Standard Code of Practice for the HSE Research Governance, Management and Support Function – Insurance and Indemnity

Evaluation of insurance and indemnity arrangements

When conducting health research there is an obligation to ensure that the appropriate insurance / indemnity arrangements are in place.

The type of research dictates the indemnity and insurance requirements with the most comprehensive requirements for sponsored clinical trials and reduced requirements for non-interventional/observational studies. This guidance should be read in conjunction with the State Claims Agency's (SCA) guidance on indemnity for clinical research, which contains checklist(s) and guidance for each type of health research. www.stateclaims.ie

Indemnity

Indemnity is a protection against possible damage or loss, typically a promise of payment should damage, or loss occur. Where a third party is involved in health research there should be an agreement in place which contains an indemnity statement for all parties involved in the health research. Template health research agreements should be used where available and the SCA are available to advice on indemnity requirements which differ from the templates.

For Clinical Trials there is a Clinical Trial Indemnity Form (CTIF)[1] which is standardised pro-forma that must be signed by third parties to conduct clinical trials in locations covered by the SCA's indemnity schemes. This pro forma should not be edited.

Insurance

Insurance requirements ensure that all parties involved have the financial resources to respond to claims where they are found liable for negligent acts or omissions arising from their role in health research and the indemnity arrangements they have entered into.

For research in health and social care the typical insurance that may be required include the following -Professional Medical Indemnity Insurance, Clinical Trial Insurance, Product Liability, Employers Liability, Public Liability and Other. An explanation of each is included below

Professional Medical Indemnity Insurance

Medical Indemnity otherwise known as medical malpractice, provides protection against the risk of medical negligence exposure. Medical malpractice cover may include a failure to diagnose, incorrect techniques or incorrect medication/prescription.

[1] https://stateclaims.ie/learning-events/clinical-trial-indemnity-form

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Delegated State Authorities (DSA's) of the SCA are covered by the Clinical Indemnity Scheme (CIS). This applies to employees of the DSA, those on a contract of service[2] and where a formal agreement[3] is in place (secondment or other). All other persons/organisations will require commercial medical malpractice insurance which provides cover for the clinical risks associated with the type of research being undertaken.

Clinical Trial Insurance

Clinical Trial Insurance is insurance for a sponsor of a clinical trial. It provides Personal injury cover to patient (negligence based claims) as a result of the trial design or protocol design. It also includes No Fault Compensation cover.

In trials sponsored by third parties such as pharmaceutical companies or academic institutions, the sponsor retains overall responsibility for trial design/protocol and should arrange Clinical Trial Insurance.

Product Liability Insurance

Product liability insurance for all producers and sellers of goods (manufacturers, intermediaries or retailers) who may incur liability to their customers and others, for injury, illness, loss or damage arising from the supply of goods. Where a product is involved in health research, product liability insurance will be required.

The SCA schemes do not provide cover for personal injury claims, which arise from defects in the product/device/item being trialled.

Where a product is used 'off the shelf', under its marketing authorisation and under its intended use, indemnity is usually provided by the manufacturer. If used off label, not as per intended use or per manufacturer's instructions or the product does not have a marketing authorisation or is not appropriately CE marked then the sponsor should arrange appropriate product liability insurance.

Employers Liability and Public Liability Insurance

Employer's liability (EL) insurance covers the legal liability of an employer for bodily injury or disease sustained by an employee, and which arises out of and in the course of the employment. Public liability (PL) insurance protects an insured party in respect of its legal

[2] **Contract of service –**A contract of service is where the contractor is under the control and direction of the DSA e.g. agency nurses, temporary staff and contract IT staff. The DSA directs not only what to do but how to do it. Please see State Indemnity Guidance: Use of Contractors for further details.

[3] A **formal agreement** should be in place (through an agency/employer or directly with the person) outlining the roles and responsibilities of all involved e.g., work hours, duties, supervision, insurance and indemnity arrangements etc.

liability to third parties for bodily injury and for any loss or damage to property which happened in connection with the insured's business.

The General Indemnity Scheme (GIS) operated by the SCA 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 and persons covered by the scheme. 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 EL, PL, and commercial motor insurance. This indemnity does not extend to cover third party negligent acts.

Members of the research team not covered by the GIS will need to have appropriate employers' liability (EL) and public liability (PL) insurance in place.

Other insurances

There are other organisational insurances which research parties should have in place these include Professional indemnity; cyber/data protection and property damage/business interruption cover. Further details on HSE cover is available from HSE Finance where applicable. Third party sponsors may also be required to provide evidence of this cover.

Intervarsity Insurance Management Group

University College Cork, University of Limerick, National University of Ireland Galway, Dublin City University, Maynooth University and Trinity College Dublin are members of the Intervarsity Insurance Management Group (IIMG) and have commercial insurance policies for its activities including research. The four main policies - employer liability, public liability, motor and professional indemnity insurance. To confirm these insurance policies apply to university staff who wish to access other premises and property in connection with university approved research, staff should check their University's insurance guidelines or confer with the University's insurance officer. Other Universities or institutions may need to list or include premises/location or research study with their insurer and should be assessed on a case by case basis.

Indemnity/Insurance Review

A role of the RGMS Function is to ensure that the appropriate insurances/indemnities are in place before a research study commences and that they continue to be in place for the duration of the study.

Standard Code of Practice for the HSE Research Governance, Management and Support Function – Insurance and Indemnity

For academically sponsored Clinical Trials the self-approval checklist contained in SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research between DSA Healthcare Enterprises and Academic Institution[4] (Appendix 5:) should be completed by the Researcher.

Where criteria are not achieved, the following should be emailed 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.

For commercially sponsored Clinical Trials, or where a DSA requires clarity on indemnity or documents provided relating to health research involving third parties, AON Ireland can be contacted directly at SCAclinicalresearch@aon.ie the following should be included in the email;

- Ethics approval letter,
- HPRA approval
- Clinical Trial Indemnity Form,
- Sponsor Insurance Certificate
- The agreement proposed between Sponsor and the DSA

This is not an exhaustive list but common issues that should be checked before requesting SCA/AON review include:

- **Clinical Trial Indemnity Form (CTIF) -** No Sponsor signature, document not trial specific, legacy (superseded version) template used, changes made to CTIF other than insertion of Study Title, Sponsor, Hospital etc

- **Ethics Approval -** Trial title not matching other documentation, partial versus full approval submitted

- **HRPA Approval -** Trial title not matching other documentation

- **Sponsor Insurance Certificate -** Insurer not regulated by the Central Bank of Ireland, general inaccuracies including, document received not being an Insurance

[4] https://stateclaims.ie/uploads/banner/SIG-10-03-Indemnity-and-Insurance-Arrangements-for-Clinical-Trials-Health-Research-Interactive.pdf

Certificate, incorrect trial name on certificate, currency non-Euro, Sponsor name not in accordance with CTIF, policy out of date, limit of Indemnity less than minimum of €6.5m in the annual aggregate or not for the duration of the clinical trial.

- **Non DSA Principal Investigators -** Submissions for Principal Investigators conducting research in Private Hospitals or who are not DSA employees.
- **Non DSA Clinical Trial Sites -** Submissions for clinical trials in non DSA organisations, e.g. Private Hospitals.

For non-interventional Research involving DSA employees the conditions / requirements of cover under the CIS are not as extensive as those listed within in SIG 10

- Researcher is a DSA employee
- Research is conducted on DSA patients in a DSA
- Research Ethics Committee (REC) approval
- Research Site Approval (DSA management approval)
- Complies with the requirements of the RGMS Framework

There is no requirement to contact the State Claims Agency.