



# **Family Planning NSW Ethics Committee**

## **Standard Operating Procedures**

## STANDARD OPERATING PROCEDURES

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**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

<b>Reference Number:</b>	<b>SOP 001</b>	<b>Date:</b>	<b>March 2016</b>
<b>Subject:</b>	<b>Family Planning NSW Ethics Committee function</b>		
<b>Purpose:</b>	To describe the function of the Family Planning NSW Ethics Committee		

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## **OVERALL FUNCTION**

1. The primary objective of the Family Planning NSW 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, to promote ethical standards of human research and to review research in accordance with the National Health and Medical Research Council (NH&MRC) *National Statement on Ethical Conduct in Human Research 2007 (National Statement)*.

### **Scope of Responsibilities**

1. The functions of the Family Planning NSW Ethics Committee are:
  - i. To provide advice to the Board on issues relating to the ethical conduct of research that might arise from time to time.
  - ii. To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
  - iii. To provide ethical oversight, monitoring and advice for research projects involving humans.
  - iv. To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
  - v. To act in accordance with NH&MRC guidelines pertaining to HRECs. The Committee will function as a properly constituted HREC in accordance with the National Statement.
  
2. Research projects involving humans will be reviewed by the Family Planning NSW Ethics Committee where the research involves participants of any institutions governed by Family Planning NSW.

This operating procedure does not prohibit Family Planning NSW from accepting an ethical approval granted by another Ethics Committee as sufficient ethical approval allowing Family Planning NSW to approve the commencement of the project, provided that such other Ethics Committee is registered with the Australian Health Ethics Committee.
  
3. 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.
  
4. Family Planning NSW Ethics Committee will assess projects submitted to it for review in accordance with the [National Statement \(2007\)](#) and any other legal requirements in order to determine their ethical acceptability.

**Family Planning NSW Ethics Committee  
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**Reference Number:**     **SOP 002**

**Date:** March 2016

**Subject:**                 **Membership composition**

**Purpose:**                 To describe the membership composition of the Family Planning NSW Ethics Committee

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1. The composition of the Family Planning NSW Ethics Committee shall be in accordance with the [National Statement \(2007\)](#). Minimum membership shall be eight members, being men and women, comprising:

- a Chair;
- a Deputy-Chair
- 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 two members with knowledge of, and current experience in, the areas of research that are regularly considered by the Family Planning NSW Ethics Committee;
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- at least one member who is a minister of religion, or a person who performs a similar role in the community;
- at least one member who is a lawyer.

The Family Planning NSW Board may appoint a Board member to the Ethics Committee. Additional members with special expertise may be appointed by the Board in special categories.

2. To ensure the membership will equip the Family Planning NSW Ethics Committee to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

3. Where required, the Family Planning NSW Ethics Committee may seek advice and assistance from appropriate experts to assist with the review of a project. However, the Family Planning NSW Ethics Committee must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

4. Additional members may be appointed to ensure the Family Planning NSW Ethics Committee has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the Family Planning NSW Ethics

Committee 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, subject to the discretion of the Board.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number:**     **SOP 003**

**Date:** March 2016

**Subject:**               **Appointment of Members**

**Purpose:**                To describe the procedure for the appointment of members to the  
Family Planning NSW Ethics Committee

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1. Members are appointed as individuals rather than in a representative capacity.
  
2. Prospective members of the Family Planning NSW Ethics Committee may be recruited by direct approach, nomination or by advertisement. The process selected must be open and transparent. Please refer to National Statement (2007) paragraph 5.1.34 – 5.1.36.
  - Where recruitment via advertisement is the process adopted, the content and publication schedule of the advertisement must be approved by the Chief Executive.
  - A staff member will be nominated to receive enquiries from prospective applicants. The information supplied will be consistent and be drawn from key source documents such as the Family Planning NSW Ethics Committee Terms of Reference and the National Statement.
  - After the closing date, the selection committee will review the applications received. The selection committee may opt to interview a small number of applications. In this case, applications will be culled by the committee on an agreed, documented basis. Applicants who query their failure to be offered an interview will be advised of the culling criteria.
  - Interviewees shall be asked to confirm their identity and provide a copy of their current Curriculum Vitae to the selection committee
  
3. A selection committee, consisting of the Chair, Ethics Executive Officer and any other Committee member appointed by the Chair shall interview the prospective applicant. Following the interview, the Chair will check the personal referees of preferred applicants or delegate the task to the Ethics Executive Officer.
  
4. The Chair of the Ethics Committee 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 NSW, 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.
  
5. New members are able to sit in on the Ethics Committee meetings to observe as a non-voting member prior to board approval.

6. The Chair and deputy positions will be nominated by the Committee then endorsed by the board. In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair.
7. 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 Family Planning NSW Ethics Committee member, and the conditions of their appointment.
8. A prospective new member will be required to sign a confidentiality undertaking (see Attachment A) upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the Family Planning NSW Ethics Committee will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the Family Planning NSW Ethics Committee will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a Family Planning NSW Ethics Committee member.
9. Members must agree to sign the Responsibilities of members of the Family Planning NSW Ethics Committee form (Attachment A) and have their name and profession made available to the public, including being published on the Family Planning NSW website.
10. Upon appointment, members shall be provided with the following documentation:
  - Family Planning NSW Ethics Committee Terms of Reference;
  - Family Planning NSW Ethics Committee Standard Operating Procedures;
  - Calendar of meeting dates
  - Responsibilities of members of the Family Planning NSW Ethics Committee
11. Membership of the Committee is reviewed by the Chair every third calendar year, regardless of the fraction of the term already served by each member. Reappointment is by application to the Chair of the Family Planning NSW Ethics Committee who will then 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 Family Planning NSW Ethics Committee, and the regular input of fresh ideas and approaches.
12. The appointment of the Chair and Deputy Chair is reviewed every third calendar year by the Board.
13. Newly appointed members shall be provided with adequate orientation. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the Family Planning NSW Ethics Committee, at the expense of Family Planning NSW, where possible in accordance with the National Statement (2007).

14. Members shall not be remunerated. Members may make an application for reimbursement of legitimate expenses incurred in attending Family Planning NSW Ethics Committee meetings, such as travelling and parking expenses, at the discretion of the Chief Executive.
15. Members may apply to the Chair, in writing, for a leave of absence from the Family Planning NSW Ethics Committee for extended periods. Steps shall be taken to fill the vacancy.
16. Membership will lapse if a member fails to attend three consecutive meetings of the Family Planning NSW Ethics Committee without reasonable excuse/apology as determined by the Chair, 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, which may arise.
17. Members will be expected to participate in relevant specialised working groups as required. The Chair will be expected to be available between meetings to participate in Executive meetings (Refer [SOP 012](#)) where required. The Chair should be contactable by phone and email.
18. A member may resign from the Family Planning NSW Ethics Committee at any time upon giving notice in writing to the Chair. Steps shall be taken to fill the vacancy of the former member.
19. Members must provide current contact details to the Ethics Executive Officer to ensure that they can be contacted as required.



