Ethical Human Research Procedure Manual

Section 1 - Introduction

(1) The University of Newcastle (University) is committed to ensuring that all research activities involving humans are conducted in a safe and ethically responsible manner and in accordance with the requirements of the National Statement on Ethical Conduct in Human Research (2023).

(2) This Procedure Manual:

a. is a supporting document to the Responsible Conduct of Research Policy;
b. provides a central resource of human research procedures; and
c. must be read in conjunction with the University's associated policies and applicable legislation.

(3) The following associated documents should be read in conjunction with this Manual where applicable:

a. Legislation and Associated External Guidelines:
    i. National Statement on Ethical Conduct in Human Research 2023
    ii. Australian Code for the Responsible Conduct of Research 2018
    iii. Australian Radiation Protection & Nuclear Safety Agency Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes
    iv. Privacy Act 1988
    v. NHMRC – Guidelines under Section 95 of the Privacy Act 1988
    vi. NHMRC – Guidelines under Section 95A of the Privacy Act 1988
    vii. NSW Human Tissue Act
    viii. NSW Health – Use of Human Tissue for Research Guideline Requirements
    ix. NSW Health Records and Information Privacy Act 2002
    x. Health Records and Information Privacy Act 2002 - Statutory Guidelines on Research
    xi. NSW Privacy and Personal Information Protection Act 1998
    xii. Privacy and Personal Information Protection Act 1998 - Statutory Guidelines on Research - section 27B
    xiii. NHMRC Statement on consumer and community involvement in health and medical research
b. University of Newcastle Policy Documents and Related Documents:
    i. Responsible Conduct of Research Policy
    ii. Collaborative Research Procedure
    iii. Disclosure of Interest Policy
    iv. Code of Practice for Higher Degree by Research Candidature
    v. Research Data and Primary Materials Management Procedure
    vi. Aboriginal and Torres Strait Islander Education and Research Framework
    vii. Volunteer Management (Including Volunteer Researcher) Policy
    viii. Volunteer Management (Including Volunteer Researcher) Procedure
c. Ethics Guidelines and Codes when working with Aboriginal and Torres Strait Islander peoples:

i. NHMRC: Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
ii. NHMRC: Keeping research on track II (companion guide to the above);
iii. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
iv. A Guide to Applying the AIATSIS Code of Ethics
v. Aboriginal Health & Medical Research Council of NSW Ethical Guidelines: Key Principles
vi. University of Newcastle Aboriginal and Torres Strait Islander Cultural and Intellectual Property Protocol

Section 2 - Document Context

Purpose

(4) This Manual is designed to ensure that human research at the University is conducted in an ethical manner and in accordance with legislation. This Manual is intended to:

a. assist Researchers to prepare for and conduct human ethics protocols that are compliant with the Statement on Ethical Conduct in Human Research (the National Statement);
b. outline the University's approach and procedures for research that involves human participants; and
c. outline the University's commitment to the safe and ethical conduct of research that involves human participants.

Scope

(5) This Manual applies to all research conducted at the University that involves human participants, human data/records, or human biospecimens.

Audience

(6) This Manual and its overarching and associated documents should be read, understood, and complied with by all people involved in human research at the University, including but not limited to:

a. Researchers who are conducting research involving human participants (including Chief Investigators / primary supervisors, co-investigators, research assistants, and students); and
b. staff who are responsible for activities and operations that relate to, or involve, research activities involving human research (including Research Ethics and Integrity Unit staff, members of the Human Research Ethics Committee (HREC), College Research Ethics Advisors, and members of the College Human Ethics Review Panels (CHERP).

(7) This document is also available to persons who may be or choose to become participants in human research conducted at the University.

(8) Researchers are strongly encouraged to read this document in its entirety prior to preparing an application for ethics approval for human research.

Section 3 - Researcher Competence and Supervision

(9) Researchers carrying out research involving human participants, their data, or biospecimens who are considered 'yet to be competent' must be under the direct supervision of a person who is competent, and a monitoring strategy must be in place until competency is attained. Competency is attained via training, demonstrated experience, and

meeting industry standards specific to the defined task.

(10) As a minimum competency requirement, all investigators (including any University staff, conjoint/honorary/affiliate appointments, students, Higher Degree by Research (HDR) candidates and volunteers who conduct research or contribute to research at the University) and professional staff supporting research, must complete the following mandatory training before they can be approved to join a human research project:

a. Research Integrity Awareness Online Module;
b. Introduction to Human Ethics Module:
    i. Introduction to Human Ethics is a new module which will become compulsory during 2024.
    ii. existing investigators will be required to complete the module before any new application, variation, progress report or registration is accepted and considered by the HREC or a CHERP.
    iii. It is expected that all named University Researchers and support staff on the application will complete the training, however, reasonable exceptions can be granted by contacting the Pro Vice-Chancellor (Research).
    iv. This training must be completed every three years.

(11) Further competency requirements for Researchers and support staff may be required to be met. This is dependent upon the nature of the project and will be determined primarily by the investigator, and as agreed by HREC or CHERP.

Section 4 - Peer Review, Institutional, and Ethical Approvals

Part A - Peer Review

(12) The peer review of research proposals that are assessed as more than low risk research must be undertaken prior to submitting an application to HREC.

(13) The peer review of research proposals must be conducted in accordance with the University's Research Peer Review Procedure for Ethics Applications.

Part B - Institutional Approvals

(14) In accordance with the National Statement research must also be authorised by each institution with responsibility for oversight of the research, before it can proceed. To fulfil this requirement:

a. research proposals submitted for ethical review must be accompanied by a completed Head of School Declaration;
b. the signing Head of School must be independent of the proposed research project and the Researchers i.e., the Head of School must not be a Researcher on the project, a member of the research group, or have a personal relationship with any member of the research team; and
c. the Head of School Declaration must be completed by the relevant College Pro Vice-Chancellor if the Head of School has any association with the proposed research.

(15) In the case of research proposals for clinical trials, additional authorisation is required from the Pro Vice-Chancellor (Research) prior to submission for ethical review.

Part C - Risk Assessment

(16) In accordance with the National Statement, Researchers are required to conduct a thorough risk assessment of the proposed research project to identify all risks of harm to research participants, and to minimise and manage these risks. Where it is determined that the level of risk is not justified by the potential benefits of the research, the research aims or methods will require reconsideration if the proposed research project is to proceed.

(17) Researchers also need to ensure they have conducted an appropriate institutional risk assessment and received any required safety clearances, prior to commencing research activities. This can include completion of a health and safety risk assessment, submission of a Safety Review form or submission via Tick@lab for high risk hazards or compliance requirements. See Risk Assessments for Teaching and Research for further information.

