

Clinical Trials Policy MPF1352

Schedule 2

ELIGIBILITY CRITERIA CONSIDERED BY THE UNIVERSITY WHEN ASSESSING CLINICAL TRIAL SPONSORSHIP REQUESTS*

The proposed Clinical Trial research objectives are aligned with the University's research, educational and ethical goals.

There are no significant unresolved quality issues with the research team.

The proposed Clinical Trial has reasonable prospects of completion as planned. Resources required to conduct the trial, including financial and personnel, appear adequate such that the University will be well positioned to discharge its responsibilities of acting as Sponsor, including having sufficient funding to cover all necessary safety monitoring and reporting costs.

The Clinical Trial is covered under the University's insurance policies or, if not, appropriate additional insurance coverage is sought by the research team through the University's Insurance Office and any additional cost (e.g. premium) is covered by funding for the proposed Clinical Trial.

The Clinical Trial is aligned with "public good" expectations.

The Coordinating Principal Investigator of a multi-centre trial is a University staff member or affiliate working on the Clinical Trial within the scope of their University role.

The Principal Investigator for a single site Clinical Trial is a University staff member or University affiliate working on the Clinical Trial within the scope of their University role.

Any conflict of interest that the Coordinating Principal Investigator or the Principal Investigator (as appropriate) has as a result of a joint or dual appointment with another institution or entity is adequately managed in accordance with applicable University policies and procedures.

The Clinical Trial is to be conducted in Australia, or, if a multi-country Clinical Trial which is:

- seeking local (Australian) sponsorship:
then the Chief Investigator for Australia is a University staff member or affiliate working within the scope of their University role
- being conducted in other countries but seeking an overall study sponsor:
then the Chief Investigator is a University staff member or affiliate working within the scope of their University role and local sponsors have been agreed for other participating countries and such local sponsors will provide appropriate insurance cover and be responsible for all legal and regulatory compliance in the other participating countries.

The University will benefit from its support of the Clinical Trial. For example, the University will have appropriate rights (such as full or partial ownership of) the intellectual property developed during the course of the Clinical Trial or being investigated as the Clinical Trial intervention.

The University will receive recognition on publications arising from the Clinical Trial.

The University is the administering Institution for the grant that is funding the research.

The Clinical Trial is part of a University-enrolled study as part of a research higher degree. The CI/PI is a University staff member or affiliate.

Additional criteria may be considered. Researchers should contact the Office of Research Ethics and Integrity to discuss exceptional requests.

*adapted from The University of Sydney, NHMRC Clinical Trials Centre (<https://ctc.usyd.edu.au>) and amended.