**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number:**     **SOP 004**

**Date:** March 2016

**Subject:**                 **Orientation of new members**

**Purpose:**                 To describe the procedure for the orientation of new members

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1. New Family Planning NSW Ethics Committee members must be provided with adequate orientation.
  
2. Orientation may involve all or some of the following:
  - Introduction to other Family Planning NSW Ethics Committee members prior to the Family Planning NSW Ethics Committee meeting.
  - Informal meeting with Chair and Ethics Executive Officer to explain their responsibilities as an Family Planning NSW Ethics Committee member, the Family Planning NSW Ethics Committee processes and procedures.
  - An opportunity to sit in on Family Planning NSW Ethics Committee meetings as an observer before their appointment takes effect.
  - ‘Partnering’ with another Family Planning NSW Ethics Committee member in the same category.
  - Priority given to participate in training sessions.
  
3. New Family Planning NSW Ethics Committee members will be provided with the following written information:
  - A list of the members’ names, emails and their roles on the Family Planning NSW Ethics Committee.
  - A copy of the *NH&MRC National Statement on Ethical Conduct in Human Research, 2007*.
  - any other relevant information about the Family Planning NSW Ethics Committee’s processes, procedures and protocols.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number:**     **SOP 005**

**Date:** March 2016

**Subject:**               **Training and Education of Family Planning NSW  
Ethics Committee members**

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

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Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the Family Planning NSW Ethics Committee, at the expense of Family Planning NSW, where possible in accordance with the National Statement (2007).

Every member of the Family Planning NSW Ethics Committee should aim to attend at least one training session every three years.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number:** SOP 006

**Date:** February 2017

**Subject:** Submission procedure for new applications

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

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1. All research projects requiring ethical review must receive approval from the Family Planning NSW Executive team before the Family Planning NSW Ethics Committee will accept the application for review.
2. All applications for ethical review must be submitted to the Ethics Executive Officer of the Family Planning NSW Ethics Committee, via email by close of business on the relevant closing date. The closing dates for new applications should normally be no later than four weeks prior to each Family Planning NSW Ethics Committee meeting. For all other business (eg. amendments to existing registered studies and/or general correspondence), submissions are due no later than two weeks prior to each Family Planning NSW Ethics Committee 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 (eg Advertisements, Participant Information and Consent Forms). The procedures for application to the Family Planning NSW Ethics Committee and the application can be accessed on <https://hrea.gov.au/>
5. All study documents submitted with the NEAF should contain a footer with;
  - Document name
  - Version number
  - Version Date
6. Cover letter should contain the following;
  - Study name
  - List of all documents submitted including their version, and date
7. Once the submission has been received and accepted by the Ethics Executive Officer, applicants will be sent an acknowledgment of receipt email which will list all documents that were submitted.
8. Application Fees; No fee will be charged for assessment by the Family Planning NSW HREC of research projects or clinical trials that are Family Planning NSW-investigator driven. For commercially sponsored clinical trial applications submitted for assessment by the Family Planning NSW HREC a fee will be charged, in accordance with NSW Health's Human Research Ethics Committees (HRECs) Fee for Review of Clinical Trials within NSW Health. At the discretion of the Executive a fee may also be charged for the ethical assessment of non-clinical trial applications arising externally.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 007**

**Date: March 2016**

**Subject: Processing of applications for review**

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

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All applications must be signed by the CEO, prior to review by the Ethics Committee. Applications will be checked for their completeness by the Ethics Executive Officer prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.

1. Once a completed application has been accepted for ethical review, the Ethics Executive Officer shall assign a unique project identification number to the project. The project will be added to the Family Planning NSW Ethics Projects register of received and reviewed applications.
2. Completed applications for clinical or other biomedical trials received by the closing date will be sent to the Ethics Scientific Subcommittee (ESSC) for scientific review (see [appendix F](#)). The ESSC will either:
  - Certify that the study proposal is scientifically sound;
  - Advise the Ethics Executive Officer that the proposal is not sound, with reasons; or
  - Request expert advice from the Scientific Advisory Group (SAG – see [appendix F](#))
  - The Scientific Advisory Committee will either certify the scientific validity of the study, or liaise with the Researcher and Ethics Executive Officer to revise the proposal.

Once a proposal has accepted sound, it will be listed on the agenda of the next Family Planning NSW Ethics Committee meeting. If a substantial number of applications are received, some may be deferred until the following Family Planning NSW Ethics Committee 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.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 008**

**Date: March 2016**

**Subject: Preparation of agenda**

**Purpose:** To describe the process and format of agenda for Family Planning NSW Ethics Committee meeting

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1. The Ethics Executive Officer will prepare an agenda for each Family Planning NSW Ethics Committee meeting.
2. All completed applications and relevant documents received by the Ethics Executive Officer will be included on the agenda for consideration by the Family Planning NSW Ethics Committee at its next available meeting.
3. The meeting agenda and associated documents will be collated by the Ethics Executive Officer and circulated to all Family Planning NSW Ethics Committee 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 two weeks prior to the meetings, giving sufficient time for review and preparation of feedback. This will include any documents submitted by an Ethics Committee member which are to be submitted to the Ethics Executive Officer in reasonable time for inclusion in the pre-circulated meeting papers.
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 shall new applications for research be tabled at the meeting.
5. Agenda items will include at least the following items:
  - i) Attendance – including apologies
  - ii) Minutes of the previous meeting
  - iii) Business arising from the previous minutes (including brief summary of correspondence)
  - iv) Amendments to approved protocols
  - v) New proposals
  - vi) General business (For noting)
  - vii) Adverse event notification
  - viii) Organisational matters
  - ix) Items without notice
  - x) Close and next meeting
6. The agenda and all documentation shall remain confidential.