Part D - Specific Protocols For Aboriginal and Torres Strait Islander Research

(18) The following types of research are deemed to be 'more than low risk' and must be assessed by the HREC:

a. research involving the targeted recruitment of Aboriginal and/or Torres Strait Islander Peoples;
b. research involving recruitment from a geographical location where a significant number (20% or more) of the population are likely to be Aboriginal and/or Torres Strait Islander Peoples;
c. research focused on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander Peoples and where the population base has a significant proportion of Aboriginal and/or Torres Strait Islander Peoples; and
d. research involving access to existing collections of data/biospecimens from Aboriginal and/or Torres Strait Islander Peoples.

(19) The HREC process for assessment for proposed research projects listed in Clause 18 must include assessment by, or advice from:

a. people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; and
b. people familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.

(20) Researchers must consult relevant Ethics Guidelines and Policies when working with Aboriginal and Torres Strait Islander Peoples (see Section 1, Clause 3) and address relevant issues of research design, ethics, culture and language within their proposed research project.

(21) The HREC will also apply relevant Ethics Guides and Policies as per Section 1, Clause 3 as their basis for assessing proposals for research with Aboriginal and Torres Strait Islander Peoples.

(22) Researchers must incorporate the values, principles, and themes of the National Statement in the design of their project. Section 4.7 of the National Statement outlines how those values, principles and themes apply specifically in research with Aboriginal and Torres Strait Islander Peoples, and the HREC will use these to assess each application.

Part E - Ethics Approval

(23) In accordance with the Responsible Conduct of Research Policy, ethics approval for research involving humans must be gained before commencement of the research. This includes research that involves human data/records or biospecimens, including but not limited to:

a. people taking part in surveys, interviews or focus groups;
b. people undergoing psychological or physiological medical testing or treatment;
c. people being observed by Researchers;
d. Researchers having access to participants' personal documents or other materials;
e. the collection and/or use of any part of a participant's body, organs, tissues, fluids, commercially available cell lines, or their exhaled breath;
f. Researchers having access to participant information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database;
g. data to be collected from social media (e.g. Facebook, Twitter, blogs etc);
h. recordings of events (e.g. public events, legal hearings) where permissions are required.

(24) The use of data, documents or records that are all publicly available (such as publicly accessible archives or publications) does not require ethical approval, except where covered by clause 23.

(25) The application for ethics approval must clearly indicate the role that the University Researcher(s) will have in the proposed research project, and list the staff or students who will conduct the research.

(26) Ethical review is undertaken according to the degree of risk involved in the research (see Part B, clauses 16 and 17). Table 1 lists the approved University Ethical Review Bodies and the types of research proposals that can be considered by each body:

Table 1 – Ethical Review Bodies

Ethical Review Body	Types of Proposals Considered
College Human Ethics Review Panels (CHERPs)	Human research proposals involving minimal or low risk, as defined by the National Statement.
Human Research Ethics Committee (HREC)	Human research proposals involving more than low risk, as defined by the National Statement.

(27) All University ethical review bodies apply the values and principles of ethical conduct outlined in the National Statement, including research merit and integrity, justice, beneficence, and respect.

(28) The HREC Constitution describes how the HREC is to operate, including the scope of its responsibilities for ethics review; and sets out the framework for operating including the establishment of sub-committees, decision-making, delegated authority, and reporting.

Ethical Review for Collaborative Human Research

(29) The University of Newcastle is committed to undertaking world-class research and encourages its Researchers to collaborate with external colleagues and institutions to achieve this. The Collaborative Research Procedure covers the establishment of collaborative agreements with external parties, including government, commercial research organisations, industry and local health districts, as well as the conditions under which the University may recognise an ethical approval granted through an external process, and the circumstances under which ethical clearance through one of the University's authorised ethical review processes is not required.

Exemptions from Ethical Review or Ethical Approval

Literature Reviews

(30) Literature reviews do not require ethical approval.

(31) Meta analyses per se do not require ethical approval. Some data custodians, however, may require ethical

approval to access data, or ethical approval may be required as part of a data licencing agreement. This will usually be assessed by the relevant CHERP under the minimal risk pathway, but is dependent on the individual project, the sensitivity of the data, and the proposed research outputs.

Quality Assurance (QA) or Evaluation Projects

(32) QA is an evaluation of the quality of an existing program, practice, activity, or process taking place inside or outside the University. QA and evaluation projects may not require approval from the HREC.

(33) The following points may help to assist in identifying when a project is a QA or evaluation activity does not require ethical review:

a. the data being collected and analysed is coincidental to standard operating procedures with standard equipment or protocols;
b. the data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;
c. the data being collected and analysed is not linked to individuals; and
d. none of the triggers for consideration of ethical review (see below) are present.

(34) If one or more of the conditions below apply, the activity cannot be deemed as QA or evaluation, and ethical review is required:

a. the data will be used to answer a research aim(s), objective(s) or be published for a research purpose;
b. the data being collected and analysed will be linked to individuals;
c. data will be obtained by individuals that do not have usual access to that data as part of standard operating procedures or routine care;
d. the activity has the potential to infringe on the privacy or professional reputation of participants, providers, or organisations;
e. the data collated and/or analysed will be used for, or shared for, a secondary purpose unrelated to the standard operating procedures or protocols that it was collected for;
f. the activity involves the collection of data, biospecimens, or requires the conduct of additional investigations beyond that which is collected routinely;
g. the activity involves testing of non-standard (innovative) protocols, equipment, or the comparison of cohorts;
h. the activity involves randomisation or the use of control/placebo groups as a comparison; or
i. the activity involves targeted analysis of data involving minority or vulnerable groups.

(35) The Human Research Ethics Committee Quality Assurance Guidelines provides further specific advice.

Part F - Research Methods

(36) Ethical review bodies must assess proposed research projects against the criteria and standards relevant to research field/s and methodology/ies, guided by the National Statement. The seven elements common to all research which will be assessed by ethical review bodies are:

a. research scope, aims, themes, questions and methods;
b. recruitment;
c. consent;
d. collection, use and management of data and information;
e. communication of research findings or results to participants;

f. dissemination of research outputs and outcomes; and
g. after the project.

(37) Research methods must:

a. be defined and outlined in the research proposals submitted for ethical review ;
b. be developed in consideration of the requirements of this Manual;
c. be undertaken as per the ethically approved research protocol throughout the duration of the research project; and
d. not be modified without a Variation Application approval (see Variation Applications).

