HUMAN ETHICS PROCEDURES

Contents

PART 1 INTRODUCTION

1.1 Purpose and application

(1) These procedures:

(a) Are informed by the National Statement on Ethical Conduct in Human Research 2025 (National Statement), the University of Sydney Research Code of Conduct 2023 and the Australian Code for the Responsible Conduct of Research 2018 and its supporting guides; and

(b) Provide a framework for ensuring that human research at the University of Sydney (the University) is ethically reviewed and monitored in accordance with the National Statement.

(2) These procedures are carried out by staff in the Ethics Office and members of the Human Research Ethics Committee (HREC) and Subcommittees.

1.2 Commencement

These procedures commenced on 10 September 2026.

1.3 Interpretation

(1) Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the University of Sydney Research Code of Conduct 2023.

National Statement on Ethical Conduct in Human Research (National Statement)	means the agreed set of principles and guidelines published by the National Health and Medical Research Council that provide a common reference for decisions about the ethical nature of human research.
National Health and Medical Research Council (NHMRC)	means the main statutory authority of the Australian Government responsible for medical research.
Human research	means research involving human participants, or their data or tissue.
Research	means the creation of new knowledge and/or the generation of new concepts, methodologies, inventions and understandings from existing knowledge, contributing to the body of knowledge - typically through publication. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Committee	means a University of Sydney Human Research Ethics Committee (HREC) assembled to review human ethics applications.
Subcommittee	means a body established by the Human Research Ethics Committee/s to expedite effective ethics review of specific matters, e.g. amendments, lower risk human ethics applications and exemptions.
myResearch Ethics	means the online research information management system.
Asynchronous meeting	means a meeting with a specific purpose that is held over a defined period of time, but participants do not need to be available to participate simultaneously (synchronously). The actual process followed can vary, but all contributions should be available for consideration by all other members before a decision is reached.

Flying minute	means a method of recording decisions made by a Committee or Subcommittee outside of scheduled meetings, for instance, the approval of matters that are time sensitive. Information is provided to all decision-makers, approvals are captured in writing and collated, and then a decision is determined based on consensus, in consultation with the Chair where required.
Workload allocation	The University Executive endorsed a standardised workload allocation of 0.1FTE for academic staff members of human research ethics committees or subcommittees (Resolution UE-21/32-7, September 2021 meeting). Schools and faculties can determine how the ethics committee member workload allocation is recognised (i.e. public service, teaching relief, research support), with a strong preference that it is not exclusively public service.

PART 2 THE HUMAN RESEARCH ETHICS COMMITTEES

2.1 Establishment and role

(1) The University established the Human Research Ethics Committees to review, monitor and maintain oversight of human research conducted by staff, students and affiliates of the University in accordance with the National Statement.

(2) The Human Research Ethics Committees' establishment, composition and functions are set out in the Human Research Ethics Committees Terms of Reference. These Terms of Reference have been informed by the National Statement.

(3) Each Human Research Ethics Committee assembles on a regular basis to review applications. Each Committee is fully constituted according to the composition set out in the National Statement and Human Research Ethics Committees Terms of Reference.

2.2 Appointment and term of membership

(1) Volunteers express interest in membership of an ethics committee, and provide a summary of their relevant experience for review by a committee chair. Subject to endorsement, members are appointed by the Deputy Vice-Chancellor (Research). Prospective members of a Human Research Ethics Committee may also be recruited by direct approach, nomination or by advertisement. Where possible, this is carried out in consultation with current members, the Chair/s and faculties.

(2) The Deputy Vice-Chancellor (Research) will provide each member with a letter including the date of appointment, length of tenure, responsibilities, membership category, a confidentiality statement, details of any benefits with which they will be provided and confirmation that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a Human Research Ethics Committee member.

(3) The term of appointment for members of a Human Research Ethics Committee is ordinarily three years.

(4) Notwithstanding clause (3), where a Committee is established for a defined pilot period or other fixed-term purpose, members may be appointed for a shorter term aligned with the duration of that period or purpose, as specified in the letter of appointment.

(5) Committee members are typically appointed for one year in the first instance, with the potential for a further two years to complete a three-year term, subject to mutual agreement. Membership is reviewed at least every three years.

(6) Members may be reappointed for an additional three-year term upon mutual agreement and are limited to a maximum of two consecutive terms. Any extension beyond this limit is at the discretion of the Deputy Vice-Chancellor (Research).

(7) Chairs of each Committee and Subcommittee are initially appointed by the Deputy Vice-Chancellor (Research) for one year with potential for a further two years upon mutual agreement. Chairs may be reappointed for an additional three-year term. Chairs are limited to two consecutive terms of three years duration per term. Any extension beyond this limit is at the discretion of the Deputy Vice-Chancellor (Research). The exception is the Human Research Ethics Committee Executive where the Human Ethics Manager is the ex officio Chair, therefore appointment requirements and term limits do not apply.

(8) Deputy Chairs of each Human Research Ethics Committee are appointed by the Deputy Vice-Chancellor (Research) with the recommendation of the Chair. Deputy Chairs are initially appointed for one year with potential for a further two years. Deputy Chairs may be reappointed for an additional three-year term. Deputy Chairs are limited to two consecutive terms of three years duration per term. Any extension beyond this limit is at the discretion of the Deputy Vice-Chancellor (Research).

(9) Deputy Chairs of each Subcommittee may be appointed informally from among the members of the Subcommittee with the agreement of the Chair.

(10) Where a casual member is appointed to fill a vacancy, their appointment will expire at the time when the appointed member returns or when their term expires. The casual member may then be appointed for an additional term.

(11) Individual members are allocated to a Committee or Subcommittee by the Research Integrity and Ethics Administration in consultation with the Chair/s, considering requirements listed in this Part and any other criteria deemed relevant. Members' preferences in relation to a particular committee and meeting dates are sought to inform decision-making about member allocation.

(12) Each member may not review any applications until they have signed a confidentiality undertaking and completed an induction program.