7. Following the meeting, all items reviewed will require correspondence to the researcher advising of any action required or that it was noted/approved during the meeting. Researchers will be emailed their study outcomes within 10 working days of the meeting date.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 009**

**Date: March 2016**

**Subject: Conduct of meetings**

**Purpose:** To describe the format of meetings of the Family Planning NSW Ethics Committee

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1. The Family Planning NSW Ethics Committee shall meet on a regular basis, which will normally be at six weekly intervals. Meeting dates and agenda closing dates shall be publicly available on Family Planning NSW website.
2. The Ethics Executive officer will email all committee members one week prior to committee meeting to confirm members attendance and ensure quorum
3. Members may attend Family Planning NSW Ethics Committee meetings in person or via teleconference.
4. The Chair may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 10). Should this occur, the Family Planning NSW Ethics Committee 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 the business has not been completed within the allocated time, then the Family Planning NSW Ethics Committee may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting should be held within 5 working days.
7. The Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee may agree to the presence of applicants/researchers, visitors or observers to a meeting.
9. Members who are unable to attend a meeting may contribute prior to the meeting through written submissions to the Ethics Executive Officer or Chair. These should normally be received at least 3 working days prior to the meeting so that copies may be made available in advance to members. The minutes should record the submission of written comments.
10. A quorum must be present in order for the Family Planning NSW Ethics Committee 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;
  - 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 Family Planning NSW Family Planning NSW Ethics Committee;
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- at least one member who is a minister of religion, or a person who performs a similar role in the community;
- 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 Family Planning NSW Ethics Committee.

11. If the meeting does not achieve quorum, the Chair shall decide if it can proceed only in exceptional circumstances. In such circumstances, decisions made by the Family Planning NSW Ethics Committee must be ratified by at least one representative from those membership categories not present.
12. Any member of the Family Planning NSW Ethics Committee who has any interest, financial or otherwise, in a project or other related matter(s) considered by the Family Planning NSW Ethics Committee, should declare such interest. This will be dealt with in accordance with SOP 022.



**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 010**

**Date: March 2016**

**Subject: Consideration of applications for ethical review by the  
Family Planning NSW Ethics Committee**

**Purpose:** To describe the process of the Family Planning NSW Ethics Committee's consideration of applications for ethical assessment

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1. The Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee present at the meeting or providing written comments in lieu of attendance.
3. The Family Planning NSW Ethics Committee will ethically assess each application in accordance with the [National Statement](#) (2007). The Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee will consider whether an advocate for any participant or group of participants should be invited to the Family Planning NSW Ethics Committee meeting to ensure informed decision-making.
5. Where research involves the participation of persons who do not speak and/or read English fluently the Family Planning NSW Ethics Committee will ensure that the researcher has put in place arrangements for an interpreter to be present during the discussion on the project, unless alternative arrangements are available (and approved by the Family Planning NSW Ethics Committee).
6. The Family Planning NSW Ethics Committee, 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 or without conditions.
  - It will defer making a decision on the project until the clarification of information or the provision of further information to the Family Planning NSW Ethics Committee.
  - It will request modification of the project.
  - It will reject the project.

7. The Family Planning NSW Ethics Committee will endeavor 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 least one layperson. Any significant minority view shall be noted in the minutes.
8. In order to facilitate consideration of an application, the Family Planning NSW Ethics Committee may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.
9. For projects where the Family Planning NSW Ethics Committee has requested clarification, the provision of further information, or modification of the project, the Family Planning NSW Ethics Committee may choose to delegate the authority to review that information and approve the project between meetings to one of the following (refer [SOP 012](#)):

- Executive Committee
- or
- Special Committee

In such circumstances, the Family Planning NSW Ethics Committee shall be informed at the next available meeting of the final decision taken on its behalf, including the reason for the decision taken and the applicant's response.

10. Exceptionally, the Family Planning NSW Ethics Committee may decide that the information should be considered at a further meeting of the Family Planning NSW Ethics Committee.
11. The Family Planning NSW Ethics Committee may conduct expedited review of projects in accordance with SOP 012.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 011**

**Date: March 2016**

**Subject: Preparation of minutes**

**Purpose:** To describe the process and format for minutes of a meeting of the Family Planning NSW Ethics Committee.

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1. The Family Planning NSW Ethics Committee Ethics Executive Officer will prepare and maintain minutes of all meetings of the Family Planning NSW Ethics Committee.
  
2. The format of the minutes will include at least the following items:
  - i) apologies
  - ii) attendance
  - iii) minutes of the previous meeting
  - iv) business arising from the previous minutes (including receipt of correspondence)
  - v) amendments to approved projects
  - vi) new applications
  - viii) Items for noting adverse event notifications
  - ix) other business
  - x) close and next meeting

All conflict of interests must be declared in the minutes under each relevant item applicable.

3. The minutes should include the recording of decisions taken by the Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee, 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 Family Planning NSW Ethics Committee, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

7. Declarations of conflicts of interest by any member of the Family Planning NSW Ethics Committee and the absence of the member concerned during the Family Planning NSW Ethics Committee consideration of the relevant application will be noted in the minutes (refer to SOP 022 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 Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee 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.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 012**

**Date: March 2016**

**Subject: Expedited review**

**Purpose:** To describe the procedure for the expedited review of research by the Family Planning NSW Ethics Committee.

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To enable the Family Planning NSW Ethics Committee 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

- Executive Committee
- Special committees

Any business conducted by expedited review will be ratified by the full Family Planning NSW Ethics Committee at its next meeting.

A definition of low risk research can be found within the National Statement (2007) at paragraph 2.1.6 and Section 5. The following examples are considered to constitute low 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.

When a request for expedited review is received by the Ethics Executive Officer or the Chair, consideration must be given to the level of risk to potential participants which the research proposal constitutes. Please refer to the National Statement (2007) section 5.

**1. 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 (low) risk to participants. Membership of the Executive Committee shall be the Chair, the Ethics Executive Officer and/or one or more other members.

**2. 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.

3. 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 i.e. Executive Committee and Special Committees will be ratified by the full Family Planning NSW Ethics Committee at its next meeting.

4. **Matters excluded from expedited review**

Research with the potential for physical or psychological harm should generally 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 justice, the protocol must be considered by the full Family Planning NSW Ethics Committee and cannot be dealt with by a sub-committee.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 013**

**Date: March 2016**

**Subject: Notification of decisions of the Family Planning NSW Ethics Committee for new applications**

**Purpose:** To describe the procedure for the notification of decisions of the Family Planning NSW Ethics Committee concerning the review of new applications.

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1. The Family Planning NSW Ethics Committee will report in writing via email to the Chief Investigator, advising whether the application has received ethical approval (including any conditions of approval), within 10 working days of the meeting, unless otherwise notified.
2. If the Family Planning NSW Ethics Committee determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the Chief 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/modification will refer to the NH&MRC *National Statement (2007)* or other relevant pieces of legislation.
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 re-submit the project at a later date.
4. All documentation submitted for re-review, should contain clear responses to requests and where appropriate, tracked changes in documentation where changes have been requested. Version number and dates in footers should be amended to reflect an update to the document.
5. The Family Planning NSW Ethics Committee shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The Family Planning NSW Ethics Committee may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant Family Planning NSW Ethics Committee meeting.
6. The Family Planning NSW Ethics Committee 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 project;
  - Name of the applicant;
  - Unique Family Planning NSW Ethics Committee project identification number;

- Version number and date of all documentation reviewed and approved by the Family Planning NSW Ethics Committee including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc;
- Date of FPNSW Ethics Committee meeting at which the project was first considered;
- Date of Family Planning NSW Ethics Committee approval;
- Duration of Family Planning NSW Ethics Committee approval; and
- Conditions of Family Planning NSW Ethics Committee approval, if any.