Part G - Recruitment Methods

(38) Researchers must develop and document their proposed participant recruitment methods prior to proceeding to peer review and ethics approval. The areas outlined in section 5 of this Manual must be considered where relevant to the particular research project.

Part H - Specific Ethical Considerations

(39) As required by the National Statement, specific ethical considerations must be addressed in any proposed research project where any of the following research groups may participate in, or be impacted by the research:

a. women who are pregnant and the human fetus;
b. people who are highly dependent on medical care;
c. people with a cognitive impairment, an intellectual disability, or a mental illness;
d. people who may be involved in illegal activities;
e. Aboriginal and Torres Strait Islander peoples; or
f. people in other countries.

Part I - Ethics Approval Record Management

(40) The Chief Investigator is responsible for ensuring that copies of external ethics approvals are registered in the University's Research Information Management Systems (RIMS) prior to the commencement of the approved research activity where this is required under Collaborative Research Procedure. Copies of the following documentation must be included:

a. external human ethics application;
b. approval letter from the external HREC;
c. any documents listed on the external approval letter (e.g. Information Statement and consent forms, surveys, assessments)
d. any correspondence with the external HREC leading to the approval (e.g. response to change requests or clarification).

(41) The RIMS User Guide for External Registrations provides instructions on how to lodge an external approval.

Part J - Disputes Regarding Decisions of the HREC

(42) Researchers may lodge a written request with the Ethics Officer (Human) for reconsideration of an ethical decision of the HREC within 14 working days of the date of the notification of HREC decision.

(43) The request must outline:

a. the reasons for the request; and
b. the evidence upon which the request is based.

(44) Requests for reconsideration will be reviewed by the HREC at their next scheduled meeting.

(45) Upon consideration of the request, the HREC may uphold its original decision or vary its decision.

(46) The HREC will notify the Researcher in writing within 10 working days of the meeting of its decision and detail the reasons for the decision.

(47) If the Researcher is dissatisfied with the procedures followed by the HREC in reconsidering its decision, the Researcher may refer the matter to the Deputy Vice-Chancellor (Research and Innovation). Upon referral, the Deputy Vice-Chancellor (Research and Innovation) can only review the procedures followed by the HREC in reaching its decision. The actual decision of the HREC cannot be reviewed.

(48) The Deputy Vice-Chancellor (Research and Innovation) may request the HREC to provide documentation or any other evidence of the procedures followed by the HREC in reaching its decision.

(49) The Deputy Vice-Chancellor (Research and Innovation) will:

a. notify the parties in writing on the date of receipt of the request for a review;
b. examine the documents provided by the HREC;
c. invite the Researcher to make any representations on the matter, in writing or in person;
d. invite the HREC Chair or nominee to make representations on behalf of the Committee, in writing or in person;
e. make a decision and notify the parties in writing of the decision within 20 working days from the date of receipt of the request for a review; and
f. either endorse the procedures followed by the HREC in reaching its decision, or request the HREC to review its procedures in reaching its decision and review its decision if procedural deficiencies are identified.

(50) If any party is dissatisfied with the decision of the Deputy Vice-Chancellor (Research and Innovation) or the dispute remains unresolved, the Deputy Vice-Chancellor (Research and Innovation) may refer the matter to an external mediator. The General Counsel and Chief Governance Officer will be responsible for identifying a person or agency external to the University to act as the external mediator.

(51) The role of the mediator will be to:

a. bring the disputing parties together to discuss the grievance;
b. assist parties to clarify the issues and to recognise areas of common interest and points of agreement, as well as points of disagreement;
c. explore with the parties possible solutions to the grievance; and
d. assist the parties to agree on a solution to be applied.

(52) The mediator shall not:

a. render judgement or act as a judge;
b. apportion blame;
c. impose solutions or penalties; or
d. act as an advocate for either party or offer legal advice.

Section 5 - Participant Recruitment

(53) Recruitment of any human participants (including advertising) cannot commence until ethical approval has been obtained.

(54) Please also see Part Q - Information Statements and Part P - Consent to Participate.

Part K - Recruitment of Participants via External Organisations

(55) Table 2 outlines the types of recruitment models that may be used to recruit participants for human research. Participants may be recruited via external organisations, including other institutions or businesses, using the following models:

a. the Distributor Model, where the external organisation is solely a conduit to potential research participants;
b. the Organisational Case Study or Workplace Research Model, where the external organisation is itself the subject of the research; or
c. a mixed model, with features of both a and b.

Table 2 – External Organisation Recruitment Models

Model	Description
Distributor Model	Provides access to a large potential participant pool of staff, customers, or members. The organisation is not the subject of research, but is used only to provide access to potential participants by distributing Information Statements, consent forms and/or surveys etc.
Organisational Study or Workplace Research Models	Involves the external organisation as the subject of the research. Researchers may, for example, be investigating aspects of the external organisation's performance, management, occupational health and safety, staff satisfaction or attitudes. Participation by the employees of the external organisation may be voluntary, or may be directed by the external organisation. The latter is most common in research by the external organisation.
Mixed Model	In this model, some aspects will be from the organisational model, and some will be from the distributor model.

(56) Table 3 outlines the consideration of timing and approach when determining which recruitment model might be used. The type of model used will affect the timing and initial approach to the external organisation, as outlined below:

Table 3 – Timing and Approach Methods

Model	Timing and Approach Method
Distributor model	Informally approach the external organisation before submitting application for ethical approval to ascertain their willingness to assist with the research. Approach a person within the external organisation who has the authority to make a decision regarding the distribution of information regarding the research, and who can distribute or direct the distribution of participant Information Statements and other information. When approaching external organisations, Researchers should: 1. identify if the external organisation has policies that preclude distributing surveys to people; 2. ensure that the external organisation is willing to distribute invitations to participate, or other material; 3. confirm that the external organisation will not be required to provide names or details of potential participants without the prior consent of the individuals involved, unless the information is already in the public domain; 4. confirm that the external organisation will not be advised of who has or has not participated in the research; 5. obtain a written indication of support, from a person within the external organisation with delegated authority, to submit with the application for ethical approval; and 6. advise the external organisation that the research will not proceed until it has been reviewed and receives ethical approval.
Organisational Study Model	An information in-principle agreement to participate in the research may be obtained from the external organisation prior to submitting an application for ethical approval. However, formal written approval must be obtained after all relevant documents have been approved by ethical review body and sighted by the external organisation. The formal approach to the organisation must be: 1. in writing; 2. addressed to a person with the appropriate authority in the organisation; and 3. accompanied by documents which have been approved by the ethical review body and already sighted by the external organisation. The accompanying documents should provide all necessary details including who is eligible to be a participant, and what will be required of them. The external organisation must be provided with an Information Statement and a consent form setting out the research and details of their involvement, in accordance with Part P and Part Q of this Manual.

