Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Ghníomhaireacht um Éilimh ar an Stát
State Claims Agency

State Indemnity Guidance

SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions

a) Introduction

The purpose of this State Indemnity Guidance (SIG) is to set out the indemnity and insurance arrangements for clinical trials health research conducted between DSA[1] healthcare enterprises and academic institutions.

b) Scope

The scope of this SIG is limited to 'clinical trials' health research, as defined in the **HSE Framework for the Governance, Management and Support of Research**[2], conducted between DSA healthcare enterprises and academic institutions.

This SIG does not apply to other types of health research carried out in DSAs such as non-interventional research or research/studies carried out as part of a graduate, post graduate, masters or doctoral thesis.[3] The SCA can be contacted separately in respect of these studies.

c) What cover[4] do the SCA managed indemnity schemes provide for clinical trials health research?

The SCA operates two schemes:

Clinical Indemnity Scheme (CIS)
Covers personal injury[5] risks and subsequent claims/liabilities arising from the negligent act or omission associated with the provision of, or failure to provide professional medical services on the part of a DSA covered by the CIS e.g. medical malpractice.

General Indemnity Scheme (GIS)
Covers personal injury and third-party property damage risks and subsequent claims/liabilities arising from the negligent act or omission on the part of a DSA covered by the GIS. This indemnity is for organisational risks including: personal injuries and property damage claims by staff, patients (arising from the provision of non-medical services) visitors and contractors which were the result of a negligent act or omission on the part of the DSA. The indemnity provides for risks similar, but not identical, to those traditionally covered by employers' liability (EL), public liability (PL), and commercial motor insurance.

These schemes apply to DSAs who are conducting/ participating in clinical trials health research.

d) Do the State indemnity schemes apply to non DSAs such as academic institutions?

The schemes operated by the SCA are to indemnify DSAs for any negligent acts or omissions in respect of certain activities. This indemnity does not extend to the academic institutions or any other third party negligent acts. Academic institutions should have adequate insurance in place to cover these liability exposures - see also parts (j) and (k).

---

[1] **Delegated State Authority (DSA) -** refers to all bodies where management of claims is delegated to the SCA. It includes the HSE and organisations in the voluntary health and social care sector to which the Minister for Health has provided an indemnity in respect of certain claims.

[2] **Clinical Trial** - a clinical trial is a type of health research. The term Clinical Trials in the HSE Framework for the Governance, Management and Support of Research includes regulated and non-regulated trials as well as clinical investigations of medical devices. Regulated clinical trials or medical device investigations are those that fall under the remit of the Competent Authority. DSAs should consult the Health Products Regulatory Authority (HPRA) if in doubt whether the clinical trial is regulated or non-regulated.

[3] The SCA intend to publish further guidance on clinical studies other than a 'clinical trial'.

[4] Cover in context of this document is commercial insurance or indemnity provided by Indemnity Schemes operated by the State Claims Agency.

[5] **Personal Injury** - Personal injury includes any disease and any impairment of a person's physical or mental condition, including minor injuries (National Treasury Management Agency (Amendment) Act 2000). Exclusions are listed in various subsequent delegation orders.

e) What conditions must be met in order for CIS to indemnify clinical trials in a DSA?

Cover under the CIS will be provided once the following conditions are met:

- A DSA medical practitioner will serve as the Principal investigator (PI)[6]/Investigator[7] for the DSA research site(s) as indicated on the appropriate ethics documentation;
- The trial is approved by the relevant Ethics Committee(s);
- The Clinical Trial Indemnity Form[8] (CTIF) is completed and signed;
- The trial is governed under Irish law.
- Appropriate insurance covers are in place, see part (f);
- Formal approval or legal agreement has been obtained from the DSA Board/Chief Executive/HSE or authorised signatories;
- The trial complies with all requirements set out in the HSE National Framework for Governance, Management and Support of Research;
- There is an appropriately approved legal agreement in place for interventional studies. As a minimum, the Clinical Trial Agreement (CTA) must identify the sponsor, clarify roles and responsibilities, include the protocol, outline funding arrangements and include relevant indemnity and insurance clauses, Intellectual Property (IP), confidentiality and data processing and sharing agreements.