A standard response will be issued, in the format set out in [Attachment B](#). Research projects may not commence until written notification that confirms this has been received.

7. If the Family Planning NSW Ethics Committee determines that a project is ethically unacceptable, the notification of the Family Planning NSW Ethics Committee's decision will include the grounds for rejecting the project with reference to the *National Statement (2007)* or other relevant pieces of legislation. A standard response will be issued, in the format set out in [Attachment C](#).
8. The status of the project shall be updated on the Family Planning NSW Ethics Committee's register of received and reviewed applications.



**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 014**

**Date: March 2016**

**Subject: Submission of amendments and extensions to approved projects**

**Purpose:** To describe the procedure for the submission and Family Planning NSW Ethics Committee review of requests for amendments and extensions to approved protocols.

1. Proposed changes to approved research projects, changes to the conduct of the research, or requests for extensions to the length of Family Planning NSW Ethics Committee approval, are required to be reported by the Chief Investigator to the Family Planning NSW Ethics Committee 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, include a summary of the proposed changes and contain revised version numbers and dates.
3. Expedited review of requests for minor amendments and extensions may be undertaken by the Ethics Expedited Review Process or by the Family Planning NSW Ethics Committee Executive between scheduled meetings at the discretion of the Chair and in accordance with SOP 012, on the condition that it be ratified at the next Family Planning NSW Ethics Committee meeting. Where an urgent protocol amendment is required for safety reasons, the Chair may review and approve the request. In such circumstances, the Family Planning NSW Ethics Committee will review the decision at its next available meeting.
4. All other requests for amendments shall be reviewed by the Family Planning NSW Ethics Committee at its next available meeting, provided the request has been received by the Ethics Executive Officer by the agenda closing date.
5. The Family Planning NSW Ethics Committee will report in writing to the Chief Investigator, 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 [Attachment D](#).
7. If the Family Planning NSW Ethics Committee 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 (2007)* or relevant pieces of legislation.

8. All documentation submitted for re-review, 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 to a protocol shall be recorded, and the status of the project shall be updated on the Family Planning NSW Ethics Committee's register of received and reviewed applications.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 015**

**Date: March 2016**

**Subject: Handling of adverse events**

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

---

1. The Family Planning NSW Ethics Committee shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the Family Planning NSW Ethics Committee 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 in a tabulated form by the Chief Investigator, and shall include all documentation as required by the Family Planning NSW Ethics Committee. This documentation shall include as a minimum:
  - Advice from the Chief Investigator as to whether, in his/her opinion, 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 adequate information is available to make this assessment
  - 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 his/her 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 NSW participants, SAEs shall be reported immediately as a detailed narrative report.
3. For all adverse event reporting, if information is available as to the total number of participants enrolled in the study, the Investigator shall make this information available to the Family Planning NSW Ethics Committee.
4. The procedures and format for notification of adverse events to the Family Planning NSW Ethics Committee shall be readily available to investigators.
5. Adverse events may be reviewed by an Executive of the Family Planning NSW Ethics Committee, which shall determine the appropriate course of action. This may include:
  - Notation on file of the occurrence;

- Increased monitoring of the project;
- Request for an amendment to the protocol and/or Participant Information Sheet/Consent Form;
- Suspension of ethical approval; or
- Termination of ethical approval.

Any such adverse events shall be reported to the Family Planning NSW Ethics Committee at the next available meeting.

6. The Chair may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
  - Referral to the Scientific Advisory Group
  - Immediate request for additional information;
  - Immediate suspension of ethical approval;
  - Immediate termination of ethical approval.
  
7. The Family Planning NSW Ethics Committee shall provide notice in writing to the investigator that it has received notification of all serious or unexpected adverse events, and the course of action it has deemed necessary to take in any or that it was noted at the meeting.
  
8. The Family Planning NSW Ethics Committee does not have to receive notification of adverse events that are related to the marketed use of a product.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 016**

**Date: March 2016**

**Subject: Monitoring of approved research projects**

**Purpose:** To describe the procedure for monitoring research projects approved by the Family Planning NSW Ethics Committee to ensure compliance with ethical approval.

---

1. The Family Planning NSW Ethics Committee will monitor approved projects to ensure compliance with its ethical approval. In doing so it may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the Family Planning NSW Ethics Committee will require applicants to provide a report at least annually, and at completion of the study. ([Attachment E](#)) Continuing approval of the research will be subject to the Chief Investigator submitting an annual compliance report which is available on the Family Planning NSW website.
  
2. The Family Planning NSW Ethics Committee shall require the following information in the annual report:
  - Progress to date or outcome in the case of completed research;
  - Maintenance and security of records;
  - Compliance with the approved protocol; and
  - Compliance with any conditions of approval.
  
3. The Family Planning NSW Ethics Committee may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
  - Random inspections of research data and signed consent forms;
  - Interview, with their prior consent, of research participants.
  
4. The Family Planning NSW Ethics Committee 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; and
  - 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 Family Planning NSW Ethics Committee shall require, as a condition of approval of each project, that investigators inform the Family Planning NSW Ethics Committee, giving reasons, if the research project is discontinued before the expected date of completion.
6. Where the Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee may withdraw approval. In such circumstances, the Family Planning NSW Ethics Committee 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. In determining the frequency and type of monitoring required for approved projects, the Family Planning NSW Ethics Committee will give consideration to the degree of risk to participants in the research project.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 017**

**Date: March 2016**

**Subject: Complaints about the conduct of a research project**

**Purpose:** To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the Family Planning NSW Ethics Committee.

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1. The Family Planning NSW Ethics Committee shall nominate the Ethics Executive Officer as the person to whom complaints from research participants, researchers, or other interested persons about the conduct of approved research projects, may be made in the first instance. The name and/or position and contact details of the Ethics Executive Officer 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 Family Planning NSW Ethics Committee Ethics Executive Officer, who shall notify the Chair as soon as possible after a complaint is received. The Chair of the Family Planning NSW Ethics Committee 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 Family Planning NSW Ethics Committee; 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 Chief Executive who shall consider referral of the complaint to that body in accordance with NSW Health's ['Complaint or Concern about a Clinician - Management Guidelines and Principles for Action' 2006](#).
4. The complainant shall be informed in writing, or otherwise, of the outcome of the Chair's investigation.
5. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chair to do so.
6. The Chair of the Family Planning NSW Ethics Committee will provide the Chief Executive or his/her nominee 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; and

- any other relevant documentation.
7. The Chief Executive will determine whether there is to be a further investigation of the complaint. Where there is no further investigation, the Chief Executive will inform the complainant and the Chair of this.
  8. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint.
  9. The panel will include, at least, the following members:
    - the Chief Executive or his/her nominee as convenor of the panel;
    - two nominees of the Chief Executive (not members of the Family Planning NSW Ethics Committee); and
    - the Family Planning NSW Ethics Committee Ethics Executive Officer.
  10. The panel will afford the Family Planning NSW Ethics Committee and complainant the opportunity to make 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.
  11. 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.
  12. The Chief Executive 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/concern is dismissed.
    - The Chief Executive directs appropriate action to be taken to resolve the complaint.