(13) Members may resign their membership by written notice to the applicable Committee or Subcommittee Chair and the Human Ethics Manager. Ethics Office staff will notify the Deputy Vice-Chancellor (Research). Members should provide the Committee with 3 months' notice of their intention to resign, wherever possible.

(14) The Deputy Vice-Chancellor (Research) may terminate the appointment of any Human Research Ethics Committee member in writing if the Deputy Vice-Chancellor (Research) is of the opinion that:

(a) It is necessary for the proper and effective functioning of the Human Research Ethics Committee;

(b) The person is no longer qualified or fit to serve on a Human Research Ethics Committee; or

(c) The person has failed to carry out their duties as a Human Research Ethics Committee member.

2.3 Frequency of meetings

(1) Each Human Research Ethics Committee meets regularly, typically on a monthly or equivalent periodic basis, or as required to meet operational needs.

(2) Meeting dates and indicative agenda closing dates are published on the University Human Ethics intranet site.

(3) Extra-ordinary meetings may be called when required.

(4) Subcommittees meet according to the schedule set out in their Terms of Reference.

2.4 Attendance at meetings

(1) Attendance at meetings is online or in person, according to the arrangements specified in each meeting request.

(2) Wherever possible, meetings are arranged to enable attendance of all members of the minimum membership categories (see the Human Research Ethics Committee Terms of Reference) and other relevant appointed members, either in person or online.

(3) Members will advise of their availability for meetings or request to be listed as an apology if they are unavailable, noting if they are still able to review applications prior to the meeting.

(4) When a Human Research Ethics Committee member is absent from four (4) consecutive regularly scheduled meetings, without an approved leave of absence, they forfeit their role on the Committee.

(5) When a Subcommittee member is absent for an extended period of time without an approved leave of absence or other arrangement, they may forfeit their role on the Subcommittee.

(6) The Ethics Office maintains a record of how many members in each membership category were present on the minutes of each Human Research Ethics Committee meeting. This information may be released publicly on request. The names of individual members are not disclosed without the consent of the members.

2.5 Attendance of researchers and observers at meetings

(1) Researchers, potential new committee members and other observers may attend a meeting (or part of a meeting) with permission from the Chair.

(2) Researchers or representatives from other organisations may present their applications and respond to questions from the Committee or Subcommittee at the discretion of the Chair, but are not present during deliberation and decision making.

(3) All observers are subject to the same confidentiality and disclosure of interest requirements as Committee members.

2.6 Conduct and structure of meetings and deliberations

(1) Meetings are conducted in an organised and orderly manner, following the order of the agenda, unless rearranged with the agreement of the Chair.

(2) The Chair leads the following order of proceedings for each item discussed:

- (a) Members who were allocated as reviewers:
  - (i) present a brief summary of the application they have reviewed and entered into myResearch Ethics;
  - (ii) explain any ethical considerations they have identified in relation to the application and the clarification/action required by the researcher; and
  - (iii) propose an outcome category as set out in the HREC Induction Manual.
- (b) Other members discuss ethical considerations and raise any additional queries to be clarified by the researcher.
- (c) The Chair determines the decision reached, preferably by general agreement or consensus.
- (d) The Secretary records:
  - (i) key discussion points not already entered into myResearch Ethics;
  - (ii) the decision and associated outcomes or special conditions to be communicated to the researcher; and
  - (iii) the dissent of any member, including the reasons where requested by the dissenting member.

(3) Decisions are determined by the agreement of a majority of members but do not have to be unanimous.

(4) Any objections or abstentions by particular members will be noted in the minutes.

(5) Decisions can only be made at a Committee meeting where the minimum membership of the Committee is present and/or the Chair is satisfied that the views of members across the breadth of relevant categories have been received and considered by the Committee before a decision is reached. This may occur via flying minute in exceptional circumstances.

(6) Quorum requirements and approval processes for Subcommittees are set out in the Terms of Reference for each Subcommittee.

2.7 Governance and administrative support

(1) The Research Integrity and Ethics Administration will provide administrative and secretariat support to each Committee, to the extent required for the Committee to discharge all its obligations under the National Statement, and can be called upon for protocol and procedural advice.

(2) A Human Ethics Officer is appointed to support each Human Research Ethics Committee in the administration of its business, including the following responsibilities:

(a) being a point of contact for applicants wishing to make application or liaise with the Committee;

(b) ensuring that proposals are provided to a Committee for consideration;

(c) ensuring that the decisions of the Committee are conveyed to researchers in a timely manner;

(d) ensuring that Committee records are maintained and made available for review by the University and authorised external reviewers;

(e) monitoring membership composition and terms, and facilitate appointments, re-appointments and acknowledgements of service;

(f) ensuring that the University submits the appropriate regulatory applications, renewals and reports as required; and

(g) where requested by the Committee, provide administrative assistance with arranging audits and monitoring activities for Committee members to carry out as relevant to projects approved by the Committee.

(3) Decisions about allocation of Committee tasks to the Human Ethics Officer/s and other Ethics Office staff is the responsibility of the Human Ethics Manager, who may seek advice from the Chair.

(4) Human Ethics Officers who attend Committee or Subcommittee meetings have the right of audience and debate, particularly in relation to providing advice on procedural matters and corporate knowledge.

2.8 Preparation and distribution of agendas and minutes

(1) A Human Ethics Officer appointed to support each Committee prepares and distributes agendas and minutes for each meeting.

(2) Agendas are circulated to the Committee at least six (6) business days before the Committee meeting. Associated applications are available in myResearch or circulated to members by the time the agenda is distributed.

(3) Applications will be reviewed in alignment with the processes and timeframes outlined in the instructions provided to committee members as part of their induction and with agendas.

(4) Minutes of the Committee meeting are reviewed by the Chair before outcomes are sent to researchers within two (2) weeks following the meeting, and then circulated to Committee members together with the next agenda. Minutes are reviewed by members who were in attendance and are approved at the next quorate meeting of the Committee.

