Family Planning Australia Human Research Ethics Committee

Terms of Reference and Standard Operating Procedures 2024

Family Planning Australia Human Research Ethics Committee

TERMS OF REFERENCE

Overall function

The primary objective of the Family Planning Australia Human Research Ethics Committee is to protect the mental and physical welfare, rights, dignity and safety of participants in research, to facilitate ethical research through efficient and effective review processes, and to promote ethical standards of human research and to review research in accordance with the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research (2023)* referred to in this document as the *National Statement*.

Scope of responsibilities

The functions of the Family Planning Australia Human Research Ethics Committee are:

1. to provide advice to the Board on issues relating to the ethical conduct of research that might arise from time to time
2. to provide independent, competent, and timely review of research projects involving humans in respect of their ethical acceptability
3. to provide ethical oversight, monitoring, and advice for research projects involving humans
4. to prescribe the principles and procedures to govern research projects involving human subjects, human tissue, and/or personal records
5. to act in accordance with NHMRC guidelines pertaining to human research ethics committees (HRECs)
6. to function as a properly constituted HREC in accordance with the National Statement
7. Research projects may include, but are not limited to, research involving pharmaceuticals, medical devices, surgical procedures, biological samples, access to health information, as well as epidemiological, social, psychological investigations and population health.
8. The terms outlined in this document do not prohibit the HREC from accepting ethical approval granted by another HREC, provided that such HRECs are registered with the NHMRC.
9. The HREC will assess projects submitted to it for review in accordance with the National Statement and any other legal requirements in order to determine their ethical acceptability.
10. The HREC will grant approval for research proposals where the review has determined that the proposal is ethically acceptable and in accordance with the aforementioned standards and guidelines.

11. The HREC will withhold ethical approval for research proposals where the review has determined that the proposal is not ethically acceptable and/or is not in accordance with relevant standards and guidelines.

12. The HREC will request amendments to research proposals in order for the proposal to be ethically acceptable and meet relevant standards and guidelines.

13. The HREC will suspend or withdraw ethical approval for research proposals where the review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.

14. The HREC will monitor the conduct of proposals through the submission of annual and final reports, and additional monitoring activities.

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Acronyms

AE	Adverse Event
AR	Adverse Reaction
CEO	Chief Executive Officer
EEO	Ethics Executive Officer
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
PERT	Project Ethics Review Team
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reaction
UAR	Unexpected Adverse Reaction
USM	Urgent Safety Measure

Key Definitions

Adverse Event	Any untoward medical occurrence in a patient, or clinical trial participant, which does not necessarily have a causal relationship with the administered investigational medicinal product.
Adverse Reaction	Any untoward and unintended response related to an administered investigational medicinal product, at any dose. All adverse events judged by either the investigator or the sponsor as having a reasonable possibility of a causal relationship to an investigational medicinal product would qualify as adverse reactions. In general, the expression 'reasonable causal relationship' means that there is evidence or argument to suggest a causal relationship.
Serious Adverse Event/Serious Adverse Reaction	Any adverse event/adverse reaction that results in death, a persistent or significant disability or incapacity, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, or is a congenital anomaly or birth defect.
Significant Safety Issue	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
Suspected Unexpected Serious Adverse Reaction	An adverse reaction that is both serious and unexpected.
Unexpected Adverse Reaction	An adverse reaction where the nature or severity is not consistent with the reference safety information of the investigational medicinal product.
Urgent Safety Measure	A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

SOP 001: Membership Composition

Purpose: *To describe the membership composition of the Family Planning Australia Human Ethics Committee.*

1. The composition of the HREC shall be in accordance with the National Statement. Minimum membership shall be eight members, with equal numbers of men and women as far as possible, comprising:

    - a Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations
    - a Deputy-Chair
    - at least two members who bring a broader community or consumer perspective and who have no paid affiliation with the institution
    - at least two members with knowledge of, and current experience in, the areas of research that are regularly considered by the Family Planning Australia Ethics Committee. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise
    - at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (e.g., medical practitioner, clinical psychologist, nurse, as appropriate)
    - at least one person who performs a pastoral care role in a community (e.g., an Aboriginal elder, a minister of religion)
    - at least one member who is a lawyer, and where possible, is not also engaged to advise Family Planning Australia

The Family Planning Australia Board may also appoint a Board member to the Ethics Committee, as well as additional members with relevant expertise. No member may be appointed to more than one category.

2. To ensure the HREC has the expertise required to assess the applications submitted for consideration, some or all of the above categories may be represented by more than one person.

3. If additional members are appointed, the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members. As far as possible, there should be equal numbers of men and women, and at least one-third of the members should be from outside the institution for which the HREC is reviewing research.

