Risk control

Research projects which need to be referred to RMP / HDI / Clinical Trials Insurer

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Research Projects which need to be referred

Research projects which need to be referred to RMP/HDI/Clinical Trials Insurer for Approval for Public / Products Liability cover to be effective

(A) Research – Public Liability

In terms of research/trials HDI are generally comfortable covering any non-interventional, non-statutory, non-invasive trials/ research projects that **do not** require referral to the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 (MHRA) or the Medical Device Regulations 2002. For example questionnaires, research projects, blood samples or swabs under the Public Liability which are Legal Liability/Negligence based.

For the avoidance of any doubt if the activity requires referral to the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 (MHRA) or the Medical Device Regulations 2002 or non-fault/non negligence conditions apply then a Clinical Trials or other suitable policy maybe be required. Please refer to your Broker for guidance on this.

Whilst we gain a better understanding of the work the institutions are undertaking the following should be referred through (this list will be developed as time progresses).

Projects that include:

- Children, vulnerable adults*, pregnant women (excluding pure questionnaire based)
- Dangerous environments*
- Any project which would be classed as invasive i.e. any samples taken (excluding straight forward blood taking)
- Significant overseas stays over 12 months
- Invasive Medical Device/Product
- US Exposure

If a project involves the following, we would expect a more specific Clinical Trials policy to be in place:

Project	Detail
Blood Products	Blood products means therapeutic substance prepared from human blood and administrated to a research subject (not the mere taking of blood). This includes (blood, blood components, blood preparation) and products of human or animal origin (products consisting of, or manufactured from e.g. body fluids, organs, tissues, cells etc…) for the medical-pharmaceutical purpose/application/use
Contraceptives Nicotine as therapeutic remedy Implants with liquid silicone	
Gene Therapy	An experimental technique that uses genes to treat or prevent disease by introducing a healthy gene into cells in place of a missing or defective gene.

Project	Detail
Pregnant women or breastfeeding women / artificial fertilization / clinical trials with frozen embryos	
A duration of more than 10 years	
Healthy persons whose health will be impaired for the purpose of the clinical trial in order to test an antidote afterwards	Please note this does not include the testing of allergens
Immunomodulators / vaccines	Immunomodulators are the active agents of immunotherapy (the aim is the treatment of disease by activating or suppressing the immune system)
Lifestyle-Products	e.g. Viagra, weight loss products, cosmetic surgery, anti-adiposis, performance-enhancing means/remedy (so-called nootropics), vaping/e-cigarettes, use of nicotine
Over 1,000 patients	
Tissue and Cell Technology	
Allogenic transplant / allografts	Transplant donor and recipient are not identical but belong to the same species
Xenogenic pharmaceutical products	Xenogenic pharmaceutical products are or contain living animal tissues or cells
Xenogenic transplantation	Transplant donor and recipient do not belong to the same species
Provocation Studies	Research subjects whose health will be intentionally impaired for the purpose of the clinical trial in order to subsequently test a drug/device/study treatment (except testing of allergic agents)
Antisense therapy	Antisense therapy is a form of treatment that uses antisense oligonucleotides (ASOs) to target messenger RNA (mRNA). ASOs are capable of altering mRNA expression through a variety of mechanisms.
Advanced therapies (ATMP)	"Gene therapy medicines, Somatic-cell therapy medicines, Tissue-engineered medicines"

If a project falls between the lines or, if it is unclear, please refer through for approval at the earliest opportunity.

(B) Product Liability

The coverage provided by HDI Global SE extends to include Products Liability. The definition of Products in the policy is-

