Ethics Glossary

ACEC - Animal Care and Ethics Committee

Adverse Event - An unexpected and unintended outcome resulting from the conduct of a research protocol. It could include reaction to a drug or intervention, psychological or emotional distress, or a complaint relating to the conduct of research.

AHEC - Australian Health Ethics Committee - AHEC is a principal committee of the National Health and Medical Research Council (NHMRC) and is responsible for the oversight of ethics committees and the development of policies and guidelines relating to the ethical conduct of research.

Anonymity - Where a person's identity is unknown and therefore cannot be disclosed. This is different to 'Confidentiality' where the identity is known but protected (ie not disclosed).

Applicant - The person who completes the ethics application form.

Australian Code - Australian Code for the Responsible conduct of research – developed as a companion document to the National Statement, the Code provides guidance for researchers and their institutions on responsible research conduct. Part A encompasses responsible research practice and principles. Part B covers breaches of the Code and misconduct in research and the institutional framework.

Clinical trial - A form of research designed to find out the effects of an intervention, including treatment of diagnostic device.

Confidentiality - The recognition that privacy should be respected and private information not divulged without permission or used for any purpose other than for which permission has been given. It differs from 'Anonymity' in which identity is protected because it is unknown and therefore cannot be disclosed. In the case of research this extends to care being taken to store data.

Conflict of interest - Where personal interest may have the potential to influence the conduct of the research. This may include a personal, professional or financial interest in the outcomes of the research.

Consent - In this context, where a person has agreed to participate in research. Consent must be freely given (without coercion or pressure) and fully informed. Consent may be written, oral, implied or in certain circumstances may be given by a third party on behalf of the participant. See ‘Informed Consent’.

Consent form - Consent form is a document signed by the potential participant acknowledging their understanding
of the information provided in the Letter to Participants and their agreement to participate in the research. In some cases, consent forms are read out loud and consent is given verbally.

Data - Pieces of information. In relation to research this can include measurements, personal details and information, recorded conversations and interviews, surveys, observations and databases.

Ethics Protocol - This is the term used to describe the research outlined in the ethics application, including background, rationale, objectives, design and methodology. It is used to avoid confusion with the term ‘project’, because it refers only to the research outlined in the ethics application.

External Approval - Ethics approval from an external (non-ACU) HREC.

Harm - Harm may be physical, psychological, reputational or social.

HREC - Human Research Ethics Committee. Australian HRECs are accredited by the National Health and Medical Research Council (NHMRC) and are constituted according to the requirements of the National Statement.

Informed consent - The process by which a person consents to participate in research after being fully informed about what the research involves, including any associated risk. This term is commonly used in a medical context in relation to treatment but its use has spread to include research generally. The concept of ‘informed consent’ is closely related to the ethical principles of Respect for Persons and Autonomy.

Low risk - The National Statement defines low risk research as where the only foreseeable risk is one of discomfort.

MOU - Memorandum of Understanding

Multi-site - Refers to research projects being undertaken by researchers from different institutions across a number of sites (eg hospitals, schools, organisations).

National Statement - The National Statement on Ethical Conduct in Human Research (2007) is Australia’s primary research ethics guidelines, developed jointly by the NHMRC, the Australian Research Council (ARC) and the Australian Vice-Chancellor’s Committee (AVCC, now Universities Australia).

Negligible risk - Risk, harm or discomfort is minimal and unlikely and no more than might be encountered normally.

NHMRC - National Health and Medical Research Council - Responsible for providing advice and guidelines relating to research ethics and health and medical research, including the administration of research funding schemes (see AHEC).

Orion - Orion (Research Information Online) is the web interface of ResearchMaster at ACU. Orion is enabled for all academic staff, research higher degree students, Research Data Collection Coordinators and Faculty Research Administrative Staff.

Use your ACU network username and password to login. To request access to Orion, complete the ‘Request for Access to Orion’ form available from the Orion home page.

**Orion Ethics** - New Human Research Ethics Applications are created and managed through the 'Ethics/Applications' menus within Orion. Access the list of applications you are associated with by clicking on 'All Applications' and open an application by clicking on the title.

**Primary HREC** - Where a research protocol involves researchers from more than one institution, one institution will assume responsibility for the oversight and administration of the protocol. This is referred to as the Primary HREC.

**Primary Researcher** - The Primary Researcher is the person who is the point of contact with the HREC and should always be an ACU staff member.

**Project** - See ‘Research Project’.

**Protocol** - See ‘Ethics Protocol’.

**Qualitative research** - This term refers to a variety of methods employed by different academic disciplines, notably and traditionally in the social sciences, to gather data. Methods include (but are not limited to) interviews, observations, participant observation, focus groups, storytelling, surveys and questionnaires.

**Research misconduct** - Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, failure to declare or manage a serious conflict of interest or to adhere to an approved research protocol.

**Research Project** - This is the term used to describe the overall research project. It incorporates the original application for funding and is distinct from the ethics protocol because it may involve more than the research outlined in the ethics protocol. A research project may have more than one ethics protocol associated with it, including animal ethics and biosafety protocols.

**Retrospective approval** - Refers to seeking ethics approval after the research has taken place. Retrospective HREC approval cannot and will not be granted under any circumstances.

**Risk** - Risk refers to the magnitude and likelihood of harm arising as a result of research. It includes risk to the research participant(s), the researcher(s) and others who may be harmed as a result of the research. Risk may occur in a number of forms, including physical, emotional and reputational.

**TGA** - Therapeutic Goods Administration - The body responsible for regulating therapeutic goods, including medicines and medical devices.