

Commercial Research- Risk Indicators

Prior to signing a contract with a client, to undertake commercial research or to supply equipment/devices, UOW must assess the risk of undertaking this work. Some of these risks will be assessed by UOW without the researcher's input (e.g. protection issues, indemnities, legal jurisdiction). However, the identification of other risks will require the input of the UOW researchers involved in the proposed project.

Some of the situations/activities that will present risk to UOW, for which the UOW researcher is in a good position to identify that they are likely to occur, are listed below. It is important that UOW staff disclose (in the Commercial Research Approval Form) any of these risks that are likely to occur in their proposed project.

- R1** The work involves undertaking clinical trials*.
- R2** UOW is going to use or access intellectual property (IP) that is owned by a third-party.
- R3** There is an actual or potential conflict of interest involved in undertaking the project.
- R4** Key staff are likely to leave UOW's employment during the course of the project.
- R5** UOW staff will be visiting environments or performing activities, whilst undertaking the project, that may cause harm or injury to people or equipment.
- R6** The project will involve UOW students.
- R7** There is potential for UOW to breach the confidentiality of the Client.
- R8** There is potential for the Client to breach UOW's confidentiality.
- R9** The project involves unlawful activities.
- R10** The project will involve testing or trialling involving human subjects.
- R11** The project will involve testing or trialling involving non-human animals.
- R12** The project involves UOW intellectual property (IP) that has been assigned or licensed to a third party.
- R13** The application of the project results will be have physical consequences on human subjects.
- R14** Participation in the project may expose the UOW researcher(s) to radiation, radioactive materials, biological hazards, etc.
- R15** UOW's reputation will possibly be damaged as a result of participating in this project.
- R16** Other potential risks as identified by the UOW researcher(s).

* Clinical trial is defined as:

1) a study or research involving humans to a) find out whether an intervention, such as treatments or diagnostic procedures, which is believed may improve a person's health, actually does so; or b) to test a drug, a surgical or other therapeutic or preventative procedure or a therapeutic, preventative or diagnostic device or service; where the nature of the study or research is such that it requires the investigator or an assistant to be a registered medical practitioner or other registered qualified health service provider; OR

2) research involving humans requiring any invasive procedure (other than ingestion of food or drink or taking of blood samples) to be undertaken by a registered medical practitioner or other registered qualified health service provider. For the purpose of this definition, "invasive procedures" means any procedure involving ingestion, application or admission of any substance or material onto or into a human's body.

Risk Management

Once you have disclosed that one or more of the above risks apply to your project, the Commercial Research Unit will contact you. Together, and with advice from Legal Services and the UOW delegate, you will develop a strategy to minimise or mitigate the risk. This may include a technical (e.g. design) solution or a legal (e.g. indemnity requirement in the contract) solution.

UOW reserves the right to disallow high risk projects from being undertaken under UOW's auspices.