STANDARD OPERATING PROCEDURE 10

Insurance for Clinical Research Studies

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Contents

Revision Chronology:	Effective date:	Reason for change:
Version 4.0	2 January 2025	Interim review and update to align details with the latest clinical trials insurance policy.
Version 3.0	24 September 2024	Biennial review: Minor updates to text only.
Version 2.0	13 July 2022	Biennial review: Change to new format. Minor amends to text.
Version 1.6	23 April 2020	Biennial review: Change to new format. Minor updates to text for clarification.
Version 1.5	18 January 2018	Biennial review: Change to new format. Additional information regarding exclusions to the blanket policy updated. Minor updates to text.
Version 1.4	23 March 2015	Biennial review: Addition of Gerling trials policy referral list.
Version 1.3	18 February 2013	New criteria for clinical trials insurance referrals added following change in Insurer.
Version 1.2	20 February 2012	Minor text changes. Change to reporting procedure to the University's Insurance Office.
Biennial review February 2010		No Changes
Version 1.1	31st January 2008	Biennial review: Format change to comply with SOP 1. Change in procedure.
Version 1.0	March 2006	

STANDARD OPERATING PROCEDURE 10
Insurance for Clinical Research Studies

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to inform the Chief Investigator (CI) or their delegate of the procedures to be followed to obtain insurance for University of Warwick sponsored studies and studies managed by WCTU. It is applicable to any research team member who is involved in a research study where there is a requirement for the study sponsor to provide cover for legal liabilities (compensation), in the event of an injury to a study participant.

For externally sponsored studies, evidence of insurance cover should be obtained and filed in the Trial/Study Master File (T/SMF).

2. Definitions

Insurance	Insurance is a financial product sold by insurance companies to safeguard individuals, organisations and / or their property against the risk of personal injury, loss, damage, or theft claims (*this is not an exhaustive list*).

3. Background

For clinical studies involving Investigational Medicinal Products (IMPs) it is a legal requirement that there should be insurance or indemnity to cover the liabilities of sponsors and investigators.

In addition, the UK Policy Framework for Health & Social Care Research (2017) states that Universities engaged in research are responsible for ensuring that they are able to compensate anyone harmed as a result of negligence on the part of staff, students, and others for whom they have legal liability; and, if they have agreed to do so, to compensate participants for non-negligent harm arising from research.

ICH GCP section 5.8 states that 'if required by the applicable regulatory requirement(s), the Sponsor should provide insurance or should indemnify the investigator / the institution against claims arising from the trial.'

The University has arranged blanket cover for the vast majority of studies in Great Britain and Northern Ireland. Only a small minority of studies need to be referred to the insurers where upon insurance coverage will be considered on a case-by-case basis. It is important that WCTU provide full details of all current trials upon request and declare any potential claims, circumstances that could give rise to a claim (examples include complaints, data high risk data breaches, injuries etc.) or protocol breaches.

The University has also arranged professional indemnity insurance. Subject to policy terms and conditions this will provide cover to compensate a third party that has suffered financial loss (non-injury) due to any neglect error or omission; breach of warranty of authority; infringement of copyright or patent right or trademark or design rights or unauthorised use of systems or programs; breach of intellectual property rights; or libel and slander committed in good faith by the University. This would normally relate to a commercial contract for a service WCTU are providing for the benefit of the University of Warwick.

The University has additionally arranged public liability insurance to cover damage to third party property or injury on a negligence basis i.e., the University must be legally liable to pay compensation rather than non-fault. Patient and Public Involvement (PPI) representatives who advise study teams are also covered by the Universities Public Liability insurance policy.

For clinical studies outside Great Britain and Northern Ireland there may be an additional premium to be paid either to cover an endorsement to the existing policy or a new local policy in the territory where the clinical study takes place. This will depend on the insurance company involved, so early discussions on requirements are strongly recommended. The time to arrange additional insurance varies from country to country and the CI should bear this in mind when considering deadlines. Premiums for overseas insurance policies may have to be paid for locally. It is strongly recommended trials in the Indian sub-continent are avoided due the extreme difficultly arranging local insurance cover.