Issues To Consider

(57) Potential participants must be made aware of the method of contact that may be used by the Researcher(s).

(58) When approaching participants via an external organisation, the Information Statement (see Part Q) must state how they have come to receive the invitation to participate in the research. For example:

> “You are being invited to participate in this research because you are a member of the Master ** Association (M**A). The M**A is distributing this invitation to its members on behalf of the researchers and has not provided any information about you to the Researcher.”

Protection of Organisational Contacts

(59) An individual's decision to participate must be informed and freely given. Recruitment methods should ensure this. Where participation is voluntary, i.e., not directed by their employing organisation, future contacts between potential participants and the Researchers should be direct i.e. not through the organisation.

(60) The Information Statement must:

a. assure potential participants in the study that the organisation will not be advised who participates; and
b. explain how potential participants can contact the Researchers for further information or to return surveys, consent forms, etc.

(61) Face-to-face activities, e.g., interviews or focus groups, should ideally be held at a venue other than the

organisation's premises. This is particularly important if participants are asked to comment on organisational practices or their relationship with the organisation and could be disadvantaged if the organisation was aware they had participated.

Anonymity

(62) When possible, participants should be able to contribute to the research anonymously. In the context of the use of online survey tools, in administering such surveys, Researchers should ensure the anonymity of participants in the following ways:

a. their identifying information must not be collected;
b. survey research, unless it has a follow-up phase, or where there is a duty of care to respond to information collected, must not ask for identifying information;
c. participants receive full information about the research and what it involves and indicate their consent by completing and returning the survey; and
d. feedback of results to participants participating anonymously can be catered for by either:
    i. publishing a summary of the results via the organisation's internal communications (e.g. newsletter, bulletin);
    ii. posting a summary on a website accessible to participants;
    iii. providing participants with a mechanism to request results separate to the anonymous survey; or
    iv. providing an email address for them to lodge a request for a summary.

(63) In other contexts, anonymity could be ensured through careful data management (see Part R of this Manual).

Participant and Researcher Contact Guidelines

(64) Where participants have been recruited through an external organisation, the following contact guidelines should be adhered to:

a. future contacts between participants and Researchers, where participation is voluntary, should be direct contact rather than through the external organisation; and
b. face to face activities such as interviews or focus groups, should ideally be held at a venue other than a venue of the external organisation.

Part L - Recruitment of University Students and Staff for Research

(65) Any research activity involving students and staff of the University will require prior ethical approval.

(66) Please refer to the Human Research Ethics Committee Quality Assurance Guidelines (and Part D clauses 5-7) for advice on quality assurance activities.

(67) It is acceptable for students to be approached after a class for the purposes of introducing an ethically approved research project and inviting their participation, with the prior approval of the Head of School, Course Co-ordinator (where appropriate), and Lecturer.

(68) Where students are being approached during or after the end of a class, there is to be no coercion from academic or teaching staff involved in the teaching unit.

(69) The introduction of a research project to students is to be undertaken by a person who does not have teaching and/or assessment responsibilities for those students, and students should be advised of their right not to participate.

Part M - Recruitment of Students from NSW Schools For Research

(70) The approval of the NSW Department of Education via the State Education Research Applications Process (SERAP) is required if research is to be conducted in NSW Government schools or TAFE Colleges. This may be sought while approval is being obtained from the University's HREC.

(71) If research is to be conducted in or involves students from schools not covered by the SERAP process (e.g. Catholic Diocese Schools, Independent Schools), approval from the relevant administrative body of that school is required.

(72) Recruitment of school students must be conducted in a manner that does not make participants or non-participants conspicuous by their decision.

Part N - Recruitment of Participants in Public Spaces

(73) Where recruitment is undertaken in a public space, participants should be made aware of the research prior to being approached. This could include the use of signage or other means of identifying the Researchers, and means to allow members of the public not to be included in an observation or other data collection process.

Part O - Recruitment Promotional Material Requirements

(74) University letterhead, appropriate to the School/College/Centre of the Chief Investigator or project supervisor, must be used on recruitment material when research is being conducted by staff or students of the University.

(75) Researchers must comply with the University's corporate standard where the University logo is used in any form. For more information please refer to the Marketing, Communications and Reputation Policy and Brand Guidelines.

(76) In some cases, where a Researcher has a dual role with the University and another institution or research centre, (e.g. University and Hunter New England Health) it may be appropriate to use a joint letterhead which supports the logos and identities of both institutions, or use the letterhead of the other institution or research centre.

(77) As a minimum requirement, acknowledgement of the University relationship in the opening paragraph of all Information Statements is required. In the case of research being conducted by students, this must extend to a statement which identifies the project as the research of a particular student(s), the course of study, and the supervisor(s).

(78) The Ethical Review Body is obligated to monitor approved research protocols, including the use of recruitment material. Where ethical approval has been granted by the University the Manager, Human Ethics must be listed on all participant information statements as being responsible for receiving complaints from participants.

(79) Where ethical approval has been granted by an external organisation, the contact for complaints should be as directed by the external ethical review body.

Section 6 - Participation in Research

(80) Researchers must ensure that a person’s decision to participate in research is voluntary and based on:

a. sufficient information;
b. an adequate understanding of the research; and
c. an adequate understanding of the implications of participating in it.

(81) Researchers must ensure that potential participants have an adequate understanding of the:

a. purpose;
b. methods;
c. demands;
d. risks; and
e. potential benefits of the research.

(82) Researchers must ensure this information is presented in ways accessible to all potential participants.

Anonymous Participation

(83) When possible, participants should be able to contribute to research anonymously.

(84) Where a participant has consented to participating anonymously, information that allows identification of a participant must not be collected as part of the research process.

(85) Participants who contribute to research anonymously must still receive an Information Statement (Part Q) that meets the requirements of this Manual.

Part P - Consent to Participate

(86) This section should be read in conjunction with Part Q – Information Statements; and relevant sections of the National Statement, including but not limited to:

a. Chapter 2.2 General requirements for consent;
b. Chapter 2.3 Qualifying or waiving conditions for consent.

When is Consent to Participate Required?

(87) Arrangements for the consent of research participants must be in accordance with the National Statement, based on giving due scope to people's capacity to make their own decisions. Consent should be a voluntary choice, based on sufficient information and adequate understanding of both the proposed research and the implications of participating in it.