2.9 Subcommittees

(1) The Human Research Ethics Committees may establish Subcommittees to expedite effective ethics review of specific matters, e.g. amendments, lower risk human ethics applications, adverse events and exemptions.

(2) Subcommittees remain under the oversight and authority of the corresponding Human Research Ethics Committee. Minutes of Subcommittee meetings are provided to the corresponding full Human Research Ethics Committee for ratification.

2.10 Benefits

(1) The Chair of a Human Research Ethics Committee receives a payment for the additional commitment required to both chair meetings and perform executive duties. Payments are funded by the Research Portfolio and payment details are included in appointment letters. Payments are made prospectively in January and July into an account nominated by the Chair's Faculty (or unit) which is compliant with the financial requirements applicable to the university. The Chair negotiates with the faculty (or unit) on the use of these funds. Payments may be made into a private account upon invoice if the Chair is external to the University. Pro-rata adjustment is made to payments where the Chair was unavailable for 1 or more scheduled meetings.

(2) In the event of the Chair's absence or unavailability for a meeting, the payment for that meeting is transferred to the account nominated by the Faculty (or unit) for the Deputy Chair or Acting Chair who undertakes the role. Should the Deputy Chair or Acting Chair be external to the University the payment for that meeting will be transferred to their nominated account upon invoice.

(3) The Deputy Chair of a Human Research Ethics Committee receives payment for chairing an Amendment Subcommittee. Payments are funded by the Research Portfolio and details are included in appointment letters. Payments are made prospectively in January and July into an account nominated by the Deputy Chair's Faculty (or unit) which is compliant with the financial requirement applicable to the university. The Deputy Chair negotiates with the faculty (or unit) on the use of these funds. Payments may be made into a private account upon invoice if the Deputy Chair is external to the University. Pro-rata adjustment is made to payments where the Deputy Chair was unavailable for 1 or more scheduled meetings.

(4) Human Research Ethics Committee members who are not continuing or fixed term University staff receive payment retrospectively to recognise their contribution to a committee. A payment is available for reviewing allocated applications on an agenda and entering their reviews and proposed outcome categories into myResearch Ethics. An additional payment is available for attending a scheduled meeting of their respective Human Research Ethics Committee, presenting the items they were allocated to review and participating in the general discussion of agenda items.

(5) Human Research Ethics Committee chairs, deputy chairs and members who are full time continuing or fixed term academic staff of the University receive a 0.1 FTE workload allocation benefit from their School (or unit) for completing duties set out in the position description for their role.

(6) Amendment Subcommittee members who are academic staff of the University receive a 0.1 FTE workload allocation benefit from their School (or unit) for completing duties set out in the position description for their role.

(7) Low Risk Subcommittee members who are academic staff of the University receive a workload allocation from their School (or unit) for completing duties set out in the position description for their role (see 1.3 above).

(8) The minimum workload allocation is not cumulative for members of multiple ethics Committees, Subcommittees or those serving in multiple committee roles.

PART 3 THE APPLICATION PROCESS

3.1 Applying for human ethics approval

(1) Ethics Office staff are available for open communication with researchers, providing guidance and resolving issues relating to ethics applications via phone, email, online or face-to-face (where possible). Consultation sessions or group presentations can also be scheduled with Ethics Office staff and/or Committee/Subcommittee members.

(2) Any of the following parties who intend to conduct human research must establish if ethics approval is required, and where necessary, obtain the applicable ethics approval or exemption from ethics approval as outlined in this Procedure:

(a) University of Sydney staff;

(b) University of Sydney students; and

(c) affiliates and others holding honorary appointments where research is to be completed under the auspices of the University or is funded by the University.

(3) Human research must not commence, or continue following amendment, without written ethics approval or an exemption, and until any conditions of approval are satisfied.

(4) Researchers are provided with the following information on the Human Ethics intranet site to assist with submitting a complete and well-thought-out application:

(a) The application process;

(b) Forms and templates to use;

(c) Guidelines for key ethical considerations, research methods and specific participant groups;

(d) A Companion Guide for completing the HREA;

(e) Indicative agenda closing dates for each Committee and Subcommittee;

(f) Relevant training; and

(g) Relevant legislation and ethics frameworks.

(5) Researchers are encouraged to consult the above information, commence a project description and draft application and then contact the Ethics Office if they require further assistance with the application process.

(6) Once a Faculty Approver has signed off an application in myResearch Ethics, it is then time stamped by the system and submitted electronically to the Ethics Office.

(7) Supporting documents are attached to the online application so they can be reviewed together.

(8) Applications are reviewed according to Part 4 below.

3.2 Responsibilities of the Chief Investigator and research team

(1) The Chief Investigator accepts ultimate responsibility for:

(a) The ethical and compliant conduct of the project described in the approved application; and

(b) The supervision of all personnel delegated to undertake any aspect of the research.

(2) The Chief Investigator must ensure that:

(a) All personnel listed on the application are provided with a copy of the approved application and any associated ethics documentation; and

(b) All personnel are informed of any conditions of approval and subsequent amendments; and

(c) All personnel listed on the application who are University staff, students or affiliates have completed any mandatory human research ethics training required by the University before commencing research activities.

(3) All researchers listed on an approved project:

(a) Must be familiar with the approved application, associated documentation and conditions of approval; and

(b) Where they are University staff, students or affiliates, must have completed any mandatory human research ethics training required by the University before commencing research activities; and

(c) Share responsibility for conducting the research in accordance with the approval and relevant policies, procedures and the National Statement.

(4) Failure to meet these responsibilities may constitute non-compliance and will be managed in accordance with Part 6 of these Procedures.

3.3 Exemptions

(1) Research may be eligible for exemption from ethics review where it satisfies the criteria set out in section 5.1.17 of the National Statement.

(2) Researchers seeking an exemption from ethics review must submit an exemption request using the process specified by the Ethics Office.

(3) Ethics Office staff will assess the information provided and may:

(a) grant an exemption from ethics review;

(b) request additional information from the researcher; or

(c) determine that the research is not eligible for exemption from ethics review.