**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 018**

**Date: March 2016**

**Subject: Complaints concerning the Family Planning NSW Ethics Committee's review process**

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

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1. Any concern or complaint about the conduct of a project should be directed to the attention of the Family Planning NSW Ethics Committee Executive Officer, who shall notify the Chair as soon as possible. Complaints may also be made directly to Chair, to the Board and/or the Chief Executive. 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 Family Planning NSW Ethics Committee 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, then he/she can refer the complaint to the Board, or delegate, or request the Chair to do so.
4. The Chair of the Family Planning NSW Ethics Committee 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; and
  - Any other relevant documentation.
5. The Board will determine whether there is to be a further investigation of the complaint.
6. If the Board determines there is to be a further investigation, then the Board will establish a panel to consider the complaint/concern. Where there is to be no further investigation, the Board will inform the complainant and the Chair.
7. The panel will include, at least, the following members:
  - The Board Chair or his/her nominee as Convenor of the panel.

- Two nominees of the *Board* (not members of the Family Planning NSW Ethics Committee).
8. The panel will afford the Family Planning NSW Ethics Committee and the complainant the opportunity to make submissions.
  9. 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 Family Planning NSW Ethics Committee acted in accordance with the NH&MRC *National Statement on Research Ethical Conduct in Human Research 2007*, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.
  10. The outcomes of this process may include:
    - The complaint/concern is dismissed.
    - The complaint/concern is referred back to the Family Planning NSW Ethics Committee 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.
  11. The panel may also make recommendations about the operation of the Family Planning NSW Ethics Committee including such actions as:
    - Review Terms of Reference and Standard Operating Procedures;
    - Review committee membership;
    - Take other such action as appropriate.
  12. Should the Family Planning NSW Ethics Committee be requested to review its decision, then the outcome of this review by the Family Planning NSW Ethics Committee will be final.
  13. The approval of the Board, its delegate or the panel cannot be substituted for the approval of the Family Planning NSW Ethics Committee.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 019**

**Date: March 2016**

**Subject: Record keeping**

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

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1. The Ethics Executive Officer will prepare and maintain electronic records of the Family Planning NSW Ethics Committee's activities, including agendas and minutes of all meetings of the Family Planning NSW Ethics Committee.
  
2. The Ethics Executive Officer 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 Family Planning NSW Ethics Committee to monitor the conduct of the research; and
  - Relevance, if any, of the Commonwealth or State (or Territory) legislation or guidelines relating to privacy of personal or health information..

The paper file shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the Family Planning NSW Ethics Committee, all approved documents and other material used to inform potential research participants.

3. All relevant records of the Family Planning NSW Ethics Committee, 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 Family Planning NSW Ethics Committee members, which 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 should leave their documents with the Ethics Executive Officer for disposal.
5. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the research or termination of the study. For clinical research, 15 years shall apply. Retention periods shall comply with NSW Health <https://www.records.nsw.gov.au/recordkeeping/rules/retention-and-disposal-authorities/general-retention-and-disposal-authorities/public-health-services-patient-client-records-gda17/part-1-the-general-retention-and-disposal/8.0.0-research-management>
6. A register of all the applications received and reviewed shall be maintained in accordance with the [National Statement \(2007\)](#).

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 020**

**Date: March 2016**

**Subject: Handling of conflicts of interest**

**Purpose:** To describe the procedure for the handling of conflicts of interest of Family Planning NSW Ethics Committee members.

---

1. A Family Planning NSW Ethics Committee member shall, as soon as practicable during the Family Planning NSW Ethics Committee meeting, inform the Chair if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the Family Planning NSW Ethics Committee.
  
2. If a Family Planning NSW Ethics Committee member is present at a meeting at which a project is considered in which they have a conflict or duality of interest, the member may, at the discretion of the Chair, be asked to leave the room. If the member remains in the room, he/she will not participate in the discussion (except to make clarifications as requested) and will not take part in the decision making process.

If the Chair has a potential conflict of interest as described above, the Deputy Chair will take over the conduct of the meeting for the proposal in question.

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

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 021**

**Date: March 2016**

**Subject: Family Planning NSW Ethics Committee reporting requirements**

**Purpose:** To describe the reporting requirements of the Family Planning NSW Ethics Committee.

---

1. The minutes of each Family Planning NSW Ethics Committee meeting will be forwarded to the Board through the - Chief Executive, following confirmation.
2. The Chair of the Ethics Committee will write to the Board seeking appointment of new members and regarding the endorsement of Chair and Deputy Chair positions. (SOP 003)
3. The Family Planning NSW Ethics Committee shall provide an annual report to the Board at the end of each financial year on its progress, including:
  - Membership/membership changes;
  - Number of meetings;
  - Number of projects reviewed, approved and rejected;
  - Monitoring procedures for ethical aspects of research in progress and any problems encountered by the Family Planning NSW Ethics Committee 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; and
  - General issues raised.
4. The Family Planning NSW Ethics Committee will provide reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NH&MRC.
5. The FPNSW Ethics Committee will provide reports to the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.

6. The Family Planning NSW Ethics Committee Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the website.

**Family Planning NSW Ethics Committee  
Standard Operating Procedures**

**Reference Number: SOP 022**

**Date: March 2016**

**Subject: Review of Standard Operating Procedures and Terms of Reference**

**Purpose:** To describe the procedure for the approval of amendments to the Family Planning NSW Ethics Committee Standard Operating Procedures and Terms of Reference.

---

1. The Standard Operating Procedures and Terms of Reference shall be reviewed every three years and amended as necessary.
2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure below:

For those proposals made by a Family Planning NSW Ethics Committee member:

- The proposal must be in writing and circulated to all Family Planning NSW Ethics Committee members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the Family Planning NSW Ethics Committee, 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 shall be ratified if two thirds of the members agree to the amendment.
- The Chair shall send the amendment to the Chief Executive for review and approval if appropriate.
- The CEO shall send the updated Term of Reference and Standard Operating Procedures to the Family Planning NSW Board for review and/or approval.

