethics Committee and approved via the NHS R&D Offices.

2.2 When the University will sponsor: The University of Glasgow will take on sponsorship for research where:

- Tissue is donated to the University by NHS patients and will not be returned to the NHS for further processing or disposal,
- The research involves healthy volunteers (see definition above),
- Recruitment does not involve NHS facilities or an association with NHS patients.

2.3 Insurance / Indemnity arrangements: The NHS provides cover for clinical negligence through its indemnity scheme (CNORIS). Where the University is sponsor, it will insure adequate insurance / indemnity is in place and that the protocol has been assessed for risk.

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