4. Where required, the HREC may seek advice from appropriate experts and/or stakeholders to assist with the review of a project. Experts may include those with expertise in qualitative health research, quantitative health research, clinical trial design, statistical analysis, or pharmacokinetics. Stakeholders may include people with a disability, people who are Aboriginal and/or Torres Strait Islander, people who are culturally and linguistically diverse, or young people. In such cases, the following conditions apply:

    - Experts and stakeholders may be recruited through direct approach, nomination, or through advertisement.

- The HREC must be satisfied that such experts or stakeholders have no conflicts of interest in relation to the project under consideration arising from personal involvement or participation in the project, financial interest in the outcome, or involvement in competing research.

5. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

SOP 002: Appointment and Conditions of Membership

Purpose: *To describe the procedure for the appointment of members, and the conditions of membership, to the Family Planning Australia Human Research Ethics Committee.*[1]

1. Members are appointed as individuals rather than in a representative capacity.2

2. Prospective members of the HREC may be recruited by direct approach, nomination, or by advertisement. The recruitment process selected must be open and transparent.

3. Where recruitment via advertisement is adopted, the content and publication schedule of the advertisement must be approved by the CEO.

4. A staff member will be nominated to receive enquiries from prospective applicants. The information supplied will be consistent, and will be drawn from key source documents such as the Family Planning Australia Ethics Committee Terms of Reference and the National Statement.

5. After the closing date, a Selection Committee, consisting of the HREC Chair, EEO and any other Committee member appointed by the Chair, will review the applications. The Selection Committee may opt to interview a small number of applications. In this case, applications will be culled by the Selection Committee on an agreed, documented basis. Applicants who do not progress to the interview stage may request a copy of the culling criteria.

6. The Selection Committee will interview the prospective applicant(s). Interviewees will be asked to confirm their identity and provide a copy of their current resume.

7. Following the interview, the Chair will check the personal referees of preferred applicants, or delegate the task to the EEO.

8. The HREC Chair will write to the Board seeking appointment of the candidates chosen by the Selection Committee. The matter will be considered at the next meeting of the Board. Appointment is dependent upon Board approval, with the Board retaining the right to veto on the grounds that the Board has good reason to believe that the person is of bad character, may pose a political risk to Family Planning Australia, or will run personal agendas at the expense of performing the work of the Ethics Committee. In instances where the veto is exercised, this will be communicated in writing to the selection committee. Members are appointed by the Board and will receive a formal notice of appointment. Candidates should not be offered appointment until the approval of the Board is received.

9. A prospective new member may sit in on the Ethics Committee meetings to observe as a non-voting member prior to board approval.

10. The Chair and Deputy Chair positions will be nominated by the HREC, and then endorsed by the board.

11. The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, and the conditions of their appointment.

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[1] In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair

[2] Guidance about the appointment of HREC members can be found in sections 5.1.34-36 of the *National Statement*

12. A prospective new member will be required to sign the following documents upon appointment:

    - a confidentiality undertaking (see Appendix A), stating that all matters of which they become aware during the course of their work on the HREC will be kept confidential, that any conflicts of interest, which exist or may arise during their tenure on the HREC will be declared, and that they have not been subject to any criminal conviction or disciplinary action that which may prejudice their standing as a HREC member

    - the Responsibilities of Members of the Family Planning Australia Ethics Committee form (Appendix A), and to have their name and profession made available to the public, including being published on the Family Planning Australia website

13. Upon appointment, members shall be provided with the following documentation:

    - Family Planning Australia Ethics Committee Terms of Reference

    - Family Planning Australia Ethics Committee SOPs

    - calendar of meeting dates

14. Membership of the Committee is reviewed by the Chair every calendar year. Those approaching three years of service since last review will be eligible for reappointment. Committee members may apply for reappointment by submitting the Responsibilities of Members form (Appendix A) and an up to date resume to the EEO. The Chair will make a recommendation to the Chair of the Board prior to an offer of reappointment being made. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

15. The appointment of the Chair and Deputy Chair is reviewed every third calendar year. The EEO will seek nominations from all Ethics Committee members for each role, and will check that nominated members are willing to accept the nominations. If only one person is nominated for each role, those members will be appointed. If there is more than one member nominated for a role, an anonymous vote will be held.

16. Newly appointed members shall be provided with adequate orientation (refer to SOP 003). Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of Family Planning Australia, where possible in accordance with section 5.2.3(c) of *the National Statement* (refer also to SOP 004).

17. Members shall not be remunerated. Members may make an application for reimbursement of legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses, at the discretion of the CEO.

18. Members may apply to the Chair, in writing, for a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.

19. As determined by the Chair, membership will lapse if a member fails to attend three consecutive HREC meetings without reasonable excuse/apology, unless exceptional circumstances exist. The Chair will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy.

20. Members will be expected to participate in relevant specialised working groups as required.

21. The Chair will be expected to be available between meetings to participate in Executive meetings (refer to SOP 012), where required. The Chair should also be contactable by phone and email.

22. A member may resign from the HREC at any time upon giving notice in writing to the Chair. Steps shall be taken to fill the vacancy of the former member.

