AU RED data entry definitions

Application References page

1. Study Type

Study Type	Definition
Clinical research	Studies, including observational studies in the clinical setting, which are designed to understand, find and treat illnesses and other health issues. Clinical research studies involve a wide range of activities from genetics to assisting medical staff and patients to communicate better. Examples include finding how genetics leads to disease or finding the best ways to counsel people who have a genetic mutation that predisposes them to a certain disease such as cancer; the relationship between smoking and heart attacks.
Clinical trial (other)	Is an interventional study that does not fall under the broad definitions of drug or device trial. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, methods of surgery, radiation therapy methods and dosage etc.
Clinical trial of a drug	Is an interventional study designed to assess the effect(s) of one or more chemical or biological agents (e.g. drugs, medicines, vaccines).
Clinical trial of a device	Is an interventional study designed to evaluate the use of any physical item used in medical treatment whether it be an instrument, piece of equipment, machine, apparatus, appliance, material or other article, and whether it is used alone or in combination with the intention of preventing, diagnosing, treating and/or curing a disease or condition. Examples include: artificial limbs, contact lenses, ventilators, catheters, implants and vibration therapy machines.
Clinical trial of a drug and device	Is an interventional study designed to assess the effect(s) of one or more chemical or biological agents and the evaluation of the use of any physical item used in medical treatment whether it be an instrument, piece of equipment, machine, apparatus, appliance, material or other article, and whether it is used alone or in combination with the intention of preventing, diagnosing, treating and/or curing a disease or condition.
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug	Is an interventional study involving the first administration of a drug to humans (healthy volunteers) or patients.
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical	Is an interventional study involving the first administration of a device to humans (healthy volunteers) or patients.

Study Type	Definition
trial – device	
First Time In Human (FTIH) or First Time In Patients (FTIP) Clinical trial – drug and device	Is an interventional study involving the first administration of a drug and device to humans (healthy volunteers) or patients.
Health Research/Social Science	Health Research studies are designed to gain information and understanding about health. The goal is to find ways to improve human health. Social science studies seek to understand social behaviour through (a) the measurement of social phenomena, (b) the discovery of social regularities, and (c) the creation of social theories. Examples include: interviews involving one or more participants, focus groups discussing a specific set of topics, observing the participant in his/her own environment or in the environment being studied.
Other (please state)	Is a study that does not fall into any of the above categories. For example: Population and public health studies which aim to develop or contribute to generalisable knowledge to improve public health practice; intended benefits of the study can include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Research activities include the collection and analysis of qualitative and quantitative survey data, the analysis of administrative datasets, economic evaluation of health care interventions, health care financing priority, evaluation of health services and health policy, GIS studies and knowledge translation. It includes population-level and health-system research, but not clinical or biomedical research.

2. Major Sponsor Type

Major Sponsor Type	Definition
Commercially Sponsored	Is where a company (pharmaceutical company or other corporate entity) takes overall responsibility for the conduct of a study and usually initiates, organises and supports the study. For clinical trials, this also involves providing indemnity for the trial, where appropriate.
Collaborative Group	Is where an academic or non-commercial collaborative research group takes overall responsibility for the conduct of a study and usually initiates, organises and supports the study. For clinical trials, this also involves providing indemnity for the trial, where appropriate.
Investigator Initiated	Is where an individual, such as a private medical practitioner, takes overall

Major Sponsor Type	Definition
Group	responsibility for the conduct of a study and usually initiates, organises and supports the study. For clinical trials, this also involves providing indemnity for the trial, where appropriate. Where the Co-ordinating Principal Investigator is an employee of a NSW Public Health Organisation (PHO), and is conducting the study as part of his/her employment, the sponsor is usually the PHO and the sponsor type 'Institution' should be ticked.
Institution	Is where an organisation such as a Local Health District or non-government organisation or private research organisation takes overall responsibility for the conduct of a study and usually initiates, organises and supports the study. For clinical trials, this also involves providing indemnity for the trial, where appropriate.
Other	Is a sponsor that does not fall into the above classifications or where a study does not have a sponsor.

3. Mode of HREC Review

Mode of HREC Review	Definition
State	Is the default value for the field and indicates that the application is not an Interstate Mutual Acceptance application.
Interstate Mutual Acceptance	Should only be selected when the application relates to a multi-centre clinical trial to be conducted in two or more states (i.e. NSW, QLD, VIC), for which only one HREC review is required. This single ethical review is facilitated under the Memorandum of Understanding for Mutual Acceptance between NSW, QLD & VIC.