(4) Researchers will be advised of the outcome in writing.

(5) The Ethics Office will keep a record of any decision to grant exemption from ethics review in accordance with section 5.1.18 of the National Statement.

(6) Where an exemption is not granted, the researcher must obtain the appropriate ethics approval before commencing the research.

(7) Research must not commence until written confirmation of an exemption or ethics approval has been received.

3.4 Externally approved research projects

(1) The University has procedures in place to reduce duplication of ethics review for research occurring across multiple institutions and countries, as recommended in Chapter 5.5 of the National Statement. Refer to the External Human Ethics Approval Procedures 2024 in the University's Policy Register.

(2) In circumstances when research will occur at particular sites, specialist jurisdictions or include certain collaborators or participant populations, ethics approval may be required from another applicable ethics review body instead of the University's ethics committees. The Ethics Office maintains information about the application process, including where to submit applications, on their Human Ethics intranet site.

3.5 Application fees

(1) External research proposals may be accepted for review by a Human Research Ethics Committee at the discretion of the Human Research Ethics Committee Chairs.

(2) The University may decline external research proposals having regard to committee capacity and other relevant considerations.

(3) A fee applies to external research proposals accepted for review. The current fee is $2,500 plus GST.

PART 4 THE REVIEW PROCESS

4.1 Timely distribution of applications to members for ethics review

(1) Agendas for scheduled meetings close approximately two-three weeks before each meeting.

(2) Ethics Office staff check applications received for apparent risk level. The application is then allocated to the next available agenda for a Human Research Ethics Committee or Subcommittee, based on the risk level, agenda closing date, date that the application was received and the intended start date of the project (if known). Where an agenda is full, subsequent applications will be allocated to the next available agenda.

(3) Ethics Office staff allocate applications to the earliest possible agenda of a relevant Committee or Subcommittee. This may mean prioritising the application over a project that is proposed to commence later. While full Human Research Ethics Committees routinely consider applications that are higher than low risk, lower risk applications may occasionally be allocated to a full Human Research Ethics Committee meeting where:

(a) an application requires review sooner than the next scheduled Low Risk Subcommittee meeting;

(b) there is no Low Risk Subcommittee in the Chief Investigator's Faculty;

(c) where proposed aspects of the research preclude review by a Low Risk Subcommittee (e.g. a waiver of consent is requested).

Further details and instructions are included in the Human Research Ethics Standard Operating Procedures.

(4) Where an application is incomplete or not ready for review by a Committee or Subcommittee, Ethics Office staff or Faculty Ethics Officers may contact the researcher to provide feedback and guidance on how to complete or enhance their application, returning the application to the researcher for them to edit and resubmit.

(5) For meetings of full Human Research Ethics Committee and Amendment Subcommittees, Ethics Office staff allocate applications to members for review, and assemble and distribute an agenda listing all applications for discussion at the meeting.

(6) For meetings of Faculty-based Low Risk Subcommittees, each Faculty appoints staff to allocate applications to members for review, and assemble and distribute an agenda listing all applications for discussion at the meeting (if applicable).

4.2 Timely consideration and review of applications

(1) Allocated reviewers complete an in-depth analysis of the application. Reviewers share their comments via myResearch Ethics prior to the scheduled meeting, and present a summary and their ethical concerns during the meeting.

(2) All members are welcome and encouraged to review applications on the agenda outside of their allocation.

(3) The Chair familiarises themselves with all applications on the agenda prior to discussion at the meeting.

(4) Following discussion, the Chair leads the Committee or Subcommittee in determining the most appropriate outcome from the Outcomes set out in the HREC Induction Manual.

(5) Ethics Office staff minute discussions and decisions from Human Research Ethics Committee meetings and Amendment Subcommittees, and communicate outcomes to the researcher/s within 10 business days following the meeting.

(6) Faculty-appointed staff minute discussions and decisions from Low Risk Subcommittee meetings, and provide outcomes to the Ethics Office for communication to the researcher/s.

4.3 Lower risk human research

(1) The University has established processes for the review of lower risk human research proposals outside a full Human Research Ethics Committee setting, in accordance with the National Statement. These procedures have been approved by the Human Research Ethics Committees, and include review by Faculty-based Subcommittees.

(2) Low Risk Subcommittees are Subcommittees of Human Research Ethics Committees.

(3) Members of Low Risk Subcommittees must be familiar with the National Statement and Terms of Reference for their Subcommittee, and understand the ethical issues that can arise in the research under review.

(4) Low Risk Subcommittees may review applications in which the maximum foreseeable risk is discomfort.

(5) A Subcommittee may be given the authority to assess applications involving one or more factors listed at 4.4(1), where this is set out in the Subcommittee's Terms of Reference.

(6) Those reviewing applications via a low risk pathway must refer any research they identify as higher than low risk to a Human Research Ethics Committee.

(7) Reviews and approvals completed outside a full University Human Research Ethics Committee will be reported to the relevant University Human Research Ethics Committee by providing minutes to a subsequent meeting for ratification.

(8) Secretariat support for Low Risk Subcommittees is a collaborative effort between the Ethics Office and the secretary appointed by the relevant Faculty, as follows:

- (a) The Ethics Office confirms the apparent level of ethical risk and allocates applications to agendas as per 4.1 above.
- (b) Where a Low Risk Subcommittee meets formally, the Faculty-appointed secretary:
  - (i) Checks for Subcommittee member availability in advance of each meeting;
  - (ii) Completes an administrative pre-review of applications allocated to the subcommittee, to check for completeness and quality, ready for effective ethics review;
  - (iii) Allocates applications to Subcommittee members for review, avoiding known or declared conflicts of interest;
  - (iv) Prepares and distributes the agenda to members, including the allocations of applications to each reviewer;
  - (v) Checks for any conflicts of interest declared, and reallocates reviewers where necessary;
  - (vi) Records the minutes of the meeting, including key notes from discussion during the meeting and outcomes to be communicated to the researcher;
  - (vii) Arranges for the Chair to review the draft minutes;
  - (viii) Provides the final minutes to the Ethics Office for the outcomes to be distributed to researchers.
- (c) Where a Low Risk Subcommittee does not meet formally, the Faculty-appointed secretary:
  - (i) Checks for Subcommittee member availability to complete reviews;
  - (ii) Completes an administrative pre-review of applications allocated to the subcommittee, to check for completeness and quality, ready for effective ethics review;
  - (iii) Allocates applications to Subcommittee members for review, avoiding known conflicts of interest;
  - (iv) Advises members of their allocated reviews;
  - (v) Reallocates reviewers where any conflicts of interest are declared;

