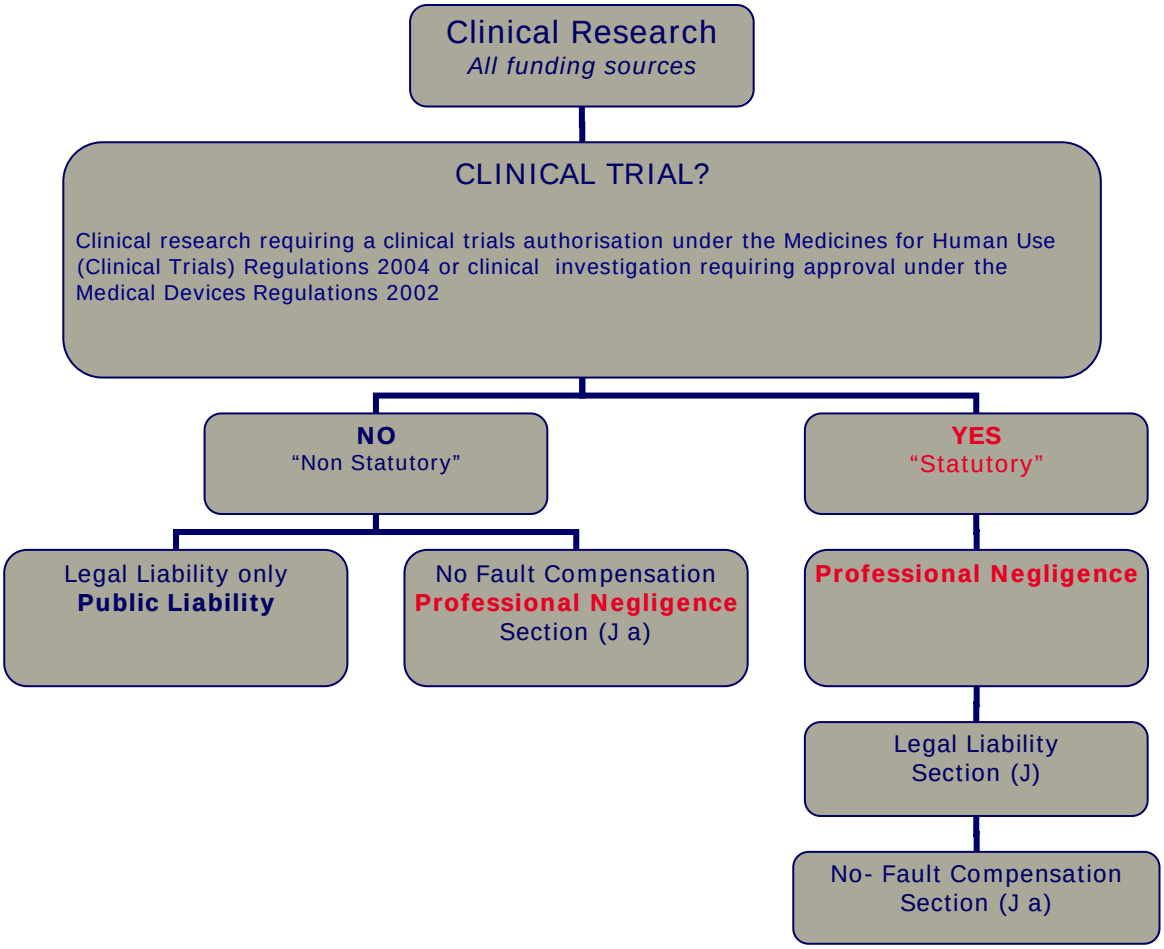
CLINICAL RESEARCH & CLINICAL TRIALS COVER OUTLINE

Effective from 1 August 2009

Summary of cover

The Public Liability (**PL**) and Professional Negligence (**PN**) Parts of the Select Policy for Universities should be viewed together when considering the Zurich approach to covering Clinical Research. The following chart determines where risk details should be allocated, and ultimately where claims would fall. If a particular research project does not immediately fit this guidance, or falls outside any underwriting parameters such as exclusion clauses, then it should be referred to underwriters.

Clinical Research Pathway



Main features

- All types of clinical research are included either under **PL** or **PN**, subject to policy terms, regardless of funding source or instructing client.
- Cover moves from **PL** to **PN** whenever the research amounts to a Clinical Trial, now defined on the statutory basis, or where the University has a necessity to provide "No Fault Compensation" for other clinical research.
- The use of the statutory definition allows for clear delineation of risk and minimal ambiguity especially because it now allows us to specify exactly what form of research is excluded from **PL**. The definition of Clinical Trial is narrower, but this

conversely means a wider range of research is now covered under **PL** where a higher and non-aggregated limit of indemnity applies.