For those proposals made by the Chief Executive:

- The Chief Executive will send the proposal to the Family Planning NSW Ethics Committee and seek the views of any relevant person.

3. Standard operating procedures, terms of reference, membership of the Ethics Committee and Ethics Committee submission documents will be maintained on the website and reviewed for currency at least every six months.



# Attachment A

## Responsibilities of Members of the Family Planning NSW Ethics Committee

In line with the *National Statement on Ethical Conduct in Human Research 2007* members of the Family Planning NSW Ethics Committee are asked to acknowledge acceptance of the following matters:

### Confidentiality

Members of the Family Planning NSW Ethics Committee have a responsibility to:-

- treat the matters discussed at meetings confidentially;
- ensure that documents are stored securely and/or disposed of in a manner that ensures confidentiality. Any unwanted papers may be returned to the Ethics Executive Officer at the end of a meeting for secure shredding.

### Conflict of Interest

If, at any time, a Family Planning NSW Ethics Committee member finds that he or she has a potential conflict of interest, the member should make the Chair aware of this. In general, a person who is involved in research that is to be discussed at the Committee may remain in the room but will not take part in discussion apart from responding to questions asked in regard to the research. If any member is unsure if they have a conflict of interest or not, they should bring it to the attention of the Chair. If the Chair is unsure, the matter should be brought to the attention of the Committee for their consideration and decision.

If, at any time, the Chair finds he or she has a potential conflict of interest, the Chair should make the Committee aware of this.

### Preparation for Meeting

Members of the Family Planning NSW Ethics Committee are requested to:-

- be prepared for the meeting by having done the appropriate amount of reading and if asked to review a research project, be prepared to comment on all aspects of the research and give the Committee an opinion as to whether it should be approved and under what conditions.
- submit any agenda items or reports in reasonable time for inclusion in the pre-circulated meeting papers;
- inform the Ethics Executive Officer if unable to attend, or arriving late; and
- if unable to attend a meeting, contribute to the meeting by providing written comments to the Ethics Executive Officer or Chair, prior to the meeting. Comments should be provided at least 3 working days prior to the meeting so that copies may be made available to members in advance of the meeting.

**During the Meeting**

Participants in meetings of the Family Planning NSW Ethics Committee should:-

- address all matters through the Chair;
- remember the need to ensure all participants in the meeting can hear any discussion;
- endeavor to stay until the end of the meeting, unless special arrangements have been made with the Chair.

**Declaration**

I declare that I have not been subject to any criminal conviction or disciplinary action, which may prejudice my standing as a Family Planning NSW Ethics Committee member. I have consented to a criminal record check, as required by NSW Health.

I will keep confidential all matters discussed at Family Planning NSW Ethics Committee meetings.

I will inform the Chair of any conflicts of interest.

I agree to my name and profession being made available to the public, including publication on the Family Planning NSW website.

Signed: ..... Date: .....

Name: \_\_\_\_\_

Please sign, date and return this document to the Ethics Executive Officer at your earliest convenience. Email: [ETHICS@fpnsw.org.au](mailto:ETHICS@fpnsw.org.au)  
POST: Ethics Executive Officer 328-336 Liverpool Rd, Ashfield NSW 2131

## **Attachment B**

### **Standard Letter for Family Planning NSW Ethics Committee Approval of New Application**

[On letterhead]

[Date]

[Name of chief investigator]  
[Address]

Dear [Chief Investigator],

**Re: R[Study #] [Study Title]**

The following documentation was reviewed by the Family Planning NSW Ethics Committee:

- Protocol Version: xx Date: xxx 200x
- Participant Information Sheet Version: xx Date: xxx 200x
- Participant Consent Form Version: xx Date: xxx 200x
- Other: (e.g. Advertisement)

**Date of meeting project was first considered:**

**Date of meeting project was approved:**

**Expiry of approval:**

[Thank you for addressing all changes requested by the committee.] *ENTER ONLY IF APPLICABLE*

Please quote reference number **R20\*\*/\*\*** in all future correspondence to the ethics committee.

The Family Planning NSW Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007) on the above meeting date.

I wish to advise that the Family Planning NSW Ethics Committee has **approved** this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below.

**Conditions Applying:**

- Family Planning NSW Ethics Committee require applicants to provide a report at least annually, and at completion of the study. Your first report is due:  
(Annual report template is attached)
- The Family Planning NSW Ethics Committee may monitor approved projects in terms of compliance with the Family Planning NSW Ethics Committee's ethical approval. In doing so, the Family Planning NSW Ethics Committee may request and discuss information on any relevant aspects of the project with the investigators at any time.

- The Family Planning NSW Ethics Committee will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project, including:
  - proposed changes in the research protocol or conduct;
  - unforeseen events that might affect continued ethical acceptability of the project;
  - serious or unexpected adverse events; and
  - if the project is abandoned for any reason.
  
- Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the research or termination of the study. For clinical research, 15 years shall apply.  
Retention periods shall comply with NSW Health record keeping guidelines;  
*<https://www.records.nsw.gov.au/recordkeeping/rules/retention-and-disposal-authorities/general-retention-and-disposal-authorities/public-health-services-patient-client-records-gda17/part-1-the-general-retention-and-disposal/8.0.0-research-management>*

This Ethics Committee is duly constituted, operates, complies with and is conducted according to the National Health and Medical Research Council's (NH&MRC) 'National Statement on Ethical Conduct in Human Research (2007)'.

Should you require further information please contact [name of Ethics Executive Officer], Ethics Executive Officer, on (02) 8\*\*\* \*\*\*\* or via [ethics@fpnsw.org.au](mailto:ethics@fpnsw.org.au).

Yours sincerely,

[Signature of Chair]

[Name of Chairperson]  
Chairperson  
Family Planning NSW Ethics Committee

# Attachment C

## Standard Response Letter for Family Planning NSW Ethics Committee Rejection of New Application

[On letterhead]

date

[insert name of Chief Investigator]  
[insert address]

Dear [insert name of Chief Investigator]

**Re: R200x-xx - [insert name of Chief Investigator]  
[Insert study title].**

Thank you for submitting the above project which was considered by the Family Planning NSW Ethics Committee at its meeting held on [insert date].

The Family Planning NSW Ethics Committee cannot approve your project for the following reasons:

1. *[Note: List each reason separately. Each reason must refer to the relevant paragraph/s of the National Statement, relevant legislation or other applicable guidelines].*
- 2.

The proposal will not be approved until the amended [documents] are revised in accordance with our correspondence.

Should you wish to discuss the Family Planning NSW Ethics Committee's review of your project, please contact [insert name and contact details of Family Planning NSW Ethics Committee Ethics Executive Officer or Chair].

