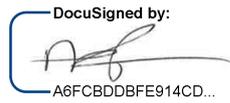


Research Governance Standard Operating Procedure 12 – Insurance

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1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found [on the Research Governance webpages](#).

Please see <https://www.bristol.ac.uk/research-enterprise-innovation/research-governance/SOPs/> for the latest version of this documentation. Printed copies are uncontrolled.

2. Background

In line with Principle 13 of the **UK Policy Framework for Health and Social Care Research**, it is a requirement of any organisation undertaking research with human participants that they hold appropriate insurance and indemnity “to cover liabilities which may arise in relation to the design, management and conduct of the research”. This protects both participants and the University by ensuring that in the event of a participant’s successful legal case for damages, the University can meet this obligation.

This SOP explains how the RGT member preparing a study for Sponsorship, reviewing a study for registration, or managing a study, can make sure appropriate insurance arrangements for the study are in place.

3. Scope

All Human Participant research should be covered by appropriate insurance. As per the flow chart below, the nature of the insurance involved and the extent to which researchers need to engage with the process will depend upon the nature of your research.

The University does not offer No Fault compensation as standard. In the unlikely circumstance that a funder or collaborator in a project requires this, it should be treated as an exception and discussed with the Insurance office.

University insurance policies do not cover Medical Malpractice. Where applicable, this should be covered by the clinicians or by their employer.

4. Responsibilities

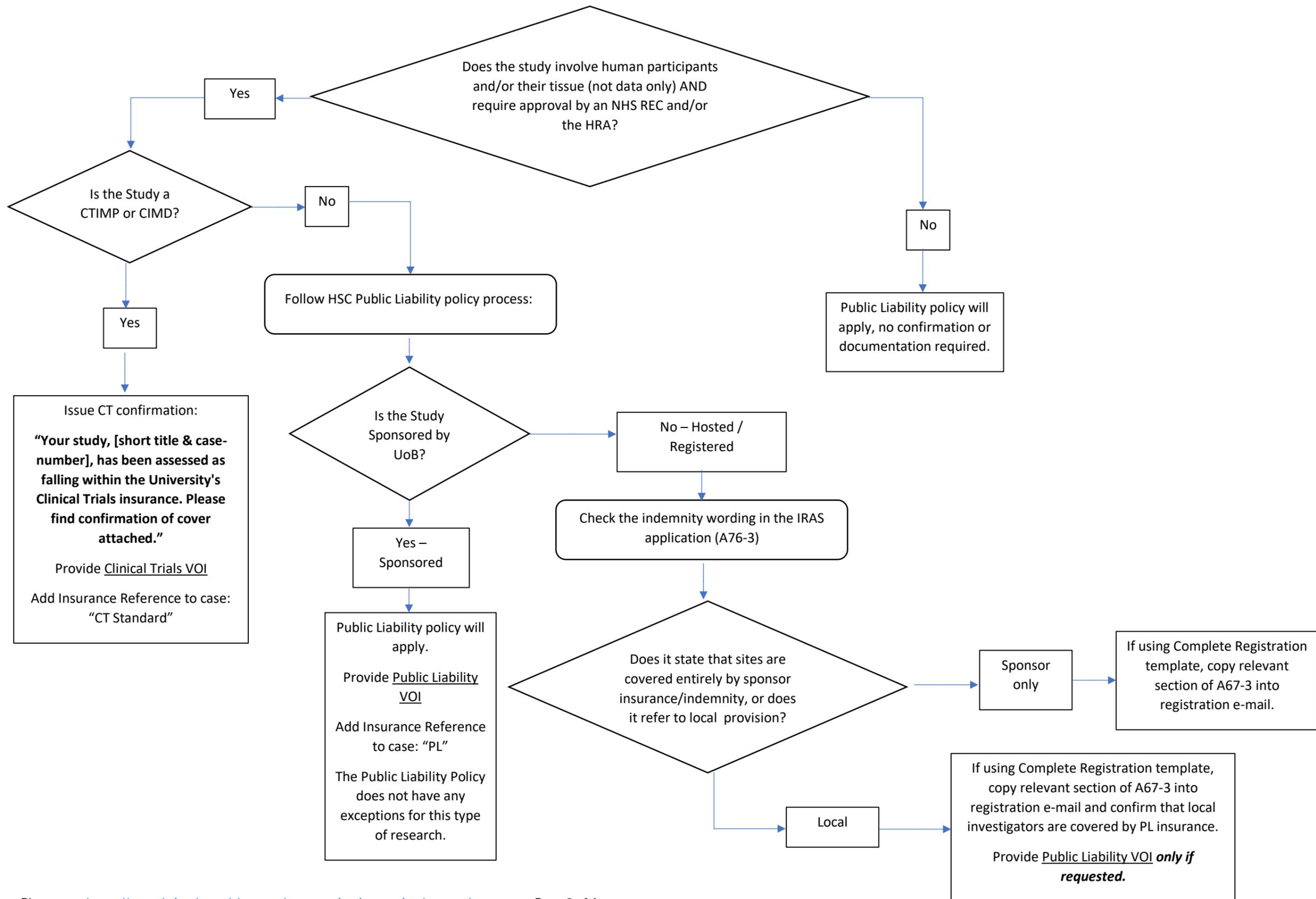
This SOP explains the role of the RGT member in determining, with the assistance of the University insurance office where necessary, what insurance or indemnity arrangements must be in place for a study to proceed. It explains moreover how they can provide appropriate certification during the study setup process, and where needed, reissue this on an annual basis as the policy renews.

5. Procedure

5.1 Determining appropriate insurance

In determining what insurance arrangements are required, the RGT member should use the below decision tree. Where there are any questions over the appropriate arrangements, the RGT member can consult with colleagues at the fortnightly NHS catch-up, with the HoRG, or with the University’s Insurance office.

Broadly speaking, studies require specific clinical trials insurance if they are a Sponsored CTIMP or CIMD, and are covered by the University’s public liability insurance otherwise. However the below explains in more detail which coverage is required, and certain exceptions to the above.



5.2 Annual renewal

Most studies are currently covered by the University’s Public Liability Insurance, which is renewed on an annual basis by the Secretary’s Office with no input from the Research Governance Team. However the annual renewal of Legal Liability for Clinical Trials Insurance does require information from the RHTMs for CTIMPs and CIMDs. The precise information needed should be discussed with the Secretary’s Office, but will include a list of current and proposed CTIMPs and CIMDs. This information should then be updated on a quarterly basis, again in discussion with the Secretary’s Office.

When confirmation of the updated Clinical Trials Insurance has been provided, the RHTMs for CTIMPs and CIMDs should pass these to the study teams for their records.

6. Related documents

Internal documents

PL VOI

Clinical trial VOI

External documents

[UK Policy Framework for Health and Social Care Research](#)