This document describes the contractual processes employed by the University of Birmingham (UoB) in assessing risk and liability associated with clinical trials for which the University is the Sponsor, and how those liabilities are covered. Two categories of clinical trial are considered: those conducted in the UK, and those conducted internationally.

**Trials conducted in the UK and sponsored by UoB**

In this setting, the clinical trial will be conducted at a site usually within the NHS, with an NHS employee as the site Principal Investigator (PI), with the UoB standard Clinical Trials Task Delegation Log in place, together with the Sponsors Clinical Trials Unit (CTU) site agreement or the Sponsors site agreement for non-CTU trials.

***Responsibility for liabilities*** is determined during the contracting process and must be defined in the clinical trial site agreement. In almost all cases, the UoB will adopt the principles of the model non-commercial agreement, which includes a clause applying a reciprocal cap of £100k for NHS liabilities not covered by the Clinical Negligence Scheme for Trusts (CNST). This should be adhered to unless exceptional circumstances can be justified. In a very few cases (where significant commercial intellectual property is being sent to sites as part of the study documents and needs to be kept confidential), a cap on liabilities may be inappropriate, or set at a much higher level. The CTU should assess the likely risk before requesting a site template and then inform the Contracts Team at request stage if the standard £100k cap should be part of the template, or whether exceptional circumstances prevail preventing a cap.

If a site then requests a deviation from the above terms an assessment must be made to determine the level of liability. Where an assessment is required, members of the Research Governance Team (RGT) should be made aware to enable a discussion with colleagues from the Contract’s Team and if necessary referral to the Clinical Trials Oversight Committee (CTOC) to agree an assessment of likely non-clinical liabilities in relation to the project.

It should be noted that the University cannot exclude liability for death and personal injury caused by its negligence, nor for fraud or fraudulent misrepresentation.

***Assessment of risk:*** In the majority of cases, following the RGT review, clinical trials insurance will be subsumed under the university’s generic policy with UMAL, the university’s insurers. For higher risks trials which meet the clinical trials insurance referral criteria, RGT should be informed at the earliest opportunity.

* At pre-award, a synopsis of the study, including the interventions and the number of patients to be recruited, must be provided to RGT as soon as possible so that any potential issues can be identified early and discussed with UMAL.
* Post award, RGT requires the protocol, participant information sheet, informed consent form and completed clinical trial questionnaire to facilitate discussions with UMAL.

In both cases, RGT will arrange CT insurance cover with UMAL who will issue a study bespoke CT Insurance letter which RGT will distribute to the CTU Trial Co-ordinator or study co-ordinator if outside of the CTUs.

It is important to note that Underwriters’ perceptions of risk may differ from the clinical assessment. If Underwriters perceive the liabilities as significant, this may result in an additional premium being quoted. If applicable, this will be identified through the initial referral process between RGT and UMAL. Where a trial is identified by Underwriters as conferring higher levels of risk, RGT will organise a meeting with the Chief Investigator, and other informed individuals to discuss the Underwriters concerns. Patient representatives who may also provide useful input will also be invited.

Where it is identified that it would be useful to have direct contact (face to face or by phone) between clinical researchers, the Senior Trial Coordinator, RGT, UMAL and our Broker, RGT will facilitate a meeting to establish the true level of liability and ensure appropriate insurance cover is arranged.

**International Trials**: Arranging cover for liabilities for trials in multiple territories is complex and needs to take into account national differences in insurance requirements for clinical trials. To ensure that Sponsor responsibilities are appropriately insured, it is the responsibility of RGT to coordinate the procurement of all international clinical trial insurance based on the trial teams’ requirements.

Any additional insurance requirements mandated through the contracting process will be managed by the CTU / Study Co-ordinator through each country’s National Coordinating Centre (NCC) for that trial, not with each participating site. The NCC template must be used and should be discussed with the Contracts Team as appropriate once insurance for that country has been confirmed following the procedures laid down in this agreement.

The flowchart below should be followed to ensure appropriate insurance can be put in place efficiently.

**UoB Process for securing clinical trials insurance**

RGT and UMAL liaise to maintain a database of country specific trials insurance requirements1

Research Protocol summary, to include:

* Intervention(s): If an interventional medical product (IMP), provide details of ownership, control and pharmacovigilance procedures
* Patient group (ages)
* Countries participating, & number of sites in each territory
* Planned number of recruited patients in each country
* Duration of trial including follow up

CTU / Study Co-ordinator submits application to RGT for sponsorship and insurance quote

RGT undertakes checklist and submission to UMAL for insurance quote. (2 week response time)

UMAL provides quote(s) to RGT who transmits this to CTU or other designated person2

CTOC may seek further quotation or review

Options

Research could be conducted under worldwide public liability insurance

Additional insurance premium in excess of expected trial budget

Additional insurance premium within expected trial budget

Insured through UoB generic insurance: No additional premium

 

