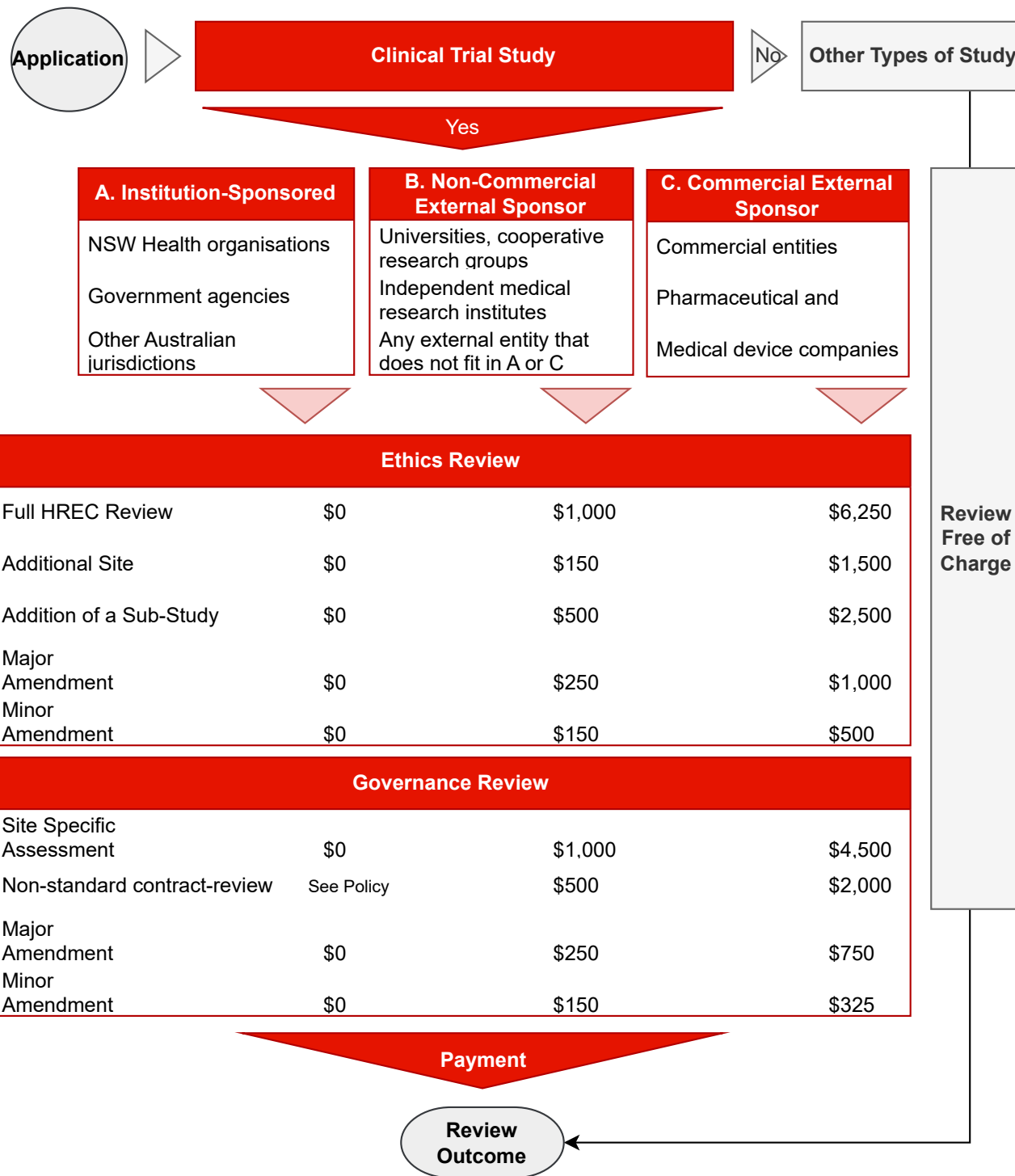


# FEE POLICY DECISION MAP

# REMARK



## A clinical trial is

Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to:

- Surgical, medical treatments or procedures
- Experimental drugs
- Biological products
- Medical devices
- Health-related service changes
- Health-related preventative strategies
- Health-related educational interventions.

## A major amendment is

An amendment that is condored more than an administrative change, and examples of major amendments are:

- Protocol amendment**
- Contract amendment**
- Revision of the study design due to safety issues
- Revisions in drug dosage, participant groups and numbers of study participants**
- Investigator brochure updates, where there are associated changes required to the
- Participant Information Sheet/ Consent Form (PISCF).**

## A minor amendment is

A minor amendment is defined as changes to the details of a research project that have no significant implications, and examples of these are:

- PISCF with changes not required to be reviewed by the Human Research Ethics Committee (HREC).**
- Investigator brochure updates where there is no change required to the PISCF.
- Change of Principal Investigator/ Coordinating Principal Investigator.**
- Minor updates to existing patient-facing documents, protocol clarification letters, advertising material and single-word changes.**