(vi) Collates and records the outcomes to be communicated to the researcher, for review by the Chair;

(vii) Arranges for the Chair to review the drafted outcomes and reasons;

(viii) Advises the Ethics Office when the outcomes are ready to be distributed to researchers:

(ix) Prepares a minutes document of consolidating outcomes and provides this to the overseeing HREC.

(d) The Ethics Office:

(i) Sends the outcomes to researchers. Where a response is required from the researcher, the Ethics Office receives these and either:

- assigns them to the same Subcommittee that reviewed the original application, allocating them directly onto the next available agenda (where available), unless the application was escalated to a full Human Research Ethics Committee; or
- allocates them to a Subcommittee Chair or Secretary to consider the response and determine the outcome.

(ii) Ensures that a copy of the minutes (collated outcomes) is made available to the Human Research Ethics Committee that oversees the Low Risk Subcommittee.

(9) Low Risk Subcommittees may give delegated authority to the Chair, Faculty-appointed Secretary or Ethics Office staff to action an approval, subject to minor concerns being satisfactorily addressed by the researcher/s.

4.4 Higher risk human research

(1) Any application that does not fit into the above parameters for exemption or low risk review must be reviewed by a fully constituted Human Research Ethics Committee, including where the proposed research involves any of the following:

HREC review triggers

(a) Potential for harm (i.e., higher risk), experienced individually or collectively by participants or non-participants. This includes physical or psychological harm, devaluation of personal worth, cultural, social, economic (e.g., jeopardise employment) or legal harm.

(b) Likelihood of causing or eliciting distress in participants due to subject matter, the procedures involved, information that might be revealed about the participant or related persons, or in some other way.

(c) Limited disclosure, active concealment and/or planned deception.

(d) Waiver of consent or the use of opt-out consent to use personal information in medical research, or personal health information.

(e) Access to identifiable health records without consent.

(f) Clinical trials (i.e. designed to find out the effects of an intervention, including a treatment or diagnostic procedure). A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

(g) Genomics, genetics, human embryos or gametes (including the derivation of embryonic stem cell lines or other products from a human embryo).

(h) Prospective collection of identifiable biospecimens (e.g. human tissue, blood, saliva, bodily fluids).

(i) Physical exertion (i.e. physical activity, exercise).

(j) Intention to expose illegal activity and research not specifically designed to, but likely to discover, illegal activity.

(k) Risk posed to the physical or emotional welfare of a University of Sydney student researcher (e.g. honours student or postgraduate student).

(l) Xenotransplantation.

(m) Aboriginal and/or Torres Strait Islander participants or focus.

(n) Indigenous/First Nations Peoples or focus in other countries.

(2) Members of a Human Research Ethics Committee must be familiar with the National Statement and Terms of Reference for the committee, and understand the ethical issues that can arise in the research under review.

(3) Where there is less than one member from each membership category present at a Human Research Ethics Committee meeting, the Chair should be satisfied that the views of absent members across the breadth of membership categories have been received and considered before any decision is reached.

(4) Where unexpected circumstances prevent the minimum membership having the opportunity to comment on reviews, decisions made at an inquorate meeting may be considered and approved via another method. For instance, this may be competed via an asynchronous meeting where members reviews are entered into myResearch Ethics with time allowed for all reviews to be considered by all of the minimum membership before an outcome is facilitated by the Chair. Alternately, if the committee only has specific concerns potentially requiring input from absent members, the review process could be finalised following consultation with absent members after the meeting. Regardless of the process followed, where matters are considered asynchronously, all contributions should be available for consideration by all other members before a decision is reached.

(5) A Committee can still provide advice or request further information from researchers without full attendance of the minimum membership.

(6) A Human Research Ethics Committee may consult outside its membership where additional expertise is needed to address ethical issues arising from potential research it is asked to review. External experts will be subject to the confidentiality and disclosure requirements set out in the Human Research Ethics Committees Terms of Reference.

(7) Committees and Subcommittees will endeavour to reach a decision by general agreement or consensus. This does not require unanimity.

(8) Committees and Subcommittees may give delegated authority to the Chair or Ethics Office staff to action an approval, subject to minor concerns being satisfactorily addressed by the researcher/s.

4.5 Prompt notification of decisions and communication with researchers

(1) The Ethics Office encourages open communication between review bodies and researchers, and a shared commitment to a constructive review process. A clear process for researchers to contact review bodies and their support staff is set out on the Human Ethics intranet site. Researcher training is provided in various formats throughout the year - both online and in person - to promote awareness of the requirements of the National Statement and guidance around the ethics review and approval process.

(2) Following the review of draft minutes by the Chair, Ethics Office staff should communicate outcomes to the researcher within 10 business days of the meeting at which their application was reviewed.

(3) Outcomes will be communicated in writing, but discussion is welcome via telephone, online or face-to-face (where possible). Researchers are welcome to contact the Ethics Office with any queries they have regarding the outcomes from the review of their application, or to schedule a consultation session with an Ethics Officer, Committee or Subcommittee member for a more in-depth discussion (where possible).

(4) Outcomes may include requests for further information or clarification. The researchers are responsible for responding to these requests within 6 months or their application will lapse.

(5) The Ethics Office allocates researcher responses to the next available agenda of the same Committee or Subcommittee (wherever possible) after the response is received.

