Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Indemnity for Research

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Related SOPs	None		

Approved by (name & role)	Tanya Turgoose Research Coordinator	**Date: 29 Jul 14**	

Standard Operating Procedure

Indemnity for Research

This SOP has been produced in accordance with the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments, the Department of Health's Research Governance Framework 2005 and ICH GCP Guidelines. This SOP will outline the procedures regarding Clinical Trial Indemnity Cover for all research conducted within Sheffield Teaching Hospitals (STH) NHS Foundation Trust.

1. Background

The Medicines for Human Use (Clinical Trials) Regulations 2004 requires that there should be a sponsor for every clinical trial. According to ICH GCP the Sponsor is responsible for the ethical and legal aspects of the study and must ensure that there are sufficient funds in place to cover all claims that might be made against it arising from the trial. It is a legal requirement for clinical trials involving medicines that there should be insurance or indemnity to cover the liabilities of sponsors and investigators.

All research conducted within STH NHS FT must have a nominated Sponsor. STH is responsible for the activities of staff and therefore must determine and assess the risks associated with any research project. STH must ensure that adequate indemnity is in place before issuing NHS R&D approval. Indemnity must be declared as part of this process in the Ethics application to be granted Ethical approval.

2. Definitions

2.1 Indemnity

The provision of indemnity is the obligation to pay for any loss or damage that has been or might be incurred by an individual, in this case whilst participating in a research study. The party providing the form of indemnity should have adequate arrangements in place to cover any costs that may occur as a result of this indemnification.

2.2 Indemnity Arrangements for Negligent Harm

Indemnity in the NHS is provided nationally by the NHS Litigation Authority (NHSLA) and only covers negligent harm. If there is negligent harm during a study with NHS R&D approval, when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts and those conducting the study.

The NHSLA are a not-for-profit part of the NHS and manage negligence and other claims against the NHS in England on behalf of the member organisations (STH NHS FT is a member organisation). The NHSLA facilitate resolving disputes fairly and help improve safety for patients and staff.

2.3 Indemnity Arrangements for Non Negligent Harm

Non-negligent harm arises where an individual has been harmed in the context of research, through no fault of an individual or institution involved in the research and even though all the correct policies and procedures have been followed.

NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose. NHS bodies cannot give advance undertaking to pay compensation when there is no negligence attributable. It is the role of the REC to decide whether or not a study can go ahead without a scheme of compensation for harm caused where there is no negligence.

The agreements between research partners clarifying who holds the respective responsibilities for the research, as well as the patient information leaflets, should specify whether there are arrangements in place for non-negligent harm. Where there are no arrangements in place for non-negligent harm, or where such arrangements are limited to consideration of ex-gratia payments,

this should be clearly stated in the agreements between the research partners and in patient information leaflets.

2.4 Indemnity Arrangements for Commercially Sponsored Research

Commercial companies acting as sponsor of their own research are expected to hold adequate insurance cover to indemnify the research. For contract clinical research, STH expects standard Association of the British Pharmaceutical Industry (ABPI) (no fault) indemnity cover or equivalent (approved by the Research Ethics Committee) to be provided by the commercial company. Such cover should be for a minimum of £2 million in respect of any one occurrence or series of occurrences arising from one event.

2.5 Indemnity Arrangements for Medicinal Products in Research

The manufacturer retains strict product liability i.e. that the product is fit for purpose. The Research Department does not require a copy of this indemnity for project authorisation.

If the research is using a licensed drug outside the strict terms of the Marketing Authorisation following an investigator led protocol, the Research Department confirms that the investigator is covered by NHS and/or University indemnity arrangements.

2.6 Indemnity Arrangements for Medical Devices in Research

All medical devices to be used in research must be acceptance tested and approved by the STH Clinical Engineering Department prior to use. As part of the acceptance testing the STH Clinical Engineering Department will ensure that adequate indemnity and insurance arrangements are in place. The Research Department does not require a copy of this approval for project authorisation.

3. Procedure

3.1 The R&D Coordinator will identify who will indemnify the research using the Guidance on Indemnity requirements attached in Appendix 1:

3.1.1 If the sponsor is an NHS Trust, Research Ethics Committees do not require evidence of Indemnity and it is assumed that the Indemnity for the study is provided by NHSLA.

i. Where STH is sponsor of a clinical trial involving medicinal products (CTIMPs) led by a University employed Chief Investigator, additional professional negligence indemnity is obtained from the University. The R&D Coordinator, with support from the R&D Manager as applicable, will review the exclusion criteria in the University Insurance Policy to ensure appropriate indemnity is in place.

