MANCHESTER 1824
The University of Manchester

Combined Professional Policy for Clinical Trials, Medical Malpractice and Professional Indemnity

Insurer: **Newline Group**

Policy Number: **B1262 FI1130519**

Policy Period: **1 June 2020 to 31 May 2021**

Section	Limits of Liability❖	Deductible✦
(1) Public liability – worldwide	£10m any one occurrence	£5k each and every occurrence
(2) Product liability – worldwide excluding USA / Canada	£10m any one claim and in aggregate	£5k each and every claim
(3) Legal liability for human clinical trials – worldwide	£10m any one claim and in aggregate	£5k / US$25k each and every claim
(4) 'No fault' compensation for human clinical trials – worldwide excluding USA / Canada	£10m any one claim and in aggregate	£5k each and every claim
(5) Errors and Omissions (Professional Indemnity) – worldwide	£10m any one claim and in aggregate	£10k / US$25k each and every claim
(6) Medical Malpractice liability – worldwide excluding USA / Canada	£10m any one claim and in aggregate	£10k each and every claim
Sections 2 to 6 combined	£10m in aggregate	

❖ The Limits of Liability are inclusive of the Deductible, interest and claimants' costs and expenses.
✦ The Deductible shall be eroded by any payment of Legal Costs.
Aggregate – the total the Insurers will pay for all covered losses sustained during the policy period.

Cover Specifications for Clinical Trials Section

The Clinical Trials section covers research projects which are sponsored, managed, designed or conducted by, or on behalf of, the University (including research undertaken by students under appropriate supervision) subject to approval by an appropriate ethics committee, and approval of any contract terms by the University's Contracts Office.

The policy provides cover for research involving human subjects via one of the following sections:

I. **No Fault Compensation for Human Clinical Trials** provides no-fault compensation in the case of harm to participants in research involving human subjects.

II. **Legal Liability for Human Clinical Trials** provides liability-only cover for injury or loss for which the University is legally liable, excluding investigations conducted on any person for a medicinal purpose.

The term 'medicinal purpose', under the insurance cover, is taken to mean:

- treating or preventing disease
- diagnosing disease ascertaining the existence, degree of, or extent of a physiological or psychological condition
- assisting with or altering in any way the process of conception or investigating or participating in methods of contraception
- inducing anaesthesia
- otherwise preventing or interfering with the normal operation of a physiological or psychological function in order to improve health or wellbeing
- testing medicinal products or devices
- taking tissue or blood samples

Conditions

Under the Insurance Act 2015, the University is required to provide all known expected facts on the risk in question to the Insurers. The policy specifically requires the University to notify the Insurers of any Clinical Trial which is conducted outside the UK, involves pregnant women or children under the age of 5, or has participants of 5000 or more, in advance of being undertaken.

The Clinical Trials Unit (CTU), Research Ethics and Governance Office and Faculty Research Office must keep good records of all research applications and approved projects. Such records must be submitted to the Insurance Office annually for insurance renewal purposes.

Exclusions (not exhaustive)

The policy does not provide cover on the following:

- **Birth Defects –** any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way directly or in-directly involving and/or related to birth defects.
- **Foetal Injury –** any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of, in connection with or in any way involving any injury or death to any foetus.
- **Inefficacy –** any liability, claim, loss, costs or expenses arising out of, caused by, resulting from, in consequence of failure of a drug or product under Trial to perform its intended purpose.
- **Criminal Act** – any act or omission which constitutes a criminal offence
- **No Written Consent** – except in Emergency Research✦, any Human Clinical Trial performed without the informed written consent of each research subject obtained prior to the participation of such research subject(s) in such human clinical trial
- **Breach of Protocol** – any act, error or omission which constitutes or involves a breach of, or failure to comply with, the terms of protocol governing the Human Clinical Trial
- **Non-Disclosure** – any circumstances which the PI was, or ought to have been, aware might give rise to a Claim prior to the inception of the policy.
- any act, error, omission, event, occurrence or Human Clinical Trial happening prior to the retroactive date of the policy
- any advice, design, specification or professional services provided for a fee (or provided in circumstances where a fee could normally be charged)

Extension

The policy extends its cover for Emergency Research✦. In certain emergency situations where research subjects lack the ability or capacity to give informed written consent, and consent from a legal representative / consulting others is not reasonably practicable, the law allows such research subjects to be recruited into Human Clinical Trial.

Providing that Health Research Authority (HRA) specific guidance is followed, exclusion is not applicable in the following cases where:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by an appropriate Research Ethics Committee;
- Consent is sought from a person with parental responsibility / legal representative as soon as reasonable practicable.

If a research subject recruited in such a manner regains the capacity or ability to give consent, written informed consent should be obtained at the earliest appropriate opportunity thereafter.

Additional Insurance Requirement

1 Research undertaken in the United Kingdom

Automatic cover is provided for research undertaken in the United Kingdom that is relatively low risk, and no additional insurance is required.

However, higher-risk projects (see Appendix A) are required to be reviewed by the Insurers on an individual basis and additional approval is required before cover is confirmed.