(6) Responses to outcomes that do not need to return to the Committee or Subcommittee may be reviewed via other methods, as determined by the Committee/Subcommittee during their meeting:

(a) Minor or straightforward ethical concerns may be reviewed by the Chair; or

(b) Administrative concerns or minor ethical concerns with predictable responses anticipated by the committee may be reviewed by a Human Ethics Officer.

(7) Where a response is considered satisfactory, Ethics Office staff will send an approval letter to the researcher/s.

(8) Where a Committee or Subcommittee cannot approve a research proposal, the reviewing body will provide a rationale for the decision, including citing the provisions of the National Statement or relevant institutional policy that underpin its decision, if relevant.

4.6 Managing conflicts of interest

(1) Following the distribution of the agenda and prior to discussion of the relevant item at the meeting, Committee and Subcommittee members declare any actual or potential conflicts of interest in items on the agenda. All declarations of interest are documented by the Secretary in any revised agendas and in the minutes, and may include:

(a) personal involvement or participation in research being reviewed;

(b) a close working or personal relationship with a researcher named on an application;

(c) financial or other interest or affiliation; or

(d) involvement in competing research.

(2) Where a member declares a conflict of interest with an item they have been allocated for review, the Secretary or Chair will rearrange review allocations to ensure applications are equitably distributed to members without conflicts of interest.

(3) Members with a conflict of interest do not participate in the discussion or decision of the related agenda item during the meeting. They either step out of the meeting room or are placed in a breakout room if joining the meeting online. The minutes reflect when each member exits and re-joins the meeting. The withdrawal of members from the meeting due to a conflict of interest will be disregarded in the calculation of a quorum.

(4) Human Research Ethics Committees and Subcommittees avoid direct communication with research sponsors to prevent any actual or perceived influence on the ethics review of the proposed research.

(5) Any experts consulted outside the membership of the committees are also subject to the conflict of interest requirements and procedures set out for members in (1) to (4) above.

4.7 Confidentiality

(1) The content of applications to the Human Research Ethics Committees and Subcommittees are confidential, unless the information exists in the public domain.

(2) The deliberations of review bodies are confidential, as are the minutes of meetings and any related correspondence.

(3) Members, observers and relevant staff sign and return an HREC Confidentiality Undertaking prior to attending any meeting of a University Human Research Ethics Committee or Subcommittee. This Undertaking covers what information is to be considered confidential, non-disclosure and use of confidential information and the continuation the member’s obligations beyond their affiliation with the Committee/Subcommittee and the University.

PART 5 MONITORING APPROVED RESEARCH

5.1 Amendment requests

(1) Requests to amend research studies approved by a Human Research Ethics Committee or Subcommittee are received by the Ethics Office and allocated to the next available Amendment Subcommittee.

(2) Outcomes of amendment applications are communicated to researchers within 10 business days of the meeting at which they were considered.

(3) Requests for extensions of research studies previously approved by a Human Research Ethics Committee or Subcommittee are received and approved by the Ethics Office, and may be escalated to an Amendment Subcommittee if required.

(4) Outcomes of extension requests are communicated to researchers within 10 business days of receiving the request.

(5) Research cannot commence in amended forms or continue beyond the approved end date until written confirmation of approval has been received from the Ethics Office.

5.2 Reports from researchers

(1) Researchers must submit reports to the Ethics Office consistent with monitoring obligations to prevent their approval from lapsing.

(2) Reports are required at least annually from researchers to provide ethics committees with updates regarding the progress or outcome of the research, secure maintenance of project-related data and compliance with the original proposal, special conditions and/or approved amendments.

(3) Researchers must submit:

  (a) an annual progress report each year by the anniversary of the original approval; and

  (b) a completion report at the conclusion of the research project or by the approval expiry date, whichever occurs first.

(4) Researchers conducting approved clinical trials must also meet the following requirements for continuation of their ethics approval:

  (a) provide reports of the progress of the trial and any safety reports or monitoring arrangements as indicated in NHMRC guidance in the form required by the Human Research Ethics Committee; and

  (b) promptly inform the Human Research Ethics Committee of any new safety information from other published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may require an amendment of the project.

(5) Reports are reviewed and continuation is approved by Ethics Office staff where progress is satisfactory, or are escalated to a Human Research Ethics Committee or Subcommittee for review where progress requires further consideration.

5.3 Reporting and handling of adverse events

(1) Adverse event must be reported for review by the Human Research Ethics Committee Executive as soon as possible or within 72 hours where a serious adverse event may impact the continued ethical acceptability of a project (e.g., privacy breaches, loss of data or damage to property etc).

(2) Adverse events, serious adverse events, serious unexpected suspected drug reactions and unanticipated serious adverse device events relating to clinical trials may be reported as a periodic summary where approved by a Human Research Ethics Committee.

(3) Ethics Office staff gather information regarding the adverse event and presents this information to the Human Research Ethics Committee Executive, who will make a recommendation on the appropriate course of action, refer a matter to the applicable review process or seek the advice of a Human Research Ethics Committee for consideration.

(4) The Human Research Ethics Committee Executive will advise the researchers or other parties of the preferred course of action in writing.

(5) If any party is not satisfied with the outcome of the Human Research Ethics Committee Executive/Human Research Ethics Committee considerations, they may make a formal complaint in writing, and follow the procedures in 6.1 below.

5.4 Discontinuation of approved research

(1) Researchers must inform the Ethics Office and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion, and why. For research at more than one site, or research where there have been multiple ethics reviews, it must be clearly established, before the research begins, how this information will be communicated.

5.5 Expiration of ethics approval

(1) Ethics approval is initially granted for four years, subject to satisfactory progress and researchers meeting annual monitoring and reporting obligations.

(2) Approval will lapse if:

(a) an annual report is not received by the due date,

(b) a completion report is not received prior to the approved project end date, or

(c) an extension application has not been approved prior to the approval expiry date.