23. Members must provide current contact details to the EEO to ensure that they can be contacted as required.

SOP 003: Orientation of New Members

Purpose: *To describe the procedure for the orientation of new members to the Family Planning Australia Human Ethics Committee.*

1. New HREC members must be provided with adequate orientation.
2. Orientation may involve all or some of the following:
    - an introduction to other HREC members prior to the HREC meeting
    - an informal meeting with the Chair and EEO to explain the member's HREC responsibilities, as well as HREC processes and procedures
    - an opportunity to sit in on HREC meetings as a non-voting observer before their appointment takes effect
    - an opportunity to 'partner' with another HREC member in the same category

    Priority will also be provided to the new HREC member to participate in training sessions (refer to SOP 004)
3. New HREC members will be provided with the following written information:
    - a list of the members' names, emails and their roles on the HREC
    - a copy of the National Statement
    - any other relevant information about the HREC's processes, procedures and protocols

SOP 004: Training and Education of Members

Purpose: *To promote ongoing education and training opportunities for all members of the Family Planning Australia Human Ethics Committee.*

1. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of Family Planning Australia, where possible in accordance with section 5.2.22 of the National Statement.

2. Every member of the HREC should aim to attend at least one training session every three years.

SOP 005: Submission Procedure for New Applications

Purpose: *To describe the procedure for the submission of new applications.*

1. All research projects requiring ethical review must receive Institutional Endorsement from Family Planning Australia before the HREC will accept the application for review. To arrange institutional endorsement, researchers should contact the Research Centre by email.[3]

2. All applications for ethical review must be submitted to the EEO of the HREC, via email[4], by close of business on the relevant closing date. The closing dates for new applications should normally be four weeks prior to each HREC meeting. For all other business (e.g., amendments to existing registered studies and/or general correspondence), submissions are normally due two weeks prior to each HREC meeting.

3. Information regarding closing dates should be readily available to prospective applicants.

4. Applications must be submitted using the Human Research Ethics Application (HREA), and shall include a cover letter, and all documentation related to the project (e.g., advertisements, participant information and consent forms). The procedures for application, as well as the application itself, can be accessed at https://hrea.gov.au. If the project is seeking ratification of approval of a committee that uses a different form, the original form may be submitted instead of the HREA.

5. All study documents submitted with the HREA should contain a footer with the:

    - document name
    - version number
    - version date

6. The submission should also include a covering letter containing the following:

    - study name
    - a brief summary of the study highlighting why approval of the HREC is being sought
    - list of all documents submitted including their version and date

7. Once the submission has been received and accepted by the EEO, applicants will be sent an acknowledgment of receipt via email.

8. No application fee will be charged for assessment by the HREC of research projects that are Family Planning Australia-investigator driven. For commercially sponsored clinical trial applications submitted for assessment by the HREC, a fee will be charged in accordance with Australia Health's HREC and Governance: Fee Policy for Review of Commercially Sponsored Research. At the discretion of the Executive Committee a fee may also be charged for the ethical assessment of non-clinical trial applications arising externally.

9. For information about the procedures for requesting amendments and extensions to approved research projects see SOP 007

[3] The email address for the Research Centre is researchcentre@fpnsw.org.au

[4] The email address for the Ethics Executive Officer is ethics@fpnsw.org.au

SOP 006: Processing of Applications for Review

Purpose: *To describe the procedure for the processing of new applications.*

1. All applications will be checked for their completeness by the EEO prior to their acceptance onto the agenda. Incomplete applications with be returned back to the applicant.

2. Once an application has been accepted as complete, the following will occur:

   - The application will be listed on the agenda of the next HREC meeting. If a substantial number of applications are received, some may be deferred until the following HREC meeting. If this occurs, priority will be given to those applications that were received first and/or urgent applications at the discretion of the Chair.

   - The EEO shall assign a unique project identification number to the project, and it will be added to the Family Planning Australia Ethics Projects register of received and reviewed applications.

3. Completed applications for clinical or other biomedical trials received by the closing date will be sent by the HREC to experts in the area consistent with point 2 of SOP 001. The expert reviewers will either:

   - certify that the study proposal is scientifically sound

   - advise the EEO that the proposal is not sound, with reasons

   - request further expert advice

   Based on the advice of the expert reviewers the HREC will either certify the scientific validity of the study or liaise with the researcher and the EEO to revise the proposal.

4. Following the meeting, the primary contact of the application will be advised of any actions or revisions required by the HREC, or that the application was approved during the meeting. Researchers will be emailed their study outcomes (see Appendix C for seeking clarification letter, Appendix D for approval letter, and Appendix E for rejection letter), within 10 working days of the meeting date consistent with SOP 013

SOP 007: Submission of Amendments and Extensions to Approved Projects

Purpose: *To describe the procedure for the submission and review of requests for amendments and extensions to approved projects.*

1. Proposed changes to approved research projects, changes to the conduct of the research, or requests for extensions to the duration of HREC approval, are required to be reported by the Chief Investigator to the HREC for review.