- **PL** cannot cover No Fault Compensation schemes
- We have created a new policy category within **PN** to address the occasional need for No Fault Compensation cover on clinical research that is not defined by statute as a Clinical Trial. This also allows for differential pricing of the risks.
- Inner Limits apply for Clinical Trials and research under **PN**.
- "No-Fault" compensation cover can be arranged under **PN** (but not **PL**).
- Automatic Worldwide cover is provided under **PN** (excluding North America, which can be considered on request, and in circumstances where a local policy is required by law).
- Cover applies automatically to general clinical research and Clinical Trials within wide parameters without the need for referral.
- Minimum excess £250 per trialist/subject.
- Trials with up to 5000 subjects automatically included: larger trials to be referred
- On specific referral under **PN**, we will consider providing cover for excluded activities and causes (see below) and large trials, subject to possible restrictions and additional premium.
- Other than defined Clinical Trials themselves there are no specific excluded activities and causes under **PL**.

Excluded activities & causes

In order for us to assess research not automatically included in cover because it may fall within policy exclusions, we need to have specific details. It may be possible to include some of this category for additional premium and/or varied terms.

We only need to know about research falling foul of the exact exclusions in the policy. Q2 of the Questionnaire lists the potentially excluded areas in general terms but the precise descriptions are as follows:

	Excluded activity or cause	Notes for referral and assessment
1	Liability for injury which attaches solely because of an **agreement** or **contract.**	We may be able to provide elements of cover on specific referral of the contract and circumstances.
2	Injury to any subject who is known to be **pregnant** at the time of the trial.	***** Do not refer if restricted to (a) measurement of physiological processes using non-invasive methods (e.g. questionnaire work) (b) administration by mouth of foods or variation of diet other than the administration of drugs or food supplements (c) collection of bodily secretions and excretions for analysis by non-invasive means, including blood sampling ** this is a new amelioration of the exclusions which will provide wider underlying cover*
3	Injury to any subject who is **under the age of 5 years** at the time of the trial.	
4	Any trial in which the medicinal purpose is either assisting with or altering in any way the *process* of **conception**, or investigating or participating in *methods* of **contraception.**	
5	Any trial involving **genetic engineering** other than a trial in which the medical purpose is *treating* or *diagnosing disease.*	Referral only needed if research does not have the purpose of treating or diagnosing disease
6	Any trial where the substance or ***** device under investigation has been **designed, manufactured or modified** by the Insured	** device trials are now specifically included in cover unless within this (or any other relevant) exclusion*.

7	Any claim where an **ABPI indemnity** is not in place for a trial sponsored by a *pharmaceutical manufacturer* or similar organisation.	Limited to sponsoring role and only where no ABPI indemnity. Funding cases where not amounting to the role of Sponsor need not be referred.
8	Any trial conducted in the **United States of America, Canada** or any territory within their jurisdictions.	It will be essential to refer any contracts to us as well as clearly identifying exactly what your role is and the potential liabilities arising.
9	Any claim *arising from* **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 it may be named.	The research or trial itself is not excluded by virtue of the conditions being investigated so need not be referred. However, we are unlikely to be willing to override these exclusions to deal with claims arising from the stated diseases themselves.
10	Any claim *arising from* the condition directly or indirectly caused by or associated with **Creutzfeldt-Jakob Disease** (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).	
11	Trials or research involving more than **5,000** subjects.	This is not a policy exclusion but we ask you to let us know about these larger projects in case special consideration is needed.

Format in which to refer these excluded cases to us:

Please submit the following:

1. Identify the reason why you believe the case is not automatically covered.
2. Provide a summary description of the content of the case including start date, planned duration, location, number of subjects etc.
3. State your role and also that of other participating parties.
4. Confirm that no other parties need to be indemnified under your cover.
5. The Patient Information Sheet.

If possible please send details just of the cases you wish us to consider, and not as part of an overall list.

Action we will take:

We will aim to make a decision on the information submitted (as above) but may need to ask more questions. If we are able to accept the risk we may require additional premium as well as certain additional insurance conditions to be applied.

Amendments to current policy wording

PUBLIC LIABILITY

We are clarifying our intention to cover clinical research anywhere in the world except North America and to exclude statutory clinical trials. We are also clarifying the existing Exclusion 8 to show that general clinical research (not requiring authorisation) is automatically included. As a result, we are also introducing a specific exclusion (13) to show that statutory/authorised Clinical Trials and Devices Trials are excluded from Public Liability.

Since we wish to make it clear that it has never been our intention to be involved with claims for human or genetic material, we are introducing a new exclusion 14.