PART 6 COMPLAINTS AND NON-COMPLIANCE

6.1 Receiving and handling of complaints

(1) Any concern or complaint about the conduct of a project approved by a University Human Research Ethics Committee or an outcome of a Human Research Ethics Committee should be directed to the attention of the Human Ethics Manager, whose contact details are to be included on the Participant Information Statements used in all approved research projects.

(2) Ethics Office staff gather information regarding complaints received and presents this information to the Human Research Ethics Committee Executive, who will make a recommendation on the appropriate course of action, refer a matter to the applicable review process or escalate the complaint to a Human Research Ethics Committee (or seek their advice) for consideration.

(3) The Human Research Ethics Committee Executive will advise the complainant of the preferred course of action in writing.

(4) If the complainant is not satisfied with the outcome of the Human Research Ethics Committee Executive/Human Research Ethics Committee considerations, or the process followed to reach them, they may appeal by referring the complaint to the Director, Research Integrity and Ethics Administration in writing.

(a) For complaints or concerns about the ethics review process, the Director will liaise with the Human Ethics Manager to evaluate the process, and investigate if the process was followed.

(b) For complaints or concerns about the decision made by the Human Research Ethics Committee, the Director determines at their discretion whether there is to be further investigation of the complaint and informs the complainant and the Human Ethics Manager of this decision. If the matter is to proceed for further review, the Director will refer information to the Human Ethics Manager and the Human Research Ethics Committee Executive, who recommends the appropriate course of action.

(5) If the complainant is not satisfied with the outcome of the appeal to the Human Research Ethics Committee Executive, they may refer the appeal to the Deputy Vice-Chancellor (Research) for consideration. The Deputy Vice-Chancellor (Research) will investigate and notify the researcher and the Human Ethics Manager of the outcome, which may involve referring information to the Human Ethics Manager and the Human Research Ethics Committee Executive. Should a University Human Research Ethics Committee be requested to review its decision, then the outcome of that review by the Human Research Ethics Committee will be final. Neither the Director nor the Deputy Vice-Chancellor (Research) can substitute their approval for the approval of a Human Research Ethics Committee.

6.2 Non-compliance

(1) Any matter of potential non-compliance with a Human Research Ethics Committee approved project identified by University staff, students, research participants or other parties is notified to the Chair of the overseeing Human Research Ethics Committee, via the Human Ethics Manager, who:

(a) seeks clarification from the Chief Investigator of the research project;

(b) takes immediate action to ensure that participant welfare is not compromised;

(c) requests an urgent suspension of research from the Deputy Vice-Chancellor (Research) as described in 5.4.14 of the National Statement, if required; and

(d) investigates further as required to determine a clear understanding of the matter for a decision to be made about the future of the research project.

(2) Where investigation suggests that there is non-compliance, the Human Research Ethics Committee Chair:

(a) notifies the Chief Investigator in writing that the non-compliant activities must cease immediately, and may suspend the project's approval; and

(b) provides a report on the matter for consideration at the next Human Research Ethics Committee meeting and invites the Chief Investigator to attend and/or provide a written response for consideration at the meeting.

(3) Upon receipt of a report from the Human Research Ethics Committee Chair, the Human Research Ethics Committee will consider the report and any response from the Chief Investigator, make a decision regarding ethics approval, and take actions as described in Table 1.

(4) In the process of reaching any decisions in Table 1, a Human Research Ethics Committee may refer a matter for consideration in an applicable institutional review process prior to making a final determination. For example:

(a) The matter may be referred to the Research Integrity Office following consultation with the Research Integrity Manager. The Human Research Ethics Committee would then make their final determination following the outcome of the research integrity review.

(b) If the matter involves potential workplace harassment, bullying, discrimination, violence of any kind or other unacceptable behaviours set out in the University of Sydney Enterprise Agreement, the matter may be reported in accordance with the relevant policies and processes.

Table 1 Human Research Ethics Committee decisions regarding ethics approval for non-compliant research

Decision	Notify	Notification	Outcome/s
Reinstate/confirm ethics approval for the project with or without conditions. (Note: Engagement with the Deputy Vice-Chancellor (Research) is necessary where the Deputy Vice-Chancellor (Research) had issued an instruction to stop the research)	Chief Investigator and personnel involved in non-compliant activities	In writing	Possible formal warning: 1. The Human Research Ethics Committee regards any lack of compliance with regulatory requirements as a most serious matter; and 2. Any future non-compliance may lead to the Committee withdrawing ethics approval for the project.
Endorse a Chair/ Deputy Vice-Chancellor (Research) suspension or suspend ethics approval for work on all or part of the project	Chief Investigator and personnel involved in non-compliant activities	In writing. Notification to the Chief Investigator may include: 1. The reasons of the Human Research Ethics Committee for the decision to suspend approval; Evidence, advice, facts and/or documents upon which the decision was made; and 2. An invitation to attend a meeting with the Committee or Chair to discuss the matter.	The Human Research Ethics Committee will not consider progress reports/renewals or variations related to the project until the suspension has been resolved. Suspension can be extended to other projects of the Chief Investigator or to any person. The Human Research Ethics Committee may require a new application for consideration rather than reinstating approval.
Withdraw ethics approval for all or part of the project.	Chief Investigator and personnel involved in non-compliant activities	In writing. Notification to the Chief Investigator may include: 1. The reasons of the Human Research Ethics Committee for the decision to suspend approval; Evidence, advice, facts and/or documents upon which the decision was made; and 2. An invitation to attend a meeting with the Committee or Chair to discuss the matter.	The Human Research Ethics Committee may require a new application for consideration rather than reinstating approval.

6.3 Withdrawal of ethics approval

(1) Where a review body finds reason to believe that:

(a) continuance of a research project will compromise participants' welfare;

(b) there are substantial deviations from the approved protocol;

(c) adverse effects of unexpected type, severity, or frequency are encountered; or

(d) the continuation of the research would disadvantage some of the participants;

it immediately seeks to establish whether ethics approval for the project should be withdrawn by a Human Research Ethics Committee. Researchers and others involved in the project will be treated fairly and with respect in this process.

