**Protocol Submission Proforma: Clinical Research Insurance**

Clinical Research - cover for negligent harm and non-negligent harm arising from a project is provided by the University's Newline Clinical Trials insurance policy. The policy document defines a "human clinical trial" very broadly as: "any investigational study conducted for the purposes of research and any research, data analysis, or other advice provided in relation to the study and its result". Consequently, this policy will be relevant if your study involves direct interventions with a research subject.

The insurers require the following information for each trial:

| | |
|---|---|
| Trial Number | |
| Trial Title and brief description in lay terms | |
| Department | |
| Location of Trial | |
| Nature of Trial * | |
| Expected Start Date | |
| Expected End Date | |
| Principal Investigator | |
| Externally Funded? | Yes/No |
| Name of Sponsor | |
| Medical Licence? | Yes/No |
| Projected/Cumulative Number of Subjects | |
| **Trials involving the following require special consideration and the insurer's prior approval must be sought:** | |
| Any pregnant research subjects? | Yes/No |
| Any research subjects under 5 years of age? | Yes/No |
| Is this an overseas trial? | Yes/No |
| More than 5,000 subjects? | Yes/No |
| Human T-Cell Lymphotropic Virus iii or Lymphadenopathy Associated Virus or variations thereof, Acquired Immune Deficiency Syndrome, HIV or any condition of a similar kind | Yes/No |
| Transmissible Spongiform Encephalopathy, Creutzfeldt-Jakob Disease (CJD), variant CJD or new variant CJD | Yes/No |
| Hepatitis | Yes/No |

* Assign to one of the following categories:-

P- Pharmaceutical

NP - Non-pharmaceutical

PS - Pharmaceutical, externally funded,

NPS - Non-pharmaceutical, externally funded,

Q - Questionnaire/interview/observation only