2 Research undertaken Outside the United Kingdom

Research undertaken wholly or partially overseas (including internet-based research that could include respondents from overseas) is considered to be high risk. They need to be submitted to the Insurers via the Insurance Office for review and approval on an individual basis before cover is confirmed. Additional insurance may be required.

If an overseas country has specific local legal requirements that insurance for research involving human subjects must comply with (which may differ from those required in the UK) and/or the insurance policy must be arranged locally, then there are three possible options for the Principal Investigators to consider:

Option A: The University's broker can make specific arrangements with a local broker to place a local insurance policy on behalf of the University for the overseas project.

This may be an expensive option for the project, but the University has control over the cover and it is the safest option from the University's point of view. Refer the project to the Insurance Office as early as possible so that the extra cost can be built into the budget of the project

Option B: The Principal Investigator can appeal to their research partner to include the University of Manchester in their local policy as a joint name.

The insurance cost is shared with a partner, thus making it less expensive for the project. However the University would not have much control over the terms and conditions of the cover and in the event of claim the process may be complicated.

Option C: The Principal Investigator may wish to negotiate with the local government/authority to waive the requirement for the CT insurance to be arranged in their country.

This is possible if they are keen for the University to go to their country and do work for them there. However, this route may take some time to channel the discussion and the negotiations.

Where there is no requirement for specific or local cover, or a where a dispensation has been obtained, the University's insurance will apply, but on a **Legal Liability basis ONLY**.

Notification Requirements and Procedures

For '**high risk research**', see Appendix A for definition, the Project Investigator (PI) of the project must inform the Insurance Office as soon as possible via ERM (Ethical Review Manager system) and provide the following to the Insurers to seek cover confirmation before starting any work:

- A copy of the research proposal/application
- A summary note detailing the activities involved in the research and highlighting any specific risks which may be involved, including the expected start and end dates and number of patients expected to be recruited in the project
- A list of countries where the research will be held if the research is to be conducted outside the UK, and notification if any of the countries involved is the home country of the investigator
- Name and address of the contract research organisation (CRO) or partner organisation

Note: If there is specific insurance cover requirements for any individual project, the additional cost must be met by the budget holder of the project.

Claim Procedure

Any event which is likely to result in a claim under this insurance should be immediately notified to the Insurers via the Insurance Office (email: insurance@manchester.ac.uk or tel: 0161 2752243)

Appendix A Definition

1 Clinical Trials

A project is defined as a "Clinical Trial", under the terms of the insurance cover, if ANY ONE of the following applies:

- Research involving physical testing of participants
- Research involving psychological intervention of participants
- Research involving the use of invasive techniques on participants
- Research to be carried out by other organisations where the University is required by contract to provide insurance cover for the research if it proceeds

2 Emergency Research

Emergency research is when treatment needs to be given urgently, and it is necessary to take urgent action for the purpose of the study.

3 High Risk Research

A project is defined as a "High Risk Research", under the terms of the insurance cover, if it is identified as a Clinical Trial (as above in 1) plus ANY ONE of the following conditions applies:

- Research conducted outside of the UK
- Research involving participants under the age of 5
- Research involving pregnant women (invasive techniques only)
- Trials with over 5000 participants

4 Physically invasive

refers to any test in which the skin of the participant is broken or an implement is inserted into any opening of the human body (e.g. eyes, ears, nose, mouth, lungs, stomach, rectum, vagina and urethra) or involves the taking of body samples such as saliva, hair, urine, faeces, sputum, skin, nails, or taking biopsies of any form for any purpose, or any form of scanning such as DEXTA scans, Ultrasound scans, MRI, fMRI, CT, or PET scanning.

5 Physical testing

refers to any test in which a participant must perform an action resulting in the use of any muscle of the body and/or involves the use of scanning procedures, eye-trackers, mounted body cameras, sensors or electrodes, or the taking of swabs from any cavity of the body, respiratory challenge testing or recording of peak flows, EEG, ECG, Exercise ECG, Treadmill work.

6 Psychological intervention

refers to any test in which purposely alters the mood of the participant or involves administering personality inventories, or any other form of psychological test.

7 No-fault cover

provides for the payment of compensation (and associated costs) to research subjects who suffer a physical or mental injury as a result of their participation. The Clinical Trials insurance policy specifies arrangements for determining the level of compensation offered. The claimant has to establish that injury has occurred as a result of the research, but does not have to establish liability.

Any decision under the no-fault arrangements is binding on the insurers but not on the claimant. If the claimant does not accept the no-fault compensation offer the cover reverts to legal liability. In this case the claimant would have to establish both that an injury has occurred and that the University is liable.

The no-fault process is subject to a confidentiality clause. Any information disclosed by the parties at the no-fault hearing cannot be relied upon if the matter reverts to a legal liability claim.

In the case of a claim for no-fault compensation there is no question of a claim against individuals. In the case of a legal liability claim, the University's insurance will cover staff and students acting in the course of their duties/studies, and members of University ethics committees, carrying out their duties.