(2) The decision to withdraw ethics approval can only be made at a quorate meeting of the Human Research Ethics Committee or Human Research Ethics Committee Executive.

(3) Where ethical approval for a research project is withdrawn:

(a) the researcher, the institution/s and, where possible, the participants are informed;

(b) the researcher promptly suspends the research and makes arrangements to meet the needs of participants, such as ensuring that appropriate counselling support or the provision of standard care continues;

(c) the research may not be resumed unless either:

(i) the researcher subsequently establishes that continuance will not compromise participants' welfare and a Human Research Ethics Committee approves the resumption; or

(ii) the research is amended to provide sufficient protection for participants, the amendment is ethically reviewed, and the amended research is approved by a Human Research Ethics Committee. This must occur in consultation with the Deputy Vice-Chancellor (Research) where the Deputy Vice-Chancellor (Research) had issued an instruction to stop the research.

PART 7 RECORD KEEPING AND REPORTING

7.1 Record keeping

(1) Human Ethics Office staff maintain written records of University Human Research Ethics Committee activities, including agendas and minutes of all meetings of University Human Research Ethics Committees and Subcommittees.

(2) The Human Ethics Office staff maintain a record for each application received including copies of the relevant correspondence between the applicant and a University Human Research Ethics Committee.

(3) Records are kept securely and confidentially in accordance with the requirements of the *Records and Information Privacy Act 2002* and the University policy on storage and retention of research data.

(4) Records are held securely for sufficient time to allow for future reference and compliance with the NSW State Records Act (1998).

7.2 Reporting

(1) The Human Research Ethics Committees establish, implement, document and notify the Deputy Vice-Chancellor (Research) of its working procedures.

(2) a Human Research Ethics Committee may, from time to time, bring to the attention of the Deputy Vice-Chancellor (Research) issues of significant concern or on which guidance or policy is required.

(3) The Human Research Ethics Committees prepare and submit annual compliance reports to the NHMRC, for provision to the Australian Health Ethics Committee and the Federal Privacy Commissioner.

7.3 Reporting on its activities to the institution

(1) The Human Research Ethics Committees will provide the University Executive Research Committee with an annual report on their activities.

(2) The Human Research Ethics Committees will provide information to the Office of the Provost in accordance with the provisions of the University's Working With Children and Vulnerable Adults Policy 2021.

PART 8 TRAINING

(1) The Ethics Office maintains online researcher training modules, committee member induction and training resources and provides additional training and information sessions to both researchers and committee members on request.

(2) University staff and students who intend to conduct human research should complete the University's human research ethics training prior to commencing human research, as specified on the Human Ethics intranet site.

(3) Newly appointed Human Research Ethics Committee members must observe a Human Research Ethics Committee meeting and complete induction training before they may review applications.

(4) For a convening Sub-committee, newly appointed Subcommittee members must observe a Subcommittee meeting and all newly appointed Subcommittee members must complete induction training before they may review applications. It is advisable to also observe a Human Research Ethics Committee meeting.

(5) Additional relevant training will be available to members of the Human Research Ethics Committees and Subcommittees during their tenure.

PART 9 DOCUMENT ADMINISTRATION

9.1 Variations

(1) These Procedures may be amended in consultation with the Human Research Ethics Committees and the Ethics Office.

9.2 Rescissions and replacements

This document replaces the following, which are rescinded as from the date of commencement of this document:

(1) Human Ethics Procedures 29 Aug 2025

9.3 Amendment history

Version	Effective date	Amendment / Description	Approved by
v240223	23 Feb 2024	- Original document.	Dr Susan Maastricht, Director, Research Integrity and Ethics Administration
v240827	27 Aug 2024	- 'Modification' updated to 'Amendment' throughout. - 4.1 and 4.2 - Points consolidated and listed in chronological order. - 4.4 (1) - Triggers for full HREC review updated. - 6.1 - Differentiation between complaints about the process or HREC decisions. - 6.2 (4) added.	Dr Susan Maastricht, Director, Research Integrity and Ethics Administration
v250829	29 Aug 2025	- 1.1 (2) - HRECs > HREC. - 2.2 - Appointment of Deputy Chairs clarified for HREC and Subcommittees. - 2.4 - Absence updated for Subcommittees. - 2.10 - Benefits and payments terminology updated. - 4.4 (1) - Subheading added for HREC review triggers. Triggers aligned with NS25. - Notes: Links updated (Hub, Related documents)	Alan Hales, Human Ethics Manager
v260702	2 July 2026	- Name changed to 'Human Ethics Procedures'. - NS, Hub and policy register links updated. - References to 2023 National Statement amended to 2025 National Statement Flexibility for appointment terms added in 2.2(4) - Responsibilities of Chief Investigator and research team added in 3.2	Dr Susan Maastricht, Director, Research Integrity and Ethics Administration
V260910	10 Sep 2026	- Public document references updated to support NHMRC HREC registration requirements - Internal and restricted-access hyperlinks removed and replaced with public references where available - 3.3 updated to include exemption request and assessment process, and reference National Statement exemption criteria - 3.5 updated to clarify acceptance of external research proposals and associated fees	Dr Susan Maastricht, Director, Research Integrity and Ethics Administration

NOTES

Human Research Ethics Procedures

Approved by: Dr Susan Maastricht, Director, Research Integrity and Ethics Administration

Date approved: 10 September 2026

Date commenced: 10 September 2026

Administrator:	Human Ethics Manager
Review date:	30 August 2027
Rescinded documents:	All previous versions of the Human Research Ethics Procedures
Related documents:	National Statement on Ethical Conduct in Human Research
	Australian Code for the Responsible Conduct of Research 2018
	University of Sydney Research Code of Conduct 2023
	External Human Ethics Approval Procedures 2024
	Human Research Ethics Committees Terms of Reference
	NSW State Records Act (1998)
	University of Sydney Working With Children and Vulnerable Adults Policy 2021
	Privacy Act 1988
	Health Records and Information Privacy Act