

**FAMILY PLANNING NSW ETHICS COMMITTEE
TERMS OF REFERENCE**

DEFINITIONS

FPNSW Board:	Family Planning NSW (FPNSW) Board
CEO:	Chief Executive Officer, Family Planning NSW or his/her delegate
FPNSW Ethics Committee:	Family Planning NSW Ethics Committee
Ethics Executive Officer:	Delegated member of the Family Planning NSW Ethics Committee Secretariat
Chair:	Chairperson of the Family Planning NSW Ethics Committee
NH&MRC:	National Health and Medical Research Council
National Statement:	<i>National Statement on Ethical Conduct in Human Research (2007)</i> or replacement
HREC:	Human Research Ethics Committee.
SOP	Standard Operating Procedure

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As an organisation which regularly undertakes human research, the FPNSW Board of Management approved the establishment of the FPNSW Ethics Committee on 2 May 2000. In November 2007, following the organisation's change of name, the name of the Committee was changed to Family Planning NSW Ethics Committee. The FPNSW Ethics Committee is registered with the NH&MRC in accordance with the National Statement.

This document reflects the following documents:

- original document entitled "*Structure and Functions of the Ethics Committee*" dated April 2000
- *Human Research Ethics Committees (HRECs) - Operations Manual (GL2005_059) NSW Health April 2005*
- *National Statement on Ethical Conduct in Human Research (2007)* referred to as the National Statement.

The objectives and protocols identified in this Terms of Reference document are articulated in detailed in the associated Family Planning NSW Ethics Committee Standard Operating Procedures.

1. OBJECTIVES

1.1 The objectives of the Ethics Committee are to:

- 1.1.1 Provide advice to the Board on the ethical acceptability of research proposals submitted to it for approval;
- 1.1.2 Provide advice to the Board on issues relating to the ethical conduct of research that might arise from time to time;

- 1.1.3 Protect the rights, including mental & physical wellbeing, dignity & safety of participants of research;
- 1.1.4 Facilitate ethical research through efficient and effective review processes;
- 1.1.5 Promote ethical standards of human research;
- 1.1.6 Review research in accordance with the National Statement;
- 1.1.7 Protect the privacy and confidentiality of participants and/or their personal health information, either directly or indirectly, in the proposals referred to it;
- 1.1.8 