Risk control

Research projects which need to be referred to RMP / HDI

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Research Projects which need to be referred

Research projects which need to be referred to RMP/HDI 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.

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 (Under the age of 18) (excluding pure questionnaire / interview based)
- Vulnerable adults* (excluding pure questionnaire / interview based)
- Pregnant women (excluding pure questionnaire / interview 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 - Products that the University have manufactured to use in research. Invasive would be anything that is implantable and/or penetrates the body
- US Exposure – Referral required when research conducted within the US. If the University is collaborating with a US entity but the University's operations remain in the UK it does not need to be referred unless the research involves any of the above
- If the University have manufactured a product which is being exported to the US, for example an invasive device a referral will be required
- Cover is subject to the usual terms and conditions of Part 2. Public Liability. Please be aware of exclusion twenty applying to this part in respect of United States of America and Canada

We are aware some Clinical Trial insurer's policies will provide legal liability indemnity as well as the standard non-negligence cover for all research undertaken by the University. Therefore, referral to HDI for non-interventional, non-statutory, non-invasive trials/ research projects may not be required. Please confirm with your Broker on the basis of cover provided by your Clinical Trial insurer.

When is a Clinical Trials policy needed?

- If cover is provided to the participant on a non-fault/non negligence basis
- 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
- If a project involves the following, we expect a more specific Clinical Trials policy to be in place as the HDI policy will not operate in respect of research / trials involving the following as detailed in the table below
- If unsure, please refer to your Broker.

HDI policy will not extend to include the following:

Project	Detail
Blood Products	Blood products mean 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.
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 to your Brokers.

(B) Product Liability

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

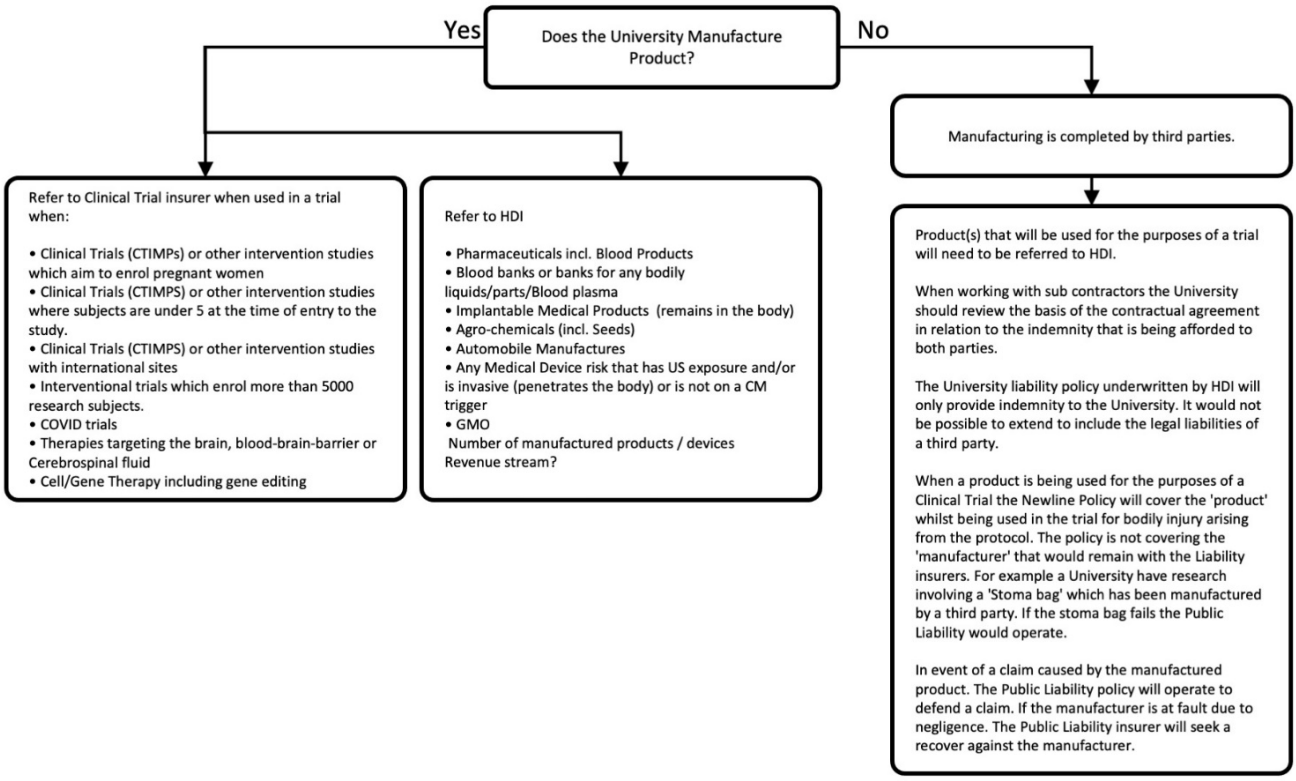
Product

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 / Software platform (Medical or otherwise). If research involves an App / Software platform 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.

*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.

**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 Prison premises, Nuclear Zones i.e., Chernobyl, War Zones, areas where the FCO have advised against travel, locations where hazardous substances/chemicals/explosives are present, mines, offshore 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.

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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.

contact@rmpartners.co.uk

Risk Management Partners

The Walbrook Building
25 Walbrook
London EC4N 8AW

020 7204 1800
rmpartners.co.uk

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