(88) Where consent has been provided, participants must be offered copies of an Information Statement and consent form to retain.

(89) Specific consent is required on the consent form if the project involves recordings that will be archived. Consent must also be obtained if Researchers believe that they may wish to re-use any recording. For the type of consent required (specific, extended, or unspecified) and procedures relating to this, refer to National Statement 2.2.14 - 2.2.18.

(90) People should not be expected to identify themselves for the sole purpose of denying consent i.e. they should only be asked to return a consent or participation form if they are consenting.

(91) Research involving medical procedures must not be undertaken without the consent of those involved or other lawful justification.

Consent for Research Participation by School Students

(92) Research conducted in schools generally requires written parental consent to be obtained for every school child who participates in research.

(93) Researchers are encouraged to design their recruitment process in a way that encourages a joint decision being reached by the parent/guardian and the student (e.g. parent/guardian consent with child assent). Where parent/guardian consent has been provided, the final decision regarding participation should generally rest with the child.

(94) If Researchers are considering using another form of consent (e.g. opt-out or child consent) they should undertake prior consultation with the appropriate governing body (eg, NSW Department of Education SERAP) for advice regarding the feasibility of the proposed approach, prior to preparing their research proposal for ethical approval.

(95) Where the Researchers have confirmed with the appropriate governing body that an opt-out consent process might be considered, a more than low risk research proposal must be submitted to the HREC for consideration. The application must address the requirements of sections 2.3.5 to 2.3.8 of the National Statement.

(96) Where it is necessary to group consenting students together, prior arrangements should be made with the school to provide alternative activities for those students for whom consent is not received.

(97) If there is any doubt about obtaining parental/guardian and/or child consent, contact your local Research Ethics Advisor or the Human Research Ethics Team for advice.

Consent to future use of data and tissue (biospecimens) in research

(98) Consent for future use of data and tissue in research may be:

a. specific – limited to a specific project;
b. extended – given for the use of data or tissue in future research projects that are an extension of the existing project, or in the same general area of research; or
c. unspecified – given for the use of data or tissue in any future research.

(99) The type of consent requested, and subsequently given by a participant, will determine when, how and if the data or tissue collected can be used in the future.

(100) Refer to the National Statement (2.2.14-18) to determine which type of consent is appropriate.

Qualifying or waiving conditions for consent

(101) 'Limited Disclosure' of the aims and/or methods of research may sometimes be required for research, but must be fully justified within the research proposal submitted for ethical approval. This approach is required because in some human research (for example, in the study of behaviour), the aims of the research cannot be met if those aims and/or methods are fully disclosed to participants during the initial consent process.

(102) Research involving limited disclosure covers a spectrum. Researchers must clarify exactly what qualification they are putting on their disclosures, for example:

a. observation in public spaces of everyday behaviour;
b. covert observation;
c. undisclosed role-playing by a Researcher to investigate participant responses;
d. telling the participants the aim of the research is one thing when it is in fact quite different.

(103) Depending on the circumstances of an individual project, it may be justifiable to employ an opt-out approach or a waiver of the requirement for consent, rather than seeking explicit consent. This will be assessed by the ethical review body on a case-by-case basis, subject to National Statement guidelines. For more information, refer to the

National Statement for:

a. limited disclosure (National Statement 2.3.1 - 2.3.4);
b. opt-out approach (National Statement 2.3.5 - 2.3.8);
c. waiver (National Statement 2.3.9 - 2.3.12).

Capacity to Give Consent

(104) Participants who provide consent must have the necessary capacity to give that consent. Where the participant demonstrates that they do not have capacity to give consent, the Researcher is required to consider any additional strategies that are needed to ensure that informed consent is obtained in accordance with the National Statement – refer to:

a. Chapter 4.2: Children and Young People;
b. Chapter 4.4 People highly dependent on medical care who may be unable to give consent; and
c. Chapter 4.5: People with cognitive impairment, an intellectual disability, or a mental illness.

(105) Where a potential participant is competent to give consent but is unable to sign a consent form or read an Information Statement, an audio recording of a reading of the Information Statement and the participant's verbal consent may suffice.

(106) It is the Researchers' responsibility to be aware of any constraints on participants in understanding the Information Statement or obtaining consent, and to propose alternate strategies to gaining informed consent in the research proposal submitted to the ethical review body.

Implied Consent

(107) Where participation in research can be conducted anonymously, as per Clause 82, consent is implied by participating.

Witnessing Consent Signatures

(108) It is not necessary to have signatures witnessed where participants are competent to sign for themselves. However, that is not to say that participants' signatures cannot be witnessed. For example, if the Researcher or a trial sponsor considered it important to have participants' signatures witnessed then the Ethical Review body would usually have no objection to this occurring, and a member of the research team could witness a participant's signature.

Templates

(109) Consent Form – Sample Content.

Renegotiating Consent

(110) In some research (e.g. projects which are long-running or complex in nature), consent may need to be renegotiated or confirmed from time to time. Participants should be told if there are changes to the terms to which they originally agreed, and given the opportunity to continue their participation or withdraw (National Statement 2.2.8, 5.2.17, 5.2.19).

Withdrawing or Declining Consent

(111) People are free to choose to not participate in a research project. They do not need a reason for their decision, and they should not suffer disadvantage as a result of their decision (National Statement 2.2.19).

(112) Participants who chose to participate in a research project are entitled to withdraw from the research at any stage (National Statement 2.2.20). Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.

(113) Where reimbursements or incentives are offered (See Part S), participants must be able to withdraw at any stage of the project without financial penalty.

Part Q - Information Statements

(114) Potential participants must be provided with an Information Statement to allow them to make an informed decision to participate, or consent to participate. Sufficient information must be made available to potential participants to ensure they understand the purpose, methods, demands, risks, and potential benefits of the research. This information should be presented in a manner that suits each participant. Researchers are encouraged to consider alternate or complimentary ways of providing this type of information to meet the needs of their target audience (e.g. infographic or video formats).

(115) Research proposals that involve a survey to be distributed or completed on-line must have an Information Statement that meets the requirements of this Manual. The Information Statement can be presented on-line, but must:

a. be provided to website visitors before they access any survey; and
b. be easily and anonymously exited from should the website visitor choose to not participate.

(116) Where research is likely to involve the collection, and other processing, of personal information and/or health information, the Information Statement must comply with the requirements of the Privacy Management Plan.

Information Statement Requirements

(117) The objective of the Information Statement is to provide information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the benefits of the research) so that a participant can make an informed choice regarding their participation.