Where conditions cannot be met please contact the SCA.

f) Who provides cover for personal injury to a patient as a result of trial design and protocol design?

The sponsor retains overall responsibility for a trial design and protocol. In that regard, the sponsor should ensure their commercial insurance is adequate. See guidance in part (g).

g) What insurance cover is needed by the academic institutions/sponsors for clinical trials/research?

The CIS provides cover for personal injury to patient participant(s) in a clinical trial or research project resulting from a DSA negligent act arising from the provision of professional medical services. There are other risks to the academic institution/sponsors in the context of clinical trials health research that require separate cover. The following items are suggested areas that may need separate consideration, as relevant; however this list is not intended to be exhaustive and a commercial insurer/broker will advise further:

- **Sponsor/Clinical Trials Insurance** – cover under the CIS works on a legal liability basis only and does not extend to include **No Fault Compensation**. The sponsor should arrange Clinical Trials Insurance, with a Limit of Indemnity of no less than €6.5m in the annual aggregate or for the duration of the clinical trial. The following items also to be considered as part of this placement:
  - Personal Injury claims arising from the Protocol Liability. Be aware of insurer exclusions which may be relevant such as those relating to minors/pregnant women, genetic testing etc.;
  - Sponsor liabilities such as auditing, monitoring, scientific advisory boards need to be considered separately.
- **Products Liability** – it is recommended that product liability insurance be arranged with a limit of indemnity not less than €6.5m in the annual aggregate. SCA managed schemes do not provide cover for personal injury claims, which arise from defects in the product/device/item being trialled. This will need to be explored with a commercial insurer/third party product provider, as relevant;
- Other organisational insurances such as employers' liability, public liability, professional indemnity, cyber/data protection and property damage/business interruption – in respect of property owned by, or, in the care, custody or control of the academic institution;

All insurances must be provided by an insurer authorised to operate in the Republic of Ireland by the Central Bank of Ireland. The insurance territorial limits and jurisdiction clauses must include the Republic of Ireland.

[6] **Principal investigator** as defined in Regulation (EU) No. 536 of 2014 means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site.

[7] **Investigator** as defined in Regulation (EU) No. 536 of 2014 means an individual responsible for the conduct of a clinical trial at a clinical trial site.

[8] The CTIF is available on the SCA website – www.stateclaims.ie.

h) Does the CIS cover multi-site trials?

The CIS will apply to multi-site trials provided all the conditions required in (e) are in place. The CIS does not extend to sites outside of the Republic of Ireland.

i) Are Clinical Research Facilities/Centres (CRF/C) staff working on a clinical trial carried out in a CRF/C/DSA facility covered for clinical negligence under CIS?

Yes. CRF/Cs are part of the CIS, therefore CRF/C staff are covered for professional medical services provided the criterion in section (e) is met.

j) Are non CRF/C academic staff working on a clinical trial carried out in a CRF/C/DSA facility covered for clinical negligence under CIS?

Where there is a formal agreement (secondment or other) in place with a DSA for non CRF/C academic staff working on a trial and part (e) is met, CIS cover will apply.

k) Are academic/CRF/C staff covered by the GIS operated by the SCA?

No. Academic providers and the CRF/Cs must have appropriate insurance in place for employers and public liability risks.

l) Are DSA/CRF/C staff covered to carry out clinical trials health research in an academic or other third party setting?

Yes. DSA/CRF/C staff are indemnified by the CIS for clinical trials health research even where part of the research is conducted on other sites, provided the conditions of part (e) are in place.

m) What is the process for obtaining CIS approval for clinical trials?

Approval is through a self-assessment process by the sponsor/researcher and DSA to ensure that all criteria set out in this document are met. Appendix A should be used for this purpose. Where criteria are not fulfilled, please email a copy of the assessment along with the following documents to stateclaims@ntma.ie for review and approval:

- Clinical Trials Indemnity form (CTIF) completed and signed;
- Confirm Clinical Trial Agreement (CTA) is in place between the academic institution and the DSA and provide a copy of the agreement/approval from the hospital;
- Sponsor insurance – Clinical Trial Cover;
- Copy of Patient Information Leaflet (PIL) – providing background on the trial (note, this is for information purposes only).

n) What are the conditions of CIS cover?