Yours sincerely  
[Chair's signature]

[insert name of Chair]  
[Insert study no + short study title]]

## **Attachment D**

### **Standard Letter for Family Planning NSW Ethics Committee Approval of Amendment**

[On letterhead]

[Date]

[Name of chief investigator]  
[Address]

Dear [Chief Investigator],

**Re: R[Study #] [Study Title]**

Thank you for your letter dated [Insert date] enclosing the following documentation for review;

- [insert submitted documents]

The above documentation was reviewed by the Ethics Committee during its meeting held [insert date] and the amendment has been approved.

This Ethics Committee is duly constituted, operates, complies with and is conducted according to the National Health and Medical Research Council's (NH&MRC) 'National Statement on Ethical Conduct in Human Research (2007)'.

Should you require further information please contact [name of Ethics Executive Officer], Ethics Executive Officer, on (02) 8\*\*\* \*\*\*\* or via [ethics@fpnsw.org.au](mailto:ethics@fpnsw.org.au).

Yours sincerely,

[Signature of Chair]

[Name of Chairperson]  
Chairperson  
Family Planning NSW Ethics Committee

[On letterhead]

**ATTACHMENT E  
FAMILY PLANNING NSW ETHICS COMMITTEE**

Annual Report (for year            )             Final Report

**Title of Project:**

**Reference File No:**

**Name of Chief Investigator:**

**Date of project approval by  
Ethics Committee**

**Date project commenced:**

**Project status:**

Completed & Completion Date:

In progress

Abandoned

Not yet started

If the project has not commenced or been abandoned,  
please explain:

**Number of subjects  
enrolled (total):**

**Is this is a multicenter  
study?**

Yes     No

**If yes, please indicate the  
number of subjects enrolled  
at Family Planning NSW**

**Number of subjects that  
have withdrawn/dropped-  
out:**

**Please indicate reasons for  
withdrawal/dropout:**

**Number of signed Consent  
Forms available for review:**

**If the number of signed Consent Forms differs to the number of enrolled subjects, please explain reasons for the difference:**

**If zero consent forms, is this due to a waiver to the consent requirement being granted by the Ethics Committee?**

Yes       No

If no, please explain:

**Preliminary results (including any publications):**

**Problems or complications arising as a result of, or during, study**

**Have all serious adverse events been reported to the Ethics Committee?**

Yes       No       N/A

**Has the project protocol been altered since approval? (If yes, give details and indicate if the HREC was informed of the changes):**

Yes       No

**Have the ethical issues in the project changed? (If yes, indicate the changes):**

**Is data storage security in accordance with NH&MRC guidelines?**

Yes       No

**Person responsible for data storage**

**Medium of data storage:**      Select from drop-down list below:

**Signature of Chief Investigator:**

**Date signed by Chief Investigator:**



# **Attachment F**

## **Family Planning NSW Scientific Advisory Group**

### **Terms of Reference**

#### **1. Statement of principle**

1.1. The National Statement on Ethical Conduct in Human Research 2007 ('the National Statement') identifies research merit and integrity as fundamental to ethical practice. This involves an assessment of factors including the appropriateness of methodology, thoroughness of literature review, expertise of researchers or research supervisors, validity of study design and adherence to the principles of research conduct.

1.2. The Family Planning NSW Ethics Committee assesses each application in accordance with the NH&MRC National Statement. The Family Planning NSW Ethics Committee 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 of a proposal.

1.3. The NSW Supplement to the National Statement requires that all clinical trials are scientifically reviewed in accordance with minimum standards, evidenced by completion of an Assessment Checklist and Certification of Scientific Review. This review may be delegated to an expert sub-group of the committee with an option to refer to an external expert or Group of experts as required.

#### **2. Objectives**

2.1. The objective of the Family Planning NSW Scientific Advisory Group is to provide advice to the Family Planning NSW Ethics Committee on the scientific rigour of research proposals submitted to it for approval as required by the Chair of the Family Planning NSW Ethics Committee. Specifically, this Group provides advice regarding scientific questions for study proposals, considers matters pertaining to the clinical management of the condition under study and ensures the quality of processes for data collection, analysis and oversight of research.

2.2. This provision is in accordance with the National Statement on Ethical Conduct in Human Research 5.1.33:

*2.2.1. The institution should ensure that the Human Research Ethics Committee (HREC) has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.*

#### **3. Functions**

The functions of the Family Planning NSW Scientific Advisory Group are to:

3.1. Provide independent, competent and timely review of research proposals submitted to it for approval with respect to their scientific validity;

3.2. Provide clear and specific advice to the Family Planning NSW Ethics Committee as to whether the research is scientifically valid or whether amendments are required.

#### **4. Scope of responsibility**

4.1. In general the composition of the Family Planning NSW Ethics Committee comprises sufficient expertise to assess the scientific validity of research proposals submitted. In some instances however it is necessary to conduct a comprehensive scientific review of proposals, with specific expertise required including but not limited to analysis of trial design, oversight, statistical calculations and matters pertaining to the clinical management of the condition under study.

4.2. The scope of this responsibility is in accordance with the guidelines on research merit and integrity outlined in the National Statement on Ethical Conduct in Human Research 1.1 (b), 1.1 (c), 1.1 (e) and 1.1 (f)

*4.2.1. Research that has merit is:*

*4.2.1.1. Designed or developed using methods appropriate for achieving the aims of the proposal;*

*4.2.1.2. Based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;*

*4.2.1.3. Conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and*

*4.2.1.4. Conducted using facilities and resources appropriate for the research.*

4.3. Research proposals will be referred to a member or members of the Family Planning NSW Scientific Advisory Group in instances where the expertise of the Family Planning NSW Ethics Committee is insufficient to appraise the scientific validity of a study.

4.4. Matters referred to the Family Planning NSW Scientific Advisory Group may include questions regarding research design, such as whether the research question is credible, the clinical relevance of the participant population, validity and reliability of primary outcome measures, and whether control arms accord with accepted standards of patient care.

4.5. The communication of potential adverse events and or potential drug interaction issues to trial participants on patient information and consent forms may also be referred to the Family Planning NSW Scientific Advisory Group.

4.6. Matters of statistical analysis may also be referred to the Family Planning NSW Scientific Advisory Group for advice on the validity of statistical analysis, questions regarding the appropriateness of sample size and whether power calculations are adequate.

4.7. Matters of oversight, such as whether safety and adverse events are adequately monitored and whether appropriate arrangements are in place for an independent Data and Safety Monitoring Board are in place, may also be referred to the Family Planning NSW Scientific Advisory Group.