(118) All Information Statements must:

a. be written in plain language, and explain any specialised terms;
b. take into consideration language and cultural issues that may be related to the target population;
c. be at the participant's level of comprehension;
d. if directed at children, contain information as brief as the detail will allow, and use language appropriate to the child's age;
e. inform the participant as to how they have come to receive an invitation to participate in the research; and
f. be presented in a way that helps the potential participant to make a decision about their participation, and support that participation, including:
    i. using small paragraphs, dot points and section headings where appropriate;
    ii. using appropriate font size and correct grammar; and
    iii. emphasising important information.

(119) The following information should also be included in the Information Statement, but kept distinct from the information required under Clause 118:

a. contact details of the Researcher;

b. any alternatives to participation;
c. the likelihood and form of publication of research results;
d. details of how to make a complaint as well as contact details of persons who should receive complaints (See Section 9);
e. full details of reimbursements or incentives that may be offered (see Part S);
f. acknowledgement of the University's relationship with any other institution or research organisation involved, where applicable;
g. how the collection and/or processing of personal information or health information will be handled confidentially and in accordance with the University's Privacy Management Plan (with specific reference to the requirements of open collection under state, federal and international legislative requirements where applicable);
h. how the research will be monitored;
i. the provision of services to participants who may be adversely affected by the research;
j. the participants' right to withdraw their consent to participate, and any implications of this;
k. the sources of funding for the research;
l. expected benefits to the wider community; and
m. any other relevant information.

(120) Consideration should also be given to providing Information Statements using alternative communication methods to account for any visual, hearing, or communication impairment.

Additional Requirements for Children and Student Participants

(121) Where parents are being requested to consent to their child's participation, the Information Statement must request parents to discuss the research invitation with their child, and state that where parents give consent to their child participating in a research project, the final decision will be the child's.

(122) Students and their parents are to be assured in the Information Statement that participation or non-participation will not affect their school assessment.

Additional Requirements for Research Involving Recording or Transcription

(123) For research projects that involve collection of audio or video recordings, Information Statements must:

a. advise participants if they will be offered reviewing or editing opportunities where the research will comprise audio or video recording or transcription; and
b. inform if any recordings of the participant obtained during the research are to be archived, or if the recording will be re-used.

Additional Requirements for Sponsored Clinical Trials

(124) Where the research involves a sponsored clinical trial, participants must be informed of any compensation available to them should they be injured as a result of their participation in the trial. The following should be added to the Information Statement:

> "In the event that you are injured as a result of your participation in this study, compensation has been made available from the sponsor and will be awarded according to the Medicines Australia 'Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial'. The compensation provided is additional to that available to you under common law and does not replace your normal legal rights."

Additional Requirements for Participants Recruited via an External Organisation

(125) Where participants are recruited via an external organisation, the Information Statement must:

a. assure participants that the external organisation will not be advised as to who participates; and
b. explain how potential participants can contact the Researchers for further information, or to return surveys or consent forms.

Additional Requirements for Research Conducted via Telephone Interviews

(126) Where telephone interviewing is to be conducted as part of the research, the Information Statement should forewarn any potential participants of any telephone contact and include the following information in the Information Statement:

a. how names, addresses and telephone numbers of the target interviewees were obtained;
b. if a particular interviewee is preferred, and why;
c. details of the nature and types of questions to be asked;
d. when the interview will take place, and its expected length; and
e. how the target population may prevent telephone contact.

(127) The Information Statement should also advise recipients who do not want to participate that they can advise the caller when they make contact.

Templates

(128) Information Statement - Template

(129) Information Statement for Anonymous Surveys or Questionnaires

Part R - Interview Recording and Transcribing

Right of Review

(130) Research participants should generally be given an opportunity to review, edit or erase any audio or video recording to which they have contributed. If this is impractical, as with group recordings, individuals should be given an opportunity to review, edit or erase their contribution on a written transcript of the recording.

(131) If Researchers are concerned that allowing participants to edit their contributions in recordings or transcripts of interview might have adverse implications for the research data, they are required to clearly demonstrate in their application for ethical approval that they will:

a. ensure participants are fully aware of the process entailed in the interview, transcription, and subsequent data analysis; and
b. offer participants an opportunity to confirm, usually in writing, their consent to use of the recording following a recorded interview or prior to commencing analysis of any data.

Privacy and Confidentiality

(132) Participants should be advised not to identify themselves or third parties in audio and video recordings, except where it is essential to the research and where participants have been fully informed of the implications.

(133) Interviewees should be asked not to name third parties on recordings without their prior consent, particularly if

their comments might be considered insulting or defamatory.

(134) Where it is essential to the research, collection of personal information and/or health information, such as the identification of a participant, must be conducted in accordance with the University's Privacy Management Plan.

(135) A recording can never be completely anonymous. Researchers should only name participants in the research if the participant has given specific consent to be identified.

(136) All transcripts should identify interviewees by code, rather than by name. If the recording and/or transcript is lost, stolen, or mislaid, this will assist in protecting an interviewee's privacy. Similarly, transcripts returned to participants cannot be guaranteed to reach that person alone.

Appropriate Handling of Interview Recordings

(137) Digital interview recordings require additional precautions to ensure security if stored on a computer or portable media. Such recordings must have password protection and appropriate secure storage in accordance with the University's Digital Security Policy and its associated documents.

(138) Where the interview recording contains personal information and/or health information, the recording must be handled in accordance with the University's Privacy Management Plan.

(139) Specific consent on the consent form is required where interview recordings are to be archived or re-used.

Transcription of Interviews or Focus Groups

(140) Transcription should usually be undertaken by the Researchers.

(141) If it is to be undertaken by persons other than the Researchers, participants must be informed as this may compromise data security and a participants' privacy.

(142) Where transcription services are utilised:

a. due diligence must be conducted to ensure that the service provider is able to meet the requirements of the University's Privacy Management Plan;
b. the service provider must sign a confidentiality agreement; and
c. Researchers must choose a service provider who uses onshore data storage.

(143) Researchers must offer participants the opportunity to review the recording or the transcript to confirm they are happy with their contribution. Researchers will be required to justify a decision to not require participants to validate their transcribed interview responses in their application to the ethical review body.

Telephone Interviewing

(144) All unsolicited telephone contact made by University Researchers must be conducted in accordance with the Telecommunications (Telemarketing and Research Calls) Industry Standard.

(145) Researchers using telephone interviewing should be aware of its methodological implications, and must meet the requirements set out in this Manual.

