

Clinical Trials and Medical Malpractice Insurance



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Insurance Manager

Clinical Trials Cover and Research Requiring Additional Insurance Referrals

Clinical Trials and Medical Malpractice Insurance

The University has a Clinical Trials and Medical Malpractice policy to support research that is not covered under the University's standard liability policies and it provides cover for the following:

- Legal Liability for Human Clinical Trials
- No fault compensation for Human Clinical Trials
- Medical Malpractice Liability

In each of these areas the limit of indemnity the University is insured up to is £10million.

The policy will respond if any claims are made against the University by research participant(s) in relation to damages or compensation caused by the University's research.

The policy cover is Worldwide, except for the No Fault compensation for Human Clinical Trials section where there is an exclusion for any trials in the USA or Canada – this means that should there be a claim from a participant this would not be covered under the policy. Trials of this nature should seriously be considered.

Criteria for Triggering an Additional Insurance Referral

The University's insurers accept that the University carries out a wide range of research that covers many different areas. Whilst they are accepting of this, there are still some areas that need additional approval from the insurers.

If your research includes any of the following, your project will need additional referral to the insurers before approval can be given to commence:

- Participants under 5 years old
- 5000 or more participants
- Research being conducted in an overseas country
- Research involving aircraft and offshore oil rigs
- Nuclear research
- Trials involving pregnant participants
- COVID19 - any research intervention and/or trials into the virus, treatment and subjects (excludes surveys and/or interviews only)

Trials involving Pregnant Participants

Over the past 5 years insurers have introduced and applied certain exclusions where applicable to certain medical research trials, the majority of these have been in relation to trials on pregnant participants. After consulting with insurers, they have indicated medical research and future trials might not be able to be conducted where it involves pregnant participants. This is not to say all the trials will be declined by the insurer but please refer to the [Insurance Manager](#) via the referral process, detailed below. Please note that this does NOT apply to research where only surveys and/or interviews are being completed as part of the research.

Whilst we work towards a solution on this please note the research may not be covered under the University's Insurance. Please always seek clarification from the [Insurance Manager](#) in research of this type.

Referral Process

Projects in these areas are automatically forwarded to the Insurance Manager when researchers submit an [online ethics application](#) and tick the appropriate boxes on P1 Q6.

If you are unsure you have done this, please contact the [Insurance Manager](#), ensuring that you include a full outline of the research and the involvement of the subjects (ideally a downloaded PDF of your full ethics application).

Should you have any queries or comments please contact Liz Windle, the University's [Insurance Manager](#).

Related Links



Approvals - Staff and Doctoral | Sheffield Hallam University

Contact us:



! Insurance Queries

Meet the team:



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