All clinical trials health research must have the appropriate DSA approval and comply with all DSA terms and conditions where relevant. All incidents relating to the particular research must be reported to the SCA. This must be done via the National Incident Management System (NIMS), which the relevant DSA will have access to. Please refer to HSE Incident Management Framework for more details.

The SCA and/or its agents may, from time to time, audit/review compliance with the requirements of this guidance.

o) Further information

For further information in respect of clinical research please refer to the HSE National Framework for the Governance, Management and Support of Health Research.

p) When to contact the SCA?

The SCA is available to advise on issues that arise in respect of insurance and indemnity queries on health research. Please email stateclaims@ntma.ie.

Table1. Summary of cover responsibilities

Cover Responsibility			
Risk	DSA	Affiliated academic institution sponsor	Other sponsor
Personal injury risks and subsequent claims / liabilities arising from the negligent act or omission associated with the provision of, or failure to provide, professional medical services on the part of a DSA covered by the CIS	CIS[9]	No Fault Compensation insurance (if required)	
Personal injury to patient (negligence based claims) as a result of the trial design or protocol design	N/A	Full cover required	Full cover required
Clinical Trial Cover	N/A	€6.5m minimum in annual aggregate	
Product Liability	N/A	€6.5m minimum in annual aggregate (where appropriate)	
Employers and Public liability	GIS for DSA negligence	Commercial cover for employers and public liability as a result of academic institution and/or sponsor negligence	
Other insurance	As appropriate	As appropriate	

[9] Operates on a Legal liability basis; does not extend to No-Fault Compensation. This indemnity does not extend to academic institutions or any third party negligent acts and as such academic institutions must have adequate insurance in place to cover these liability exposures.

Appendix A: CIS Clinical Trial Self Approval Check Sheet

DSA name and contact details	**Name:** **Contact:**	
Sponsor name and contact details	**Name:** **Contact:**	
Academic institution name and contact details	**Name:** **Contact:**	
Principal Investigator name and organisation contact details and their status	**Name:** **Contact:** **Status: DSA Employee** ☐ **Joint DSA/academic institution employee**[10] ☐ **Academic institution appointee** ☐	
Details of study		
CIS Cover		
DSA Clinician is the PI for the DSA site and/or for multi-site trials	**Yes** ☐ **/ No** ☐	
Approval and agreement from DSA Board/Chief Executive/HSE or authorised signatories	**Yes** ☐ **/ No** ☐	
Appropriate legal agreement in place	**Yes** ☐ **/ No** ☐	
Ethics Committee(s) approval	**Yes** ☐ **/ No** ☐	
Signed Clinical Trial Indemnity Form in place	**Yes** ☐ **/ No** ☐	
Clinical Trial Insurance cover in place for sponsor Specifically ensure the following is checked and confirmed: • Policy date consistent with trial dates. • Scope of policy consistent with trial. • Includes protocol cover.	**Yes** ☐ **/ No** ☐	

[10] Where you are deemed a joint DSA/academic institution employee you must have a consultant/clinical post with the hospital in order to fulfill this requirement. Where DSA staff hold a dual affiliation, they must specify which organisation (i.e. the DSA or the academic institution they will represent).

• Exclusions reviewed and do not conflict with trial e.g. pregnant women, minor and genetic testing. • Minimum Limit of €6.5million in annual aggregate. • Territorial limit includes the Republic of Ireland. • Insurer is authorised to operate by Central Bank of Ireland.		
Product liability cover for products and devices (€6.5million in annual aggregate.)	**Yes ☐ / No ☐** **N/A ☐**	

Where criteria (green box) are not achieved, please email the following to stateclaims@ntma.ie for review:

- Self approval check sheet.
- Clinical Trials Indemnity form completed and signed (CTIF).
- The agreement in place between academic institute and the DSA.
- Sponsor insurance – Clinical Trial Cover.
- Copy of Patient Information Leaflet (PIL) – providing background on trial. For information purposes only, not for review by SCA.

Completed by_____ Date_____

The SCA reserve the right to request a copy of this form for any trial conducted where CIS cover applies. The requirements for CIS cover may change from time to time, please visit our website for the most up to date version of this assessment form.