2. Requests shall outline the nature of the proposed changes and/or request for extension, reason/s for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must be submitted in a tracked format, as well as a clean, finalised format. Applicants should include a summary of the proposed changes in the covering letter, including document revision numbers and dates.

3. Expedited review of requests for minor amendments and extensions may be undertaken by the Ethics Expedited Review Process between scheduled meetings at the discretion of the Chair and in accordance with SOP 012, on the condition that it is noted at the next HREC meeting. Where an urgent protocol amendment is required for safety reasons, the Chair or a delegate appointed by the Chair may review and approve the request. In such circumstances, the HREC will review the decision at its next available meeting.

4. All other requests for amendments shall be reviewed by the HREC at its next available meeting, provided the request has been received by the EEO by the closing date.

5. The HREC will report in writing to the Chief Investigator and/or nominated contact person, advising of the ethical approval of the proposed amendment and/or request for extension, within 10 working days of the meeting at which the request was considered.

6. A standard response will be issued, in the format set out in Appendix B for approvals, and Appendix C for seeking clarification.

7. If the HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information, clarification, or modification should refer to *the National Statement* or relevant pieces of legislation.

8. All documentation submitted in response to committee feedback as set out in paragraph 2, should contain clear responses to requests, and where appropriate, tracked changes in documentation where changes have been requested.

9. All reviewed and approved requests for amendments and extensions shall be recorded, and the status of the project shall be updated on the HREC's register of received and reviewed applications.

SOP 008: Preparation of Agenda

Purpose: *To describe the process and format of agenda for a Family Planning Australia Human Ethics Committee meeting.*

1. The EEO will prepare an agenda for each HREC meeting.
2. All completed applications and relevant documents received by the EEO will be included on the agenda for consideration by the HREC at its next available meeting.
3. The meeting agenda and associated documents will be collated by the EEO and circulated to all HREC members. All new projects will be sent to the Committee three weeks prior to meetings. Amendments and other relevant meeting documentation will be forwarded to Committee members 1-2 weeks prior to a meeting, giving sufficient time for review and preparation of feedback.
4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chair. Under no circumstances are new applications for research received after the closing date to be tabled at the meeting.
5. Agenda items will include at least the following items:
    - attendance (including apologies)
    - minutes of the previous meeting
    - business arising from previous meetings (including brief summary of correspondence)
    - amendments to approved research projects
    - new applications
    - general business (for noting)
    - adverse event notifications
    - organisational matters
    - items without notice
    - close and next meeting
6. The agenda and its related documentation shall remain confidential.

SOP 009: Conduct of Meetings

Purpose: *To describe the format of meetings conducted by the Family Planning Australia Human Research Ethics Committee.*

1. The HREC shall meet on a regular basis, which will be at approximately six weekly intervals. Meeting dates and submission closing dates shall be publicly available on Family Planning Australia website.

2. The EEO will email all committee members one week prior to committee meeting to confirm members' attendance and ensure quorum.

3. Members may attend HREC meetings in person or via teleconference. At the discretion of the Chair, meetings with a short agenda may be held online. If an agenda item cannot be resolved over phone/email, then a face-to-face meeting will be held.

4. The Chair may cancel a scheduled meeting if a quorum cannot be achieved (Refer to point 10). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.

5. The Chair may cancel a scheduled meeting if there is insufficient business to be conducted.

6. Meetings will be scheduled for an allocated time. If all business has not been completed within the allocated time, the HREC may either continue the meeting until all agenda items have been considered, or schedule an additional meeting. If an additional meeting is called for, the meeting should be held within 5 working days. Researchers should be notified of the delay as soon as practicable after the initial meeting.

7. The HREC meeting will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room details in the meeting agenda.

8. Notwithstanding paragraph 7, the HREC may agree to the presence of applicants/researchers, visitors or observers to a meeting prior to that meeting being held.

9. Members who are unable to attend a meeting may contribute prior to the meeting through written submissions to the EEO or Chair. These should be received at least 3 working days prior to the meeting so that copies may be made available in advance to other members. The minutes should record the submission of written comments.

10. A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum shall exist when a representative of each of the following categories is present:

    - a Chair (or Deputy Chair acting in their stead)
    - at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work
    - at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC
    - at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people

- at least one person who performs a pastoral care role, for example, an Aboriginal elder, or a minister of religion
- at least one member who is a lawyer

In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following categories: Chair/Deputy Chair, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.

11. If the meeting does not achieve quorum, the Chair shall decide if it can proceed in exceptional circumstances. In such circumstances, decisions made by the HREC must be ratified by at least one representative from those membership categories not present.

12. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC should declare such interest. This will be dealt with in accordance with SOP 019.

SOP 010: Consideration of New Applications for Ethical Review

Purpose: *To describe the process of ethical review and assessment for new applications.*

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date.

2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.