Advance Written Advice

(146) As a general rule, the target population should receive advance written advice, and an Information Statement to forewarn them that telephone contact will be made (See Part Q – Clauses 126-127).

(147) An exception to sending written advice in advance of the telephone survey may be accepted by the HREC when a spontaneous response is required, or when the questions are demonstrably not sensitive or are not soliciting personal information.

The Telephone Interview and Script

(148) An indicative interview script must be submitted with the application to the ethical review body.

(149) The script introduction must clearly identify the caller, the University, and the project; and must refer to any written advice previously sent to potential interviewees.

(150) In situations where advance written notice has not been provided, the script must also:

a. identify the Ethics Officer (Human) contact details for complaints;
b. indicate how the Researcher can be contacted; and
c. provide an offer of written information if required by the potential participant.

(151) The specific nature of the call should not be disclosed if a third party answers.

(152) The script must cater for people who have not received the written material sent to them, for example, where mail has been lost or people have changed addresses. All potential participants must have:

a. received an Information Statement, unless Clause 115 applies; and
b. considered whether they are willing to participate prior to the interview.

(153) Researchers are advised to ascertain if interviewee's wish to continue after each 5 to 10 minute period, and to warn if questions about sensitive issues are about to be asked.

(154) The conclusion of the interview should include a thank you statement on behalf of the Researcher and the University, for the interviewee's time.

Training

(155) Researchers using telephone interviews must provide the ethical review body with details of the training of interviewers, including student interviewers.

Part S - Incentives for Participating in Research

(156) Incentives to participate in research may be offered to potential research participants to cover the costs associated with participating in the research. Costs will usually include:

a. travel;
b. parking; and/or
c. any accommodation or meals that may be required.

(157) Reimbursement may also be necessary to cover associated costs such as income forgone, childminding fees, or similar expenses.

Types of Incentives

(158) Incentives may be provided in the form of:

a. cash;

b. in kind (e.g. parking or shopping vouchers); or
c. course credit.

(159) An alternative option is to recognise participants' willingness to participate by, for example, providing tickets in a prize draw. If a prize draw method is used, it is considered a gratuitous lottery and must be conducted in accordance with the Lotteries and Art Unions Act 1901 (NSW).

(160) Other methods may be acceptable, but all incentives and reimbursements must comply with relevant law. Cash payments, for example, are subject to Health and Safety Guidelines (refer Section 3.1.9 Offsite Visit / Interview Safety Guidelines).

(161) Researchers may provide incremental payments when successive components or activities involving participants are completed.

Informing Participants

(162) If an incentive or reimbursement is to be offered, participants must be advised of the type and amount and any conditions affecting when or how it will be paid. The type or amount may be indicated on advertising posters or handouts.

(163) Full details of incentives or reimbursements must be provided on the participant Information Statement and given to potential participants in sufficient time to allow them to ask questions and make informed decisions.

(164) It cannot be a condition of payment that a participant completes their involvement prior to receiving an incentive reimbursement.

Incentive Amounts

(165) The level of any incentive offered must not induce or entice a person to take risks and must be commensurate with the activity. For example, an incentive for a very brief commitment that involves little cost or inconvenience to participants is likely to be small compared to that for longer involvements that might cause the participant to forego income or experience marked inconvenience.

(166) The ethical review body is obliged to ensure that the level of incentive or reimbursement offered is commensurate with the activity and not an unreasonable inducement for a person to participate themselves, or to involve those for whom they are legally responsible.

(167) Where the preferred incentive for participation is course credit, students should not be encouraged to accept a level of risk higher than would be considered acceptable where course credit was not available.

(168) The amount of incentive or reimbursement may be challenged by the ethical review body where it seems high. Researchers are strongly advised to provide a brief justification of incentive and reimbursement amounts in their application to facilitate ethical review body decision making.

Section 7 - Maintenance of Approved Research Projects

Variation Applications

(169) Proposed amendments to an approved human ethics protocol, including changes to personnel (additions, removals) must be made using a Variation Application submitted to the ethical review body.

(170) The proposed amendments cannot be implemented until the Variation Application has been approved.

Safety Monitoring

(171) Researchers must comply with any safety monitoring conditions of approval for research projects, particularly those involving clinical trials.

(172) Researchers are responsible for informing the Manager, Human Ethics if they become aware of any new safety information that may impact on the continued ethical acceptability of their research.

Adverse Event Reports

(173) It is the responsibility of the first named Researcher (Chief Investigator / primary supervisor) on an ethically approved research proposal to report adverse events.

(174) Adverse events, however minor, must be recorded by the Researcher as observed by the Researcher or as volunteered by a participant in the research. Full details are to be documented, whether or not the Researcher (or their research team members) consider the event to be related to the research substance or procedure.

(175) Serious or unforeseen adverse events must be reported by the first named Researcher:

a. to the University, via the Manager, Human Ethics, within 24 hours of the occurrence of the event or the Researcher receiving advice of the event; and
b. via submission of an Adverse Event Report within 72 hours of the occurrence of the event or the Researcher receiving advice of the event.

(176) Serious adverse events are defined as:

a. Causing death, life threatening or serious disability;
b. Causing or prolonging hospitalisation;
c. Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure;
d. Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma; or
e. Any other event which might affect the continued ethical acceptability of the project.

(177) Where an adverse event is related to a potential breach of privacy, the Researcher should immediately contact the University's Privacy and Rights to Information Manager for appropriate guidance in managing the event.

(178) Adverse events which do not fall within the definition of serious or unexpected, including those from other sites involved in the research, are to be reported in detail at the time of the annual progress report.

(179) The requirements for reporting adverse events are communicated to the Researcher(s) in the initial ethical approval letter.

(180) The Manager, Human Ethics is responsible for:

a. the initial review of all adverse event reports; and
b. referral of all adverse event reports for review by the relevant ethical review body.

(181) The ethical review body may:

a. consider escalation of monitoring of the project;
b. consider withdrawing ethical approval of a project where concerns or risks cannot be mitigated; or
c. require a Researcher to amend procedures based on information provided in adverse event reports. In this event Researchers are required to submit a Variation Application for approval (Clauses 169-170).

(182) Where the ethical review body recommends that an adverse event may warrant suspension or cessation of a research project, they will escalate the matter to the Deputy Vice-Chancellor (Research and Innovation) for consideration under Section 8 of this Manual.

Progress Reports

(183) Researchers are required to prepare and submit a progress report for each research project on an annual basis, due on the anniversary of the project approval date.

(184) Failure to submit a progress report when requested will result in the expiry of ethical approval. Researchers will receive notification of the expiry as well as advice that all research activity must cease immediately (except in rare cases where it would pose harm to a participant).