The University's Clinical Trials Policy covers no fault compensation subject to the policy's terms and conditions. Fault coverage is covered by the University's Public Liability Policy where the University of Warwick is legally liable to pay the claim. The policy will not cover the taking of blood samples or similar activities required for the trial. The NHS should carry out this function or if not possible the University of Warwick's Group Insurance Manager should be advised for insurance cover to be arranged through the Medical Malpractice policy.

4. Procedure

4.1 Responsibilities

Chief Investigator (CI) (or delegate)	• Ensure that insurance is in place for the duration of the study. • Ensure the Group Insurance Manager is kept informed of any extensions to the project to ensure cover is maintained • Inform the Group Insurance Manager of any potential claims arising from their study • If the study falls outside of the cover provided by the University's clinical trials insurance or the study will be sponsored by an external sponsor, the CI must arrange alternative arrangements to ensure adequate provision.
Sponsor	• Ensure adequate insurance provision is in place to cover the range of projects undertaken by their staff.
Quality Assurance (QA) Team	• Maintain the insurance spreadsheet to include details of current studies requiring insurance cover and provide copies on request to the Group Insurance Manager. • Report any ICO/reportable data breaches/other serious breaches to the Group Insurance Manager immediately. • Report changes to the study timelines (e.g., early study closure) to the Group Insurance Manager.
Group Insurance Manager	• Renewal of the annual Clinical Trials blanket insurance policy with support of WCTU as appropriate. • Receive and deal with any event reports which may lead to a claim.

4.2 When?

Most research projects are covered by the University of Warwick's clinical trials (CT) policy and the responsible person must contact the University's Insurance team in the Finance Office when any new study protocol is produced to arrange for appropriate cover. (For studies managed within WCTU, this can be facilitated via the QA team). The CT policy covers staff and individuals working with trial teams e.g. PPI representatives on oversight committees in connection with the University of Warwick's business activities.

Some studies may incur an extra insurance premium which must be funded from the study budget or by the academic department. If the funding body does not fund additional insurance costs, the research team should liaise with the Group Insurance Manager to confirm costs and identify from where these will be funded. Where this is the case, initial insurance enquiries should be made at the pre-award stage. Obtaining an insurance quote may take several months for certain countries e.g. Nepal and may involve the provision of detailed information on the study, so it is advisable to begin the process early. The Grants and Contracts Team in Research and Impact Services can assist with referrals at this early stage and advise on any exclusions or if additional premiums may be required.

4.3 How?

Insurance Services should be notified of all new studies (via: insuranceservices@warwick.ac.uk and r.campbell-kelly@warwick.ac.uk) as soon as possible after the grant has been awarded and a draft protocol is produced (for WCTU studies, this may be done by the CI, Trial Manager, SPM or QA). The Group Insurance Manager attends the Warwick Sponsorship and Oversight Committee meetings and reports back to the committee if additional premiums may be required.

Where the University of Warwick general clinical trials policy is adequate to cover a research study, the **annual certificate of insurance** (to be filed in the Trial/Study Master File (T/SMF)) can be downloaded via: https://warwick.ac.uk/services/finance/insurance/keypolicies/clinicaltrials/

The policy is renewed in August each year - follow the link above to ensure you have the current certificate filed

Any relevant correspondence should also be filed appropriately. Certificates of any additional policies or premiums should be filed once received from the Insurance Office. A note should be made of the expiry date (usually 31 July each year unless it is a standalone insurance policy) and the certificate for the upcoming year downloaded and filed for each year the study is active to demonstrate ongoing cover.

A study specific certificate to cover the full duration of a study may be requested. Contact Insurance services using: insuranceservices@warwick.ac.uk to request a certificate. A copy of the study protocol will need to be submitted along with the request and details of the start and end dates of the project.