3. The HREC will ethically assess each application in accordance with the National Statement. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.

4. The HREC will consider whether an advocate for any participant or group of participants, as outlined in Section 4 of the National Statement, should be invited to the HREC meeting to ensure informed decision-making.

5. Where research involves the participation of persons who do not speak and/or read English fluently, the HREC will ensure that the researcher has put in place arrangements for an interpreter to be present during any consultation with the participants as part of the project, unless alternative arrangements are available (and approved by the HREC).

6. The HREC, after consideration of an application at a meeting, will make one of the following decisions:

    - it will approve the project as being ethically acceptable with standard conditions, and with or without any additional conditions
    - it will defer making a decision on the project until the clarification of information, or the provision of further information to the HREC
    - it will request modification and re-submission of the project
    - it will reject the project

7. The HREC will endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the project, provided that the majority includes at leastone layperson. Any significant minority view shall be noted in the minutes.

8. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.

9. For projects where the HREC has requested clarification, the provision of further information, or modification of the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following (refer to SOP 012):

    - the Executive Committee
    - a Special Committee
    - the Chair

- the EEO

In such circumstances the HREC will be informed regarding the final decision at the next available meeting, including the reason for the decision taken and the applicant's response.

10. The HREC may decide that the information should be considered at a further meeting of the HREC.

11. The HREC may conduct expedited review of projects in accordance with SOP 012.

SOP 011: Preparation of minutes

Purpose: *To describe the process and format for minutes.*

1. The EEO will prepare and maintain minutes of all meetings of the HREC.

2. The format of the minutes will include at least the following items:

   - attendance (including apologies)
   - minutes of the previous meeting
   - business arising from previous meetings (including brief summary of correspondence)
   - amendments to approved research projects
   - new applications
   - general business (for noting)
   - adverse event notifications
   - organisational matters
   - items without notice
   - close and next meeting

   All conflicts of interest must be declared in the minutes under each relevant item applicable (see point 7)

3. The minutes should include the recording of decisions made by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.

4. In relation to the review of new applications or amendments, the minutes shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.

5. In recording a decision made by the HREC, any significant minority view will be noted in the minutes.

6. To encourage free and open discussion, and to emphasise the collegiate character of the HREC, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

7. Declarations of conflicts of interest by any member of the HREC, and the absence of the member concerned during the HREC's consideration of the relevant application, will be noted in the minutes (refer to SOP 019 regarding a member's declaration of a conflict of interest).

8. The minutes will be produced as soon as practicable following the relevant meeting and should be checked by either the Chair and/or the Deputy Chair for accuracy.

9. The minutes will be circulated to all members of the HREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes will be acknowledged as true and accurate by the Ethics Committee, at the next HREC meeting.

10. An electronic copy of each meeting's minutes will be retained in a confidential 'Minutes' file.

11. The ratified minutes of each Committee meeting shall be forwarded to the Board.

SOP 012: Expedited Review

Purpose: To describe the process of expedited ethical review by HREC- appointed subcommittees.

1. To enable the HREC to assess Committee business, re-submissions and amendments that involve minimal (low) risk as quickly and thoroughly as possible, the following review mechanisms have been established:

    - the Executive Committee (expedited review sub-committee)
    - the special committees (with specialist expertise)

2. Any business conducted by expedited review will be ratified by the full HREC at its next meeting.

3. A definition of lower risk research can be found within *the National Statement in Chapter 2.1 Risk and benefit* . Paragraphs 5.1.12 to 5.1.14 and 5.1.17 describe the requirements of non- HREC ethical review of lower risk research. The following examples are considered to constitute lower risk research:

    - social science questionnaires on non-controversial, non-personal issues
    - general surveys where participation is anonymous
    - interviews involving non-personal or non-intrusive information
    - observation studies in public situations which focus on non-sensitive issues
    - studies of existing de-identified data, documents, records, pathological or diagnostic specimens
    - studies that do not involve an intervention that could result in significant harm to participants

4. When a request for expedited review is received by the EEO or the Chair, consideration must be given to the level of risk to potential participants which the research proposal constitutes. Please refer to section 5 of *the National Statement*.

5. **Executive Committee:** The Executive Committee may be convened by the Chair between scheduled meetings to review minor items of business arising from the previous meeting and/or ethical issues that are considered to be of minimal or low risk to participants. Membership of the Executive Committee shall be the Chair, the EEO and/or one or more other members.

6. **Special Committees:** The Special Committee may be convened by the Chair between scheduled meetings to review minor items of business arising from the previous meeting and/or ethical issues that are considered to be of minimal risk to participants where meeting in person may not be necessary. Membership of a special committee can be limited to the Chair, in verbal or written consultation with one or more named members that were present at the meeting or who submitted written comments on an application.

7. The decision to convene any sub-committee will be at the discretion of the Chair, as advised by the committee and having regard to the issues requiring expedited review. The proceedings of these sub-committees will be ratified by the full HREC at its next meeting.