(185) Progress reports will be reviewed by the Research Ethics and Integrity Unit and escalated to the HREC Chair or CHERP Convenor if the progress report raises concerns.

(186) When considering concerns, the HREC Chair or CHERP Convenor may:

a. require a Researcher to amend procedures based on information provided in progress reports. In this event Researchers are required to submit a Variation Application for approval (see Clauses 169-170); or
b. recommend suspension of ethical approval to allow further time and consideration where concerns or risks cannot be immediately mitigated.

Final Progress Reports

(187) A Final Progress Report is required to be submitted by the Chief Investigator (CI) to the ethical review body as soon as practicable once the research is completed.

Section 8 - Suspension or Cessation of Research

Deputy Vice Chancellor (Research and Innovation) Responsibilities

(188) The Deputy Vice-Chancellor (Research and Innovation) may suspend or cease a research project:

a. as a result of application of the Research Breach Investigation Procedure;
b. when notified by the ethical review body of a change in risk where participants' welfare becomes compromised; or
c. when an adverse event indicates participants' welfare is compromised.

(189) All suspension / cessation actions must be conducted in accordance with the University's Student Code of Conduct, and address the following principles:

a. fairness, respect and due process;
b. clear and transparent communication with all relevant parties; and
c. suitable transition arrangements for all relevant parties and the project.

(190) The Deputy Vice-Chancellor (Research and Innovation) must communicate any suspension or cessation instructions to the Chief Investigator, and other Researchers involved in the project.

Chief Investigator Responsibilities

(191) As soon as becoming aware that a research project is to be discontinued before the expected completion date, the CI must notify:

a. the ethical review body that granted approval;
b. external collaborators involved in the project;
c. research staff involved in the project; and
d. participants (where possible).

(192) In the event a CI is unable to fulfill the obligations of Clause 191 the supervisor of the CI (e.g. Head of School; College Pro Vice-Chancellor) must ensure the above requirements are met.

Section 9 - Complaints

(193) Complaints about Researchers or the conduct of research, may be made by participants, Researchers, institutional staff, or others. (For disputes regarding HREC decisions, see Part J).

(194) Participants who have concerns about their rights as a participant in research, should initially raise their concerns with the Researcher. If they have a complaint about the conduct of research, the Ethics Officer (Human), who oversees a complaints process independent of the Researcher, should be contacted.

(195) The Ethics Officer (Human) is the nominated person to whom complaints about Researchers, or the conduct of an approved research project, may be directed. The Ethics Officer (Human) can be contacted via human-ethics@newcastle.edu.au.

(196) Where the complaint identifies potential breaches of the Australian Code for the Responsible Conduct of Research, the matter will be handled in accordance with the University's Research Breach Investigation Procedure and any relevant enterprise agreement.

(197) Where the complaint identifies matters considered to be misconduct or serious misconduct in relation to a University staff member who is subject to an Enterprise Agreement, the matter will be handled in accordance with the relevant enterprise agreement.

(198) Where the complaint may be in relation to a breach of privacy, the matter must be referred to the University's Privacy and Rights to Information Manager.

(199) All other complaints will be handled in accordance with the University's Complaint Management Policy.

(200) Complaints may be made anonymously.

(201) Where complainants are identifiable, unless permission is granted by the complainant, their personal details shall be retained confidentially with access limited to the following:

a. the Manager, Human Ethics;
b. Chair of the HREC; and
c. authorised senior officers of the University.

(202) In receiving complaints in accordance with this Manual, the Manager, Human Ethics will:

a. provide acknowledgement of a complaint to the complainant within two working days;
b. advise the HREC Chair and Chief Investigator of the nature of the complaint within two working days, and invite a response from the CI;
c. work to resolve the complaint (where relevant);
d. refer to the HREC for determination where deemed necessary or appropriate; or
e. report the nature of the complaint and the action taken to the HREC at the next scheduled meeting; and
f. provide the complainant with written notification of the outcome of the complaint investigation process.

(203) Where deemed necessary or practical the HREC Chair may undertake the responsibilities outlined in Clause 201 or collaborate with the Manager, Human Ethics.

(204) Where the Manager, Human Ethics or HREC Chair, is unable to resolve a complaint, the matter will be referred to the Deputy Vice-Chancellor (Research and Innovation) and/or the University's Complaints Officer. Written notification of the outcome of a complaint will be provided to the complainant by either of these parties in the instance where the complaint is escalated.

Status and Details

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Responsible Executive	Craig Simmons Deputy Vice-Chancellor (Research and Innovation)
Enquiries Contact	Research Ethics and Integrity Unit

Glossary Terms and Definitions

"University" - The University of Newcastle, a body corporate established under sections 4 and 5 of the University of Newcastle Act 1989.

"Risk" - Effect of uncertainty on objectives. Note: An effect is a deviation from the expected, whether it is positive and/or negative.

"Risk assessment" - The overall process of risk identification, risk analysis, and risk evaluation.

"Working day" - Any day other than Saturday, Sunday, or a public holiday in Newcastle, on which business may be conducted.

"Course" - When referring to a course offered by the University, a course is a set of learning activities or learning opportunities with defined, assessed and recorded learning outcomes. A course will be identified by an alphanumeric course code and course title. Course types include core courses, compulsory courses, directed courses, capstone courses and electives. For all other uses of this term, the generic definition applies.

"Credit" - When referring to course credit, credit is the recognition of equivalence in content and learning outcomes between different types of learning and/or qualifications. Credit can reduce the amount of learning required to achieve a qualification. For all other uses of this term, the generic definition applies.

"Personal information" - Has the same meaning as in the Privacy and Personal Information Protection Act 1998 (NSW).

"Student" - A person formally enrolled in a course or active in a program offered by the University or affiliated entity.

"Candidate" - With regard to Higher Degree by Research it has the same meaning as student. For all other instances it is a person considered for appointment to a position.

"External parties" - Any individual or organisation external to the University.

"Health information" - As defined in the Health Records and Information Privacy Act 2002, or any replacing legislation.

"Lecturer" - All teaching academics including lecturers (of all levels), sessional academics and conjoint academics.

"Research" - As defined in the Australian Code for the Responsible Conduct of Research, or any replacing Code or document.

"School" - An organisational unit forming part of a College or Division, responsible for offering a particular course.

"Staff" - Means a person who was at the relevant time employed by the University and includes professional and academic staff of the University, by contract or ongoing, as well as conjoint staff but does not include visitors to the University.

"College" - An organisational unit established within the University by the Council.