Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Indemnity and Sponsorship of research studies**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	24/08/11	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	21/08/2012	Periodic Review	Final v 3.0
Final v 3.0	06/10/2014	Periodic Review	Final v 4.0
Final v 4.0	01/12/2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the necessary arrangements that researchers must adhere to, to ensure that studies involving human subjects are appropriately sponsored and indemnified.

It specifies the arrangements between the University and the Belfast Health and Social Care (HSC) Trust regarding the sponsorship of research involving Trust patients and clients and who the authorised signatories are for the Clinical Trials of Investigational Medicinal Products and studies governed by the HSC Research Governance Framework.

2. Introduction

The Research Governance Framework for Health and Social Care, December 2006, and the Medicines for Human Use (Clinical Trials) Regulations 2004 require that research is sponsored. Through sponsorship the University is confirming that everything is ready for the research to begin:

- Taking responsibility for putting and keeping in place arrangements to initiate, manage and fund the study;
- Satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;
- Satisfying itself the study has ethical approval before it begins;
- For clinical trials involving medicines, seeking a clinical trial authorisation and making arrangements for investigational medicinal products;
- Satisfying itself that the arrangements are in place and maintained for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of Suspected Unexpected Serious Adverse Reactions.

Where the research involves patients, clients and/or staff and/or premises of Health and Social Care, the study must receive research governance approval from the relevant HSC Trust.

The University's Regulations for Research Involving Human Participants state that all studies involving human participants or their data, whether gaining research governance through the University or the Trust, must be recorded in the University's Human Subjects Research Database.

The purpose of indemnity is to provide legal protection in the event of an unforeseen adverse circumstance arising during the course of a research project.

3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

4. Responsibilities

4.1 Chief Investigator

The Chief Investigator (CI) is responsible for ensuring that the research has been through the appropriate research governance arrangements as specified in the University's Regulations relating to Research Involving Human Participants and, if necessary, with the host Health and Social Care (HSC) Trust.

He/she should discuss the study, at the earliest opportunity, with the University's Research Governance Team who will provide advice on the relevant research governance arrangements.

The CI must ensure that the study is logged onto the Human Subjects Database and that the correct level of risk is designated to the proposed research. The risk levels are detailed in the below table:

Risk	Descriptor
Level 1	Those projects which although involving human subjects are in no way associated with a medicinal purpose or do not involve issues such as alcohol and illicit drug use or higher risk sexual behaviour. Level 1 projects essentially involve research into, for example, behaviour, attitudes, rights and education issues. These projects do not include an intervention[1].
Level 2	Those projects that have more relevance to healthcare and include, for example, survey work on access to health care or issues, such as alcohol and illicit drug use or higher risk sexual behaviour. These projects do not include an intervention[1].
Level 3	These projects essentially involve research involving collecting data (including risk factor data) in human subjects and correlating this with, for example, health status, and advances in diagnostics. The projects do not involve altering treatment regimens or the standard of routine care that these individuals receive. These projects do not include an intervention[1].
Level 4	These studies generally either involve an intervention which has the aim of changing health status or behaviour or involve procedures that are generally more invasive in nature, but do not have the attributes/characteristics of Level 4b studies.
Level 4b	These studies involve Clinical trials of Investigational Medicinal Products or clinical trials into medical devices or involve procedures which aim to induce illness or other conditions (eg inflammation) in study subjects for the purpose of testing the efficacy of new treatment approaches.

[1]An intervention is classed as a change directly related to the study that may alter the research subject's health, physically or mentally and includes any potential to alter behaviour as a result of participation.

A desktop audit of the Human Subjects Database is conducted annually involving a randomly selected sample of studies. The database entry for each study is then reviewed by Senior Management and Academics from a range of disciplines across the University.

5. Procedure

5.1 Funding for Research

Where external funding is sought for a research study, the CI should liaise with the relevant Research Support Officer (RSO) for the School. It is at this early opportunity that an assessment is made as to whether the research involves human participants,

their data and/or the health service, and whether there are any pertinent ethical implications.

5.2 Research Governance

The researcher should provide the University's Research Governance Team with the protocol, any participant information sheets/consent forms, copies of the peer review, a copy of the CI's CV and other relevant CV's, and Good Clinical Practice training certificate, if appropriate. All studies with a level 4b insurance risk must be reviewed by the Clinical Trial Sponsorship Group (CTSG). The CTSG must approve all such studies before the University will assume the role of Sponsor. The research team must provide all documentation as requested and attend the group if required. In addition to sending the documentation to the RGO, the researcher should also approach, if necessary, the host Trust and comply with the research governance arrangements of that Trust.

The CI should ensure that the research is reviewed by an appropriate ethics committee for the research, as outlined in the University's Regulations for Research Involving Human Subjects.

5.3 Research Sponsor

The Research Governance Team will liaise with the Trust and negotiate the appropriate sponsorship arrangements and the division of same, when necessary. The Memorandum of Understanding for Research Governance between the University and Trust(s) will be applied on a case by case basis. For all CT-IMPs intentions to sponsor, and sponsorship agreements will be signed by the Director of Research and Enterprise or their nominee.

The CI will receive written notification of either full sponsorship by the Trust or University, or that the two organisations have entered into a co-sponsorship arrangement. In the event of a co-sponsorship agreement the CI will be required to sign the co-sponsorship agreement. All researchers must comply with the requirements of a co-sponsorship agreement.

Where the University is the sole sponsor, the CI will be advised of the same through a formal letter of sponsorship. This letter will outline the University's requirements of the CI to ensure that the necessary indemnity arrangements are in place.

5.4 Indemnity arrangements

All research must be appropriately insured prior to commencement. The current 'clinical trials' insurance policy provides for both Negligent and Non-Negligent Harm.

Negligent Harm: Any action or process that is held by a court to have caused harm as a result of lack of due diligence, lack of care, omission or duty or an act of carelessness towards a participant in a research study.

Non-negligent Harm: Circumstances where there is no specifically identified causative factor relating to the harm of a participant in a research project, but harm is likely, on the balance of probabilities, to have arisen from the participant taking part in the research.

There are certain exclusions within the 'clinical trials' insurance policy. These are highlighted to the CI when the research is being entered onto the Human Subjects Database, which is found under My Research on Queen's On-line.

5.5 Permission to Start

The study must not commence until the CI, or site PI, is in receipt of the appropriate permissions documentation from the University and/or other interested parties.

6. References

Medicines for Human Use (Clinical Trials) Regulations 2004 accessed October 2014): http://www.opsi.gov.uk/si/si2004/20041031.htm

Research Governance Framework for Health and Social Care, December 2006 (accessed October 2014): http://www.dhsspsni.gov.uk/research_governance_framework.pdf