8. Matters excluded from expedited review:

   - Research with the potential for physical or psychological harm should not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

   - Where the Chair considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence, and/or justice, the protocol must be considered by the full HREC and cannot be dealt with by a sub-committee.

SOP 013: Notifications of decisions of the Ethics Committee for new applications

Purpose: To describe the process for the notification of decisions concerning the review of new applications.

1. The HREC will report to the nominated contact person (in writing, via email) whether their application received ethical approval (including any conditions of approval), within 10 working days of the meeting, unless otherwise notified.

2. If the HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the contact person should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification will refer to the National Statement or other relevant legislation. Such correspondence will be set out in the format of Appendix C.

3. If the requested information is not received from the applicant within 3 months, the project will be dismissed and the applicant will be required to submit a new application.

4. All documentation submitted in response to Committee feedback should contain clear responses to requests, and where appropriate, tracked changes in documentation. Version number and dates in footers should be amended to reflect an update to the document.

5. The HREC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification, or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant, or may invite the applicant to attend a HREC meeting.

6. The HREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification, or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:

    - title of the project
    - name of the applicant
    - unique Family Planning Australia Ethics Committee project identification number
    - version number and date of all documentation reviewed and approved by the HREC
    - date of Family Planning Australia Ethics Committee meeting at which the project was first considered
    - date of HREC approval
    - duration of HREC approval

    A standard response will be issued in the format set out in Appendix D. Research projects may not commence until written notification is received by researchers.

7. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant legislation. A *standard response* will be issued, in the

format set out in Appendix E.

8. The status of the project shall be updated on the HREC's register of received and reviewed applications.

SOP 014: Handling of Adverse Events

Purpose: *To describe the procedure for reporting and handling adverse events.*

1. The HREC shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the HREC promptly. This includes Serious Adverse Events (SAEs) that have occurred at other institutions participating in studies using the study drug or device.

2. Notifications of adverse events must be submitted by the Chief Investigator or sponsor, and shall include all documentation as required by the HREC. This documentation shall include as a minimum:

    - if adequate information is available, advice from the Chief Investigator as to whether the adverse event was related to the protocol, or in the case of a drug/device trial, whether the adverse event was related to the study drug/device
    - if related to the study drug/device, advice as to whether the event was expected or unexpected
    - advice from the Chief Investigator as to whether, in their opinion, the adverse event necessitates an amendment to the project and/or the patient information sheet/consent form
    - advice as to whether the event has been notified to the Independent Safety and Data Monitoring Board (if one exists)
    - for Family Planning Australia participants, SAEs shall be reported immediately using the SAE reporting form in Appendix F
    - the total number of participants enrolled in the study

3. The procedures and format for notification of adverse events to the HREC shall be readily available to investigators. Reporting should be consistent with the NSW Government procedure Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations.

    - All SSIs should be reported to the HREC using the form in Appendix G.
    - those implemented as USMs should be reported within 72 hours
    - those not implemented as USMs should be reported within 15 calendar days
    - All adverse events that are serious and unexpected/related to the trial should be reported within 72 hours using the form in Appendix F.
    - All other adverse events should be reported using the Annual Progress Report form (Appendix H).

4. Adverse events may be reviewed by the Chair or delegate of the HREC, which shall determine the appropriate course of action. This may include:

    - notations on file of the occurrence
    - increased monitoring of the project

- request for an amendment to the protocol and/or participation information sheet/consent form
- suspension of ethical approval
- termination of ethical approval

Any such adverse events shall be reported to the HREC at the next available meeting.

5. For those adverse events deemed serious and requiring immediate attention, the Chair may take the appropriate course of action including:
   - referral to expert reviewers
   - immediate request for additional information
   - immediate suspension of ethical approval
   - immediate termination of ethical approval
6. The HREC will contact the Chief Investigator, in writing, acknowledging the receipt of reported SAE, as well as provide details regarding the appropriate course of action that has been determined by the committee.

SOP 015: Monitoring of Approved Research Projects

Purpose: *To describe the procedure for monitoring approved research projects to ensure compliance with ethical approval.*

1. The HREC will monitor approved projects to ensure ongoing ethical compliance. In doing so, the Committee may request relevant project information or documentation at any time. Chief Investigators are also required to submit an annual progress report to maintain approval, as well as a report at the conclusion of the project (Appendix H).

2. The HREC shall require the following information in the annual report:

    - progress to date or summary of results and final outcomes in the case of completed research
    - maintenance and security of records
    - compliance with the approved protocol
    - compliance with any conditions of approval

3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:

    - random inspections of research data and signed consent forms
    - interviews, with prior consent, of research participants

4. The HREC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:

    - proposed changes in the protocol
    - any unforeseen events that might affect continued ethical acceptability of the project (refer to SOP 015)
    - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol

5. The HREC shall require, as a condition of approval of each project, that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.