The exact wording changes are shown as follows:

Amendments to Section 1 – Geographical Limits

- Geographical Limits (c) of Section 1 - Special Definitions is amended to read:

  (c) in respect of Products and clinical research worldwide other than USA, Canada and any territory within their jurisdiction.

Amendments Section 12 – Exclusions

- Exclusion 8 – Professional Liability, Errors and Omissions is replaced by the following:

  8. Professional Liability, Errors and Omissions and Clinical Trials

  Injury, DAMAGE or Financial Loss resulting from errors or omissions in advice, design or specification provided by the INSURED or anything used or supplied in such connection provided that this exclusion will not apply to clinical research for which the following authorisation is not required:

  (a) a clinical trials authorisation from the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004
  (b) a clinical investigation requiring approval under the Medical Devices Regulations 2002.

- Exclusion 13 is added as follows:

  13. Clinical Trials

  Injury, DAMAGE or Financial Loss resulting from any clinical research requiring a clinical trials authorisation from the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 or clinical investigation requiring approval under the Medical Devices Regulations 2002.

- Exclusion 14 is added as follows:

  14. Human or Genetic Material

  Injury, DAMAGE or Financial Loss resulting from the use retention storage or disposal of any human corpse or any human tissue or organs or other human biological or genetic material.

PROFESSIONAL NEGLIGENCE

Schedules relating to both the Legal Liability section (Part J) and the No Fault Compensation section (Part J a) will show the following revised definition of a Clinical Trial to make it clear that only Trials defined by statute are included:

Clinical Trial

any clinical research requiring a clinical trials authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004 or clinical investigation requiring approval under the Medical Devices Regulations 2002 or

Where required by specific customers, we will also add a second category of clinical research under Section J (a) only (No Fault Compensation) by extending the Clinical Trial definition under that section as follows:

Clinical Trial

(1) clinical research requiring a clinical trials authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004 or clinical investigation requiring approval under the Medical Devices Regulations 2002 or

(2) an investigation or series of investigations conducted on any person for treating or preventing disease, diagnosing disease or ascertaining the existence, degree of or extent of a physiological or psychological condition, inducing anaesthesia or otherwise preventing or interfering with the normal operation of a physiological or psychological function

Other changes to the wording:

The effect of three standard exclusions concerning pregnancy, contraception and conception and children under 5 will be lessened by modifying the relevant exclusions – they have been incorporated into a new Exclusion 1 to which a completely new proviso has been added. In practice this means that fewer details will need to be referred to Zurich for special consideration, e.g. questionnaire based research in these specific categories.

The entire list of exclusions is shown below. Note that Exclusions 2-6 are exactly as previously, but re-ordered. Exclusion 7 now refers in addition to modification of a substance to reflect our original intention.

SECTION 3 – Exclusions

The INSURER will not be liable in respect of:

1. **Conception, Contraception, Pregnancy and Young Children**

(a) any Clinical Trial in which the medicinal purpose is either assisting with or altering in any way the process of conception, or investigating or participating in methods of contraception

(b) any Injury to any Research Subject who is known to be pregnant at the time of the Clinical Trial

(c) any Injury to any Research Subject who is under the age of 5 years at the time of the Clinical Trial

except in respect of Injury arising solely and directly from any of the following:

(i) the measurement of physiological processes using non-invasive methods

(ii) administration by mouth of foods or variation of diet other than the administration of drugs or food supplements

(iv) the collection of bodily secretions and excretions for analysis by non-invasive methods

(v) the sampling of blood from the antecubital fossa or back of the hand using the venepuncture vacuum system

2. **Contracts**

the failure of the INSURED to fulfil its obligations under any contract entered into with the Research Subject.

3. **Creutzfeldt-Jakob Disease**

any claim arising from any condition directly or indirectly caused by or associated with Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease

4. Genetic Engineering

any Clinical Trial involving genetic engineering other than a Clinical Trial in which the medicinal purpose is treating preventing or diagnosing disease

5. Hepatitis

any claim arising from 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 it may be named

6. Legal liability under agreement

any liability for Injury which attaches solely because of an agreement or contract

7. Substances

any Clinical Trial where the substance under investigation has been designed, manufactured or modified by the INSURED.

Important Notes

1. Clinical research or Clinical Trials cover can only be considered once a Clinical Trials Questionnaire has been completed for both new insurance and renewal of existing polices.

2. The outline of cover given above takes effect for all Clinical Trial business with effect from 1 August 2009 for new and existing customers.

All queries relating to this outline should be referred to the Zurich Underwriting department at Farnborough

RGW
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