Product

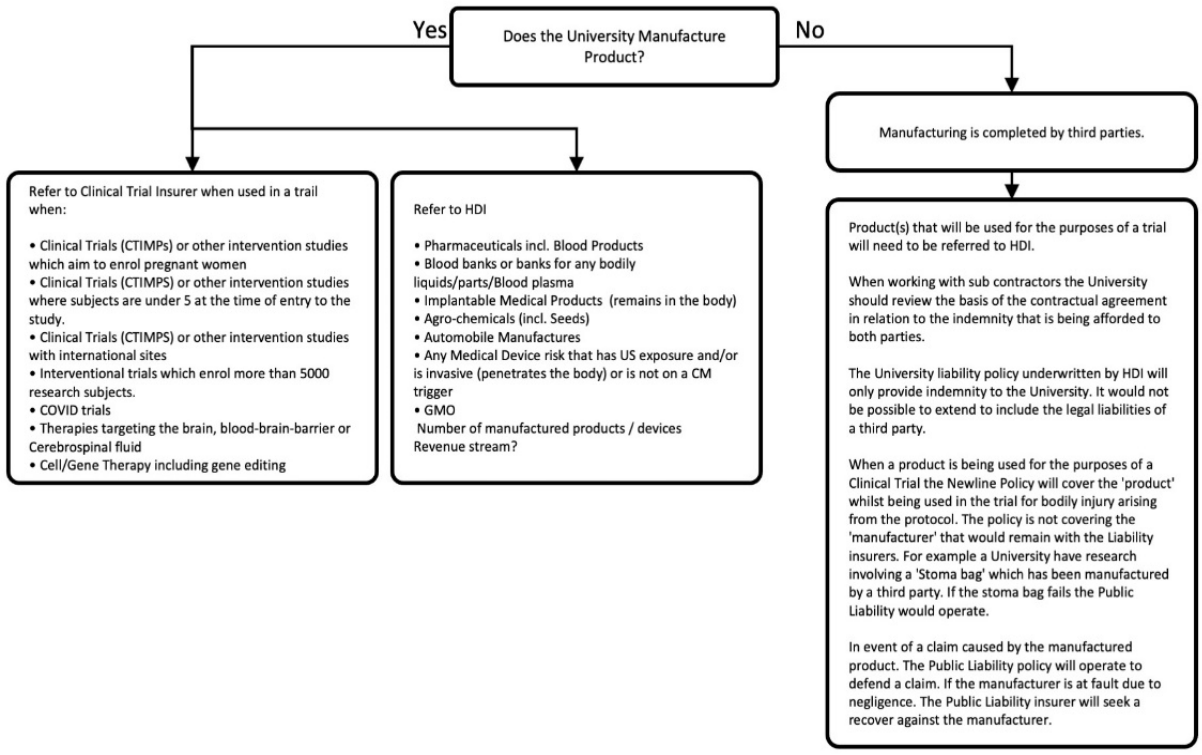
Product (or Products where applicable) shall mean goods including containers packaging labels and instructions accompanying the Product manufactured sold supplied distributed altered constructed repaired serviced designed tested installed or processed by or on behalf of the Insured and which are not in the possession of the Insured at the time of the Occurrence.

The definition of Products would not extend to include Apps (Medical or otherwise). If research involves an App please refer to your Broker.

All products manufactured/sold which coverage is sought under the terms of the policy need to be declared as usual through RMP, please see flowchart below for more details.

Should the product form part of a research project which requires referral to the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 (MHRA) or the Medical Device Regulations 2002 or non-fault/non negligence conditions apply then this product is unlikely to benefit from the indemnity provided by the Products Liability policy insured with HDI Global SE. Please refer to your Broker for guidance on this.

Nothing in this guidance note overrides or replaces anything contained in the Policy Wording and Schedule issued to the Insured. Detailed reference should be made to these documents for full details, language and intention of the coverage provided.



*Dangerous Environments

Any environment or situations where, after risk assessment, the institution feels that an individual (s) might be exposed to a significant/greater degree of risk than that of normal/usual day to day institution activities which might influence the mind of a prudent Underwriter in relation to the provision of policy cover. Examples, include Nuclear Zones i.e. Chernobyl, War Zones, areas where the FCO have advised against travel, locations where hazardous substances/chemicals/explosives are present, mines, off shore and extreme height or under water . This list is not exhaustive and should at any time an institution be unsure then a referral should be made.

Vulnerable Adults

Those participants who are in need of special care, support or protection because of age, disability, or risk of abuse or neglect. Referral is not required for research that may cause distress that ‘may’ make them vulnerable.

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Further information

For access to further RMP Resources you may find helpful in reducing your organisation's cost of risk, please access the RMP Resources or RMP Articles pages on our website. To join the debate follow us on our LinkedIn page.

Get in touch

For more information, please contact your broker, RMP risk control consultant or account director.

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