6. Where the HREC is satisfied that circumstances have arisen such that a research project is *not being, or cannot be*, conducted in accordance with the approved project, the HREC may withdraw approval. In such circumstances, the HREC shall inform the Chief Investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.

7. If the HREC withdraws or suspends approval for a project, the Chief Investigator may submit an appeal of the decision in writing to the Chair. Such appeal should include a clear justification for why approval should not be withdrawn/suspended and/or a clear explanation of the steps to be taken to ensure ethical conduct of the research henceforth.

In the case of an appeal, the Committee may consider the written appeal only, or invite the Chief investigator to attend the scheduled meeting to engage in a conversation about the project.

8. In determining the frequency and type of monitoring required for approved projects, the HREC will give consideration to the degree of risk to participants in the research project.

SOP 016: Complaints about the Conduct of a Research Project

Purpose: *To describe the mechanism for receiving, handling, and responding to complaints concerning the conduct of an approved project.*

1. The HREC nominates the EEO as the person who receives complaints from research participants, researchers, or other interested persons regarding the conduct of approved projects. The name and/or position and contact details of the EEO must be included in the participant information sheet and/or consent form for each project.

2. Any concern or complaint about the conduct of a project should be directed to the attention of the EEO, who shall notify the Chair as soon as possible after a complaint is received. The Chair of the HREC will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The investigation will take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. If the complaint is substantiated, action may include the requirement for amendments to the project, including increased monitoring by the HREC, suspension of the project, termination of the project, or other action to resolve the complaint.

3. Where the complaint concerns a serious matter within the jurisdiction of the Health Care Complaints Commission, the Chair will notify the CEO who shall consider referral of the complaint to that body in accordance with Australia Health's Managing Complaints and Concerns about Clinicians (2018).

4. The complainant shall be informed in writing, or otherwise, of the outcome of the Chair's investigation. If the complainant is not satisfied with the outcome of the investigation they will be referred to the CEO, or their nominee, for further discussion. The Chair will provide the CEO (or their representative) with all relevant information about the complaint, including:

    - the complaint
    - material reviewed in the Chair's investigation
    - the results of the Chair's investigation
    - any other relevant documentation

5. The CEO will then determine whether further investigation is required, and the CEO will notify the outcome to all relevant parties. In the event that further investigation is required, the CEO will establish a panel to consider the complaint.

6. The panel will include, *at least*, the following members:

    - the CEO or their nominee as convenor of the panel
    - two nominees of the CEO (not members of the HREC)
    - the EEO

7. The panel will afford the HREC and complainant the opportunity to make further submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with an opportunity to make submissions.

8. The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.

9. The CEO will notify the complainant and the Chair of the outcome of the investigation, and the investigator if an allegation has been made against them. The outcomes may include:

   - the complaint is dismissed
   - the CEO directs appropriate action to be taken to resolve the complaint

SOP 017: Complaints about the Committee's Review Process

Purpose: *To describe the procedure for receiving and handling concerns or complaints from investigators about the Family Planning AustraliaHuman Research Ethics Committee's review process.*

1. Any concern or complaint about the conduct of a project should be directed to the attention of the EEO, who shall notify the Chair as soon as possible. Complaints may also be made directly to Chair, to the Board, and/or to the CEO. Ideally, the grounds of the concern or complaint should be detailed in writing.

2. The Chair will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action.

3. Where appropriate, the Chair will respond to the complainant in writing. If the complainant is not satisfied with the outcome of the Chair's investigation, they can refer the complaint to the Board (or delegate), or request the Chair to do so.

4. The Chair of the HREC will refer all unresolved complaints to the Board with all relevant information about the complaint/concern, including:

    - the complaint
    - material reviewed in the Chair's investigation
    - the results of the Chair's investigation
    - any other relevant documentation

    The Board will determine whether the complaint requires further investigation.

5. If the Board determines there is to be a further investigation, then the Board will establish a panel to consider the complaint. Where no further investigation is required, the Board will inform the complainant and the Chair.

6. The panel will include, at least, the following members:

    - the Board Chair or their nominee as Convenor of the panel
    - two Board-appointed nominees (not members of the HREC)

7. The panel will afford the HREC and the complainant the opportunity to make submissions.

8. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance *the National Statement*, its Terms of Reference, SOPs, or otherwise acted in an unfair or unbiased manner.

9. The outcomes of this process may include:

    - the complaint is dismissed
    - the complaint is referred back to the HREC for consideration, bearing in mind the findings of the panel

- referral to an expert(s) in the discipline of research of the project under consideration for their assessment and comment

10. The panel may also make recommendations about the operation of the HREC including such actions as:

    - review Terms of Reference and SOPs
    - review committee membership
    - take other such action as appropriate

11. Should the HREC be requested to review its decision, the outcome of this review by the HREC will be final.

12. The approval of the Board, its delegate or the panel cannot be substituted for the approval of the HREC.

SOP 018: Record Keeping

Purpose: *To describe the procedure for the preparation and maintenance of records of the Family Planning Australia Human Research Ethics Committee's activities.*

1. The EEO will prepare and maintain electronic records of the HREC's activities, including agendas and minutes of all meetings of the HREC, and any submissions to the Chair or EEO including complaints and adverse events. See point 5 for retention periods.