## **5. Membership & process of consultation**

5.1. Composition:

The composition of the Family Planning NSW Scientific Advisory Group shall include members with expertise in specific areas. These shall include:

*5.1.1. A member or members with expertise in the clinical management of conditions represented in research proposals;*

*5.1.2. A members or members with expertise in qualitative health research;*

*5.1.3. A member or members with expertise in quantitative health research;*

*5.1.4. A member or members with expertise in clinical trial design;*

*5.1.5. A member or members with expertise in statistical analysis;*

*5.1.6. A member or members with expertise in pharmacokinetics.*

5.2. The Family Planning NSW Scientific Advisory Group is not required to meet as a group. Members could be consulted individually on matters relating to their specific area of expertise or could be consulted as a group. Research proposals will be distributed to member/s with specific expertise by the Ethics Executive Officer. If required, Family Planning NSW Scientific Advisory Group members may consult one another or engage directly with the relevant Chief Investigator if the proposal warrants discussion. Family Planning NSW Scientific Advisory Group members will

provide documentary advice to the Family Planning NSW Ethics Committee regarding the scientific validity of proposals reviewed.

5.3. All members must be independent of FP NSW and institutions sponsoring or conducting the research under review.

## **6. Appointment**

6.1. The Family Planning NSW Board shall appoint members to the Family Planning NSW Scientific Advisory Group, in consultation with the Chair of the Family Planning NSW Ethics Committee, and other senior organisational officers, as appropriate.

6.2. Prospective members may be recruited by direct approach, nomination or by advertisement, or by other means as deemed appropriate.

6.3. A selection committee, consisting of the Chair of the Family Planning NSW Ethics Committee, the Ethics Executive Officer and any other interested Family Planning NSW Ethics Committee member shall interview prospective applicants, consult with the Family Planning NSW Ethics Committee members and make a recommendation to the Family Planning NSW Board.

6.4. Appointments will allow for continuity, the development of expertise within the Family Planning NSW Scientific Advisory Group, and the regular input of fresh ideas and approaches.

## **7. Term of Appointment**

7.1. Membership will be reviewed every third calendar year, regardless of the fraction of the term already served by each member.

7.2. Reappointment of Family Planning NSW Scientific Advisory Group members will be by application to the Chair of the Family Planning NSW Ethics Committee.

7.3. A member may resign from the Family Planning NSW Scientific Advisory Group at any time upon giving notice in writing to the Chair of the Family Planning NSW Ethics Committee. Steps shall be taken to fill the vacancy of the former member.

7.4. The Family Planning NSW Board may terminate the appointment of any member of the Family Planning NSW Scientific Advisory Group member if the Family Planning NSW Board is of the opinion that:

*7.4.1. It is necessary for the proper and effective functioning of the Family Planning NSW Scientific Advisory Group;*

*7.4.2. The person is not a fit and proper person to serve on an Family Planning NSW Scientific Advisory Group;*

*7.4.3. The person has failed to carry out their duties as an Family Planning NSW Scientific Advisory Group member.*

7.5. Members will be provided with a letter of appointment which will include 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 Family Planning NSW Scientific Advisory Group member.

## **8. Conditions of appointment**

8.1. Members must agree to their name and profession being made available to the public, including being published on the website.

8.2. Members are not offered remuneration.

8.3. Members will be required to sign a statement undertaking:

- 8.3.1. *That all matters of which he/she becomes aware during the course of his/her work on the Scientific Advisory Group member will be kept confidential;*
- 8.3.2. *That any conflicts of interest, which exist or may arise during his/her tenure on the Family Planning NSW Scientific Advisory Group member will be declared; and*
- 8.3.3. *That he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a Family Planning NSW Scientific Advisory Group member.*

## **9. Conduct of business Procedures**

9.1. A sub-group of the Family Planning NSW Ethics Committee comprising those occupying the researcher and health professional roles will be formed to assess integrity and rigour of research proposals submitted. The group will be called the Ethics Scientific Sub Committee (ESSC). The ESSC will be selected by the Family Planning NSW Ethics Committee members.

9.2. Assessment Checklists (Appendix 1) for each new proposal submitted will be distributed to ESSC members three weeks prior to the Family Planning NSW Ethics Committee Meeting.

9.3. ESSC member/s will have seven days from receipt of papers to confer with each other by telephone or email to complete the Assessment Checklist

9.4. The checklist may be completed jointly or separately by ESSC members.

9.5. Every item on the Assessment Checklist must be satisfactorily answered to proceed to Scientific Review Certification.

9.6. If any item is incomplete or if there is any disagreement among ESSC members as to whether a study meets the standards stipulated in the Assessment Checklist, the research proposal must be referred to the Ethics Executive Officer.

9.7. The Ethics Executive Officer will delegate review of proposals with incomplete or inconclusive Assessment Checklists to a member or members of the Family Planning NSW Scientific Advisory Group.

9.8. If the Assessment Checklist is satisfactorily completed by the ESSC, a delegate of the ESSC will inform the Ethics Executive Officer and the Certification of Scientific Review (Appendix 2) may be signed by a delegate of the ESSC immediately prior to the Family Planning NSW Ethics Committee meeting.

9.9. Only proposals that have a signed Certification of Scientific Review will be reviewed at the Ethics Committee meeting.

9.10. In instances where the ESSC cannot sign the Certification of Scientific Review, research proposals will be referred to the Family Planning NSW Scientific Advisory Group.

9.11. Any gaps or inconsistencies in the Assessment Checklist, together with advice from the ESSC, will be used to determine which expert Family Planning NSW Scientific Advisory Group member or members will provide scientific review of the proposal.

9.12. Research proposals are sent to the member or members of the Family Planning NSW Scientific Advisory Group with an Assessment Checklist and Certification of Scientific Review for completion.

9.13. The member or members of the Family Planning NSW Scientific Advisory Group will review the study and apply the Assessment Checklist.

9.14. The member or members of the Family Planning NSW Scientific Advisory Group is encouraged to seek clarification of research details from the Chief Investigator as necessary.

9.15. Family Planning NSW Scientific Advisory Group members may confer with one another as necessary regarding the rigour of research proposals.

9.16. Family Planning NSW Scientific Advisory Group members may seek amendments from the Chief Investigator of the research proposal.

9.17. If such amendments are received four days prior to the Family Planning NSW Ethics Committee Meeting, the amended proposal from the Chief Investigator may be reviewed at that meeting.

9.18. Proposals with scientific amendments to be reviewed by the Family Planning NSW Ethics Committee will have new versions tabled at the meeting, along with the Certification of Scientific Review documenting correct version numbers of papers.

9.19. If amendments required by the Family Planning NSW Scientific Advisory Group are not received four days prior to the next Family Planning NSW Ethics Committee Meeting, the proposal will be deferred to a subsequent meeting.