3.1.2 If the sponsor is a commercial company, the company provides an indemnity document in the standard Association of British Pharmaceutical Industry (ABPI) format. This is usually an appendix to the contract/clinical trial agreement (CTA). In the absence of this:

i. The Sponsor will take out appropriate insurance cover in respect of its potential liability and must provide a copy of the relevant clinical trials insurance certificate to the R&D Coordinator. Such cover should be for a minimum of £2 million in respect of any one occurrence or series of occurrences arising from one event.

ii. Where standard ABPI indemnity cannot be provided, the Research Department reviews the protocol specific risks to ensure the level of cover provided is adequate (and where appropriate liaises with the Legal and Corporate Governance office) to assess the exposure of the Trust and the investigators to litigation.
In cases of contractual or indemnification complexity the opinion of the Trust's lawyers is sought.

3.1.3 If the sponsor is a non-commercial institution other than an NHS Trust, e.g University, the sponsor ensures that adequate insurance cover is in place (ensuring any

exclusions or conditions are provided for) and provides a copy of the insurance certificate to the R&D Coordinator.

3.2 In the event of an injury or claim of injury:

3.2.1 The PI informs the patient that compensation can be sought and provides written details on how to claim by providing the STH leaflet “Tell Us what you think” available from the Patient Services Team.

3.2.2 At the earliest opportunity, the PI informs the Sponsor, employer and any other relevant party.

3.2.3 If the PI has a substantive or honorary contract with STH, the PI follows the STH process for incident reporting available via the intranet as soon as the potential incident occurs.

3.2.4 If the PI is also a University of Sheffield employee, the PI should also report the incident to University Finance Department, Research Office, Line Manager/Head of Department and Safety Services Department, as appropriate.

3.2.5 If the PI is also a Sheffield Hallam University employee, the PI should also report the incident to their Insurance Officer, Research Office and Line Manager/Head of Department.

3.2.6 The STH Legal and Corporate Governance Department deals with each claim on a case by case basis in conjunction with the NHSLA and any other parties involved i.e. University or Commercial Sponsor.

Appendix 1: Guidance on Indemnity Requirements

Table 1: Type of Indemnity

NHS indemnity	1	The research is carried out by a professional employed by the NHS body. The study may be designed by a local investigator or a third party e.g. commercial company or an investigator based at the university or other NHS body. NHS indemnity covers STH staff with substantive contracts and university staff who may be University employees with honorary contracts conducting the trial. It also covers those working on the study under their direct supervision.
	2	The STH Trust owes a duty of care to the person harmed during a clinical trial. This may be a patient, a healthy volunteer or STH staff.
	3	Proof of indemnity is required by the Research Ethics Committee for negligent harm.
University insurance	4	The research is carried out by a professional employed by the University. The study may be designed by a local investigator or a third party e.g. commercial company or an investigator based at the university or other NHS body.
	5	Non NHS work carried out on behalf of the University. This may include experimentation, research, trials and consultancy involving human subjects or volunteers not recruited by virtue of their status as NHS patients.
	6	Proof of indemnity is required by the Research Ethics Committee for negligent harm.
	7	Proof of indemnity is required by the Research Ethics Committee for non- negligent harm.
Commercial insurance and indemnity	8	A commercial sponsor contract outs the research which is to be carried out by a professional employed by an NHS body or University. The protocol is designed by the commercial sponsor and not the investigator.
Manufacturer Product Liability	9	The research is conducted using a drug (supplied with or without charge) following an investigator led protocol.
Product trials and loans of equipment or goods Indemnity	10	The research will use equipment supplied by a third party i.e. commercial company
	11	Indemnity is required to cover use of the equipment and is not related to clinical negligence of the PI or research team.
	12	The research will use equipment supplied by STH Medical Physics Department
Professional Indemnity	13	Indemnity cover is required for private practice or other work undertaken outside the NHS contract.
	14	Indemnity cover is required to provide assistance with GMC or disciplinary hearings or any criminal charges that result from clinical practice in the NHS

Please note that more than one type of indemnity may apply to your research.

Appendix 2

Associated Documents

	Document	Research Department Network Location	Website	Database	Created by
	NHS Indemnity : Arrangements for Clinical Negligence Claims in the NHS	N/A	http://www.nhsla.com/claims/Documents/NHS%20Indemnity.pdf	N/A	NHSLA
	University Insurance Policy	S:\General\Research Governance\Indemnity and Insurance\UoS	N/A	N/A	University

Appendix 3

SOP Revisions and History

SOP number	Effective date	Reason for change	Author
THIS SOP			
C104 v 2.6	29 July 14	Addition of review of University Insurance Policy Exclusion criteria for STH Sponsored CTIMPs led by University employed Chief Investigators	DP
PREVIOUS SOPs			
C104 v 2.5	23 July 2013		JB & TL
C104 v 2.4	05 July 2011		