2. The EEO will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:

   - unique project identification number
   - the Chief Investigator(s)
   - the name of the responsible institution or organisation
   - title of the project
   - ethical approval or non-approval with date
   - approval or non-approval of any changes to the project
   - duration of the approval
   - the terms and conditions, if any, of approval of the project
   - whether approval was by expedited review
   - name of any other review body whose opinion was considered
   - action taken by the HREC to monitor the conduct of the research
   - any adverse events or complaints reported
   - relevance, if any, of the Commonwealth or State (or Territory) legislation or guidelines relating to privacy of personal or health information

   The file shall contain a copy of the application, including signatures, and any relevant correspondence including that between the applicant and the HREC, all approved documents and other material used to inform potential research participants.

3. All relevant records of the HREC, including applications, membership, minutes and correspondence will be kept as confidential files in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (HRIPA)* and the *State Records Act 1998*.

4. To ensure confidentiality, all documents provided to HREC members that are no longer required are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal are responsible for returning their documents to the EEO for disposal.

5. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period of retention for non-clinical research is *at least 5 years* after the date of publication, completion of research, or termination of the study. For clinical

research, or research with potential long term effects on humans, *15 years* shall apply. Retention periods comply with. General Retention and Disposal Authority: GA47

6. A register of all the applications received and reviewed shall be maintained in accordance with *the National Statement.*

SOP 019: Handling of Conflicts of Interest

Purpose: *To describe the procedure for Family Planning Australia Human Ethics Committee members to report conflicts of interest with projects or other HREC related matters, as well as the management of these conflicts.*

1. A HREC member shall, as soon as practicable during the HREC meeting, inform the Chair if they have a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC. At the discretion of the Chair this member may be asked to leave the room during any current or future discussion of the project. If the member is not asked to leave the room, they cannot participate in the discussion (except to make clarifications as requested), and will not take part in the decision making process.

2. If the Chair has a potential conflict of interest, the Deputy Chair will take over the conduct of the meeting for the proposal in question. In the absence of the Deputy Chair, the committee may nominate a member to act as the Chair for the proposal in question.

3. All declarations of conflict of interest will be minuted.

SOP 020: Reporting Requirements

Purpose: *To describe the reporting requirements of the Family Planning Australia Human Research Ethics Committee.*

1. The minutes of each HREC meeting will be forwarded to the Board through the CEO, following confirmation by the Ethics Committee members.

2. The Chair of the Ethics Committee will write to the Board seeking appointment of new members, as well as regarding the endorsement of Chair and Deputy Chair positions (SOP 002).

3. The HREC shall provide an annual progress report to the Board at the end of each financial year, including:

    - changes to membership and current membership
    - number of meetings and attendance of each member
    - number of projects reviewed, approved and rejected
    - number of amendments reviewed, approved and rejected
    - monitoring procedures for ethical aspects of research in progress, and any problems encountered by the HREC in undertaking its monitoring role
    - description of any complaints received, and their outcome
    - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval
    - general issues raised

4. Terms of Reference, SOPs and membership will be available upon request to the general public, and will be posted on the website.

SOP 021: Review of SOPs and Terms of Reference

Purpose: To describe the procedure for the approval of amendments to the Family Planning Australia Human Research Ethics Committee SOPs and Terms of Reference.

1. The SOPs and Terms of Reference shall be reviewed every three years and amended as necessary.

2. The SOPs and Terms of Reference may be amended by following the procedure below:

    - For those proposals made by a HREC member:

        - The proposal must be in writing and circulated to all HREC members for their consideration.

        - The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.

        - The proposal will be ratified if two thirds of the members agree to the amendment.

        - The Chair shall send the amendment to the CEO for review and approval if appropriate.

        - The CEO shall send the updated SOPs and Terms of Reference to the Family Planning Australia Board for review and/or approval.

    - For those proposals made by the CEO and/or delegate:

        - The CEO will send the proposal to the Family Planning Australia Ethics Committee and seek the views of any relevant person.

3. SOPs, terms of reference, membership of the Ethics Committee, and Ethics Committee meeting and submission dates will be maintained on the website.

List of Appendices

Appendix A	Responsibilities of Members Form
Appendix B	Standard Approval Letter (amendment)
Appendix C	Standard Further Clarification Letter (amendment/new application)
Appendix D	Standard Approval Letter (new application)
Appendix E	Standard Rejection Letter
Appendix F	Serious Adverse Event Reporting Form
Appendix G	Significant Safety Issue Form
Appendix H	Annual/Final Progress Report Form
To view appendices, click on the relevant hyperlink and it will open in your default web browser.	