For any studies requiring cover *not* routinely provided by the university's clinical trials insurance policy (e.g., for overseas projects), it is good practice to seek advice at the earliest opportunity. This will enable an assessment to be made as to whether the proposed activity is covered by an existing University insurance policy or if additional premiums or cover will be required. For studies applying

for University of Warwick Sponsorship which may require payment of additional premiums, written confirmation of this assessment should be requested from Insurance Services and provided to the Research Governance Team in Research & Impact Services (R&IS) via sponsorship@warwick.ac.uk .

For studies being sponsored by an external institution, the CI must ensure they are aware of, and comply with, the requirements of their sponsor organisation.

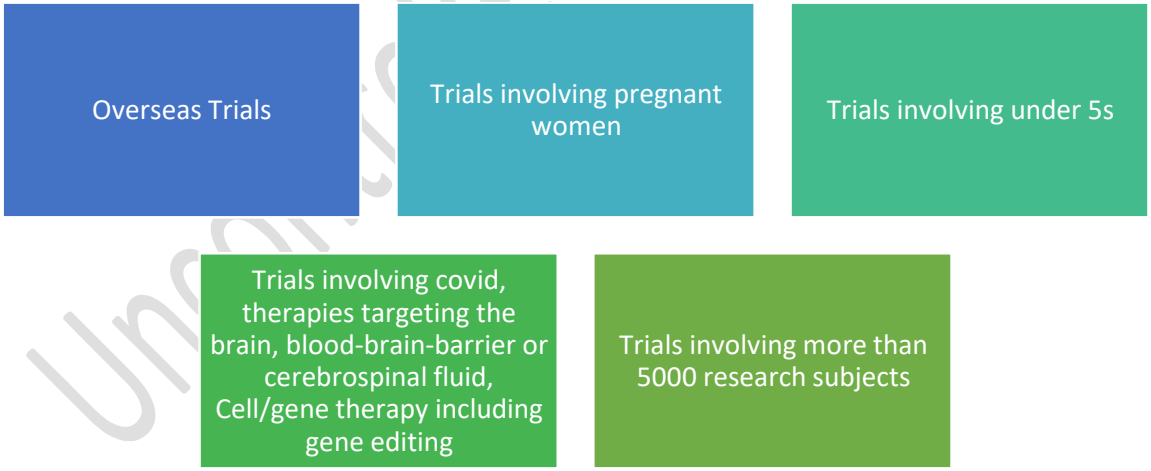
Each year a list of ongoing trials must be declared to the insurers for the main policy. Any new trials that start during the policy year (1 August to 31 July inclusive) must be included in the list. The end dates for each trial must be viewed monthly and if any need to be extended then the CI or delegate must liaise with the Group Insurance Manager for the insurer to be informed.

For trials that are insured separately and are for a period longer than 12 months the CI must budget for an annual cost for insurance cover.

For research studies being undertaken overseas a local insurance policy may need to be purchased in addition to the cover provided by the University of Warwick.

Please note that each country may have different insurance requirements and extra costs may be incurred in purchasing these policies and take into account that sufficient notice (likely to be several weeks) must be provided to allow the University's brokers adequate time to purchase such policies that may be required. On a rare occasion a country may be uninsurable therefore early contact with the Group Insurance Manager could save considerable time and effort.

Details of trials that are not automatically insured or may need payment of an additional premium are, but not necessarily limited to, the following:



The clinical trials insurance policy specifically excludes the following:

1. Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever named.

2. Hepatitis, Human T-Cell Lymphotropic Virus Type (HTLV) or Lymphadenopathy Associated Virus (LAV) or the mutants, derivatives or variations thereof or Acquired Immune Deficiency Syndrome (AIDS) or any syndrome or condition of a similar kind howsoever it may be named; Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD);

3. Liability arising prior to 1 August 2013.

List of abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
PPI	Patient & Public Involvement
QA	Quality Assurance
R&IS	Research and Impact Services
SOP	Standard Operating Procedure
SPM	Senior Project Manager
T/SMF	Trial/Study Master File
WCTU	Warwick Clinical Trials Unit