Proceed with trial

Proceed with trial

Refer to CTOC3 & 5

If trial funding secured; complete insurance information template4

**Notes**

1. **A country specific trials insurance requirements database to be held within Research Governance.**
2. **CTU’s must designate a senior member of staff who will be the designated liaison person regarding international trials insurance.**
3. **If the additional insurance premiums are in excess of expected trial budget; a request for the additional costs to be covered from the core insurance funding account must be submitted to CTOC. Submission to CTOC is undertaken by Research Governance. *NB*** As CTOC sit every 6-8 weeks RGT will confirm to the Senior Trial Coordinator the date of the next scheduled meeting
4. **Insurance information template to be completed by CTU or study co-ordinator and submitted to RGT as soon as funding secured, and it is confirmed that the trial will definitely proceed with international partners.**
5. **Approval by Head of College is required in addition to approval by CTOC**

**This table lists some areas of potential risk within clinical trials and how liabilities are covered. Blue shaded areas indicate category of liability. The table should be read in conjunction with the explanatory notes provided.**

|  |  |  |
| --- | --- | --- |
| **Risk** | **Covered by** | **Notes** |
| **UoB liability Additional cover may be required via UMAL** | **NHS ResolutionClinical Negligence Scheme for Trusts in England \*** | **NHS Liabilities outside of clinical negligence** |  |
| **Site wrongly diagnoses patient** |  |  |  |  |
| **Site enrols ineligible patient on to study (e.g. incorrectly submits a patient as eligible) and patient comes to harm** |  |  |  |  |
| **Site deviates from protocol and patient suffers injury as a result** |  |  |  |  |
| **Site treats patient according to protocol and patient suffers injury** |  |  |  | ^ see notes |
| **Fault in design of the study leads to patient injury** |  |  |  | ^ see notes |
| **Patient injury but no one is at fault** |  |  |  | ^ see notes |
| **Patient data are inappropriately shared by site** |  |  |  | Site responsibility, however, ^^see notes  |
| **Patient data are inappropriately shared by Sponsor** |  |  |  | # see notes  |
| **Commercial data are inappropriately shared by Sponsor** |  |  |  |  |
| **Commercial data are inappropriately shared by Site** |  |  |  | University may have a contractual liability through an agreement with pharma i.e.; that it cannot be insured where a third party (the NHS) is responsible for the error. A risk assessment is required to assess level of cap if applied by site under NHS liability |
| **Drug is lost or damaged through mistake by site** |  |  |  | Whether the NHS or the University is responsible for the loss depends on the agreement between the parties. Given drugs may be stored in refrigerated units, the question of the adequacy of engineering breakdown cover arises. There may be some automatic coverage. For high value drugs see additional notes\*\* |
| **Drug is lost or damaged through mistake by Sponsor** |  |  |  | Whether cover is automatically in place will depend on values and situations  |
| **Equipment provided to site by Sponsor malfunctions, or is lost or damaged** |  |  |  | The University’s Public & Products Liability cover is automatically operative. \*\*\* |

**Notes**

^ Additional cover dependent on UMAL referral process. ‘Non-negligent’ cover operative unless excluded.

^^ If University sued as Sponsor, it may not have cover and will look to subrogate from the site, but success may be limited by £100K cap defined in model non-commercial agreement.

# Claims by patients for financial loss under the Data Protection Act are covered, but other costs may not be, such as hiring PR, admin costs in contacting patients, loss of reputation.

\* Or equivalent scheme in devolved nations: Devolved nations’ indemnity schemes: For Scotland, the Clinical Negligence and Other Risk Indemnity Scheme ("CNORIS"), for Wales, the Welsh Risk Pool ("WRP"), for Northern Ireland, the Clinical Negligence Fund in Northern Ireland (“CNFNI”).

\*\* Where the trial involves high value drugs, these can be insured by UoB as ‘property’ rather than as part of clinical trials cover however this is **potentially very expensive** as insurers will not agree to this cover without charging a **significant premium!** In order to complete the contractual agreement it needs to be clear about who owns the drug and who is responsible for its care. If this approach is adopted, it should be flagged to RGT at the earliest opportunity and cover cannot be assumed. **Do not delay** this insurance referral as this element falls under “property” insurance and outside the 2 week turnaround time agreed with UMAL for CT insurance enquiries. On receipt of this enquiry, RGT will notify the Head of Insurance for UoB who will lead negotiations with our insurance provider.

To manage expectations: Referral to the insurance provider for this type of property insurance is mandatory and may take up to 8 weeks before a final decision is given

\*\*\* A warranty on the equipment may be applicable. The Property Damage risk may be subject to agreement for management of the equipment. Where equipment is provided by the Sponsor to a site to support a trial, an agreement should make clear who owns the equipment, who is responsible for maintaining it and who bears the risk should the equipment malfunction or be used inappropriately. If equipment is being shared as part of a study and the University is retaining ownership, then this should be flagged to the Research Insurance Administrator so that insurance of the equipment can be discussed with the insurance provider