GIS STATE INDEMNITY GUIDANCE 10: INDEMNITY AND INSURANCE ARRANGEMENTS FOR PATIENT FOCUSED CLINICAL RESEARCH BETWEEN DSA HEALTHCARE ENTERPRISES AND ACADEMIC INSTITUTIONS

a) Introduction

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

b) Scope

"Clinical trials", in this document, refers to patient focused interventional or observational studies, regulated and unregulated, involving Interventional Medicinal Products (IMP)s, medical devices[2] etc., which involve professional medical services[3]. This SIG does not apply to research/studies carried out as part of a graduate, post graduate, masters or doctoral thesis. The State Claims Agency (SCA) can be contacted separately in respect of these studies.

c) What cover[4] do the SCA managed indemnity schemes provide for clinical 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 CIS DSA i.e. 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 GIS DSA. 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 motor commercial insurance.

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

d) Do the State indemnity schemes apply to non DSA's 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 must have adequate insurance in place to cover these liability exposures - see also (j) and (k).

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

Clinical trial indemnity will be provided by the CIS once the following conditions are met:

- A DSA clinician will serve as the Chief Investigator[6] (CI) as indicated on the appropriate ethics approval.
- The trial is approved by the relevant Ethics Committee(s).
- The Clinical Trial Indemnity Form[7] (CTIF) is complete.
- The trial is governed under Irish national 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.

1 **Delegated State Authority (DSA) -** refers to all bodies delegated to the SCA, it includes the HSE Hospitals and Community Healthcare Organisations (including S38 Voluntary Hospitals and Disability Sector) and some S39s delegated to the CIS only.

2 Definitions available in the Corporate Enabling of Clinical Research (CECR) guidance documents available on the Clinical Research Development Ireland (CRDI) website.

3 **Professional Medical services** as defined in S.I. 628 of 2007 "services provided by registered medical practitioners or registered dentists of a diagnostic or palliative nature, or consisting of the provision of treatment, or the conduct of research in respect of any illness, disease, injury or other medical condition"

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 Act 2000. Exclusions are listed in various subsequent delegation orders.

6 **Chief investigator** as defined in S.I. 190 of 2004 means - a) in the case of a clinical trial conducted at a single trial site, the investigator for that site, or (b) in the case of a clinical trial conducted at more than one trial site, the authorised health care professional, whether or not he or she is an investigator at any particular site, who takes primary responsibility for the conduct of the trial.

7 The CTIF is located in the resources section of the SCA website stateclaims.ie

- There is an appropriately approved legal agreement in place for interventional studies. As a minimum, the CTA must identify the sponsor, clarify roles and responsibilities, include the protocol, outline funding arrangements and include relevant indemnity and insurance clauses, 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 negligent act during the provision of professional medical services. There are other risks to the academic institution/sponsors in the context of patient focused research that require separate cover. The following items are suggested areas that may need separate consideration, as relevant; however this list is in no way intended to be exhaustive and your commercial insurer/broker will advise further:

- Sponsor/Clinical Trials Insurance – CIS indemnity 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. 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 no 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 to 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 to include the Republic of Ireland.

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. 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[8], 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.

[8] Currently CRF/C's are awaiting formal Delegation by the Department of Health to the Clinical Indemnity Scheme.

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

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

m) What if the sponsor is a commercial or a non-affiliated academic institution?

CIS will apply in the same way to a commercial sponsor or a non-affiliated academic institution provided the conditions in part (e) and (g) are fulfilled.

n) How is CIS approval provided for clinical trials and research?

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 institute and the DSA for interventional studies. For other trials, 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, not for review by the SCA.

o) What are the conditions of CIS cover?

All clinical trials/research must have the appropriate DSA approval and comply with all DSA terms and conditions where relevant.

All incidents relating to clinical trials/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 any of the information outlined in this document.

Academic institutions should provide a yearly declaration to the SCA of all clinical trials/research carried out between academic institutions and DSAs.

p) Further information

Further information in respect of clinical research is available from the:

- HSE Research and Development Unit.
- Corporate Enabling of Clinical Research (CECR) guidance documents available on the Clinical Research Development Ireland (CRDI) website.

q) When to contact the SCA?

The SCA is available to advise on issues that arise in respect of insurance and indemnity queries on clinical trials.

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:**
Chief Investigator (CI) 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 CI for the 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 for interventional studies	☐ **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. • 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.	☐ **Yes** ☐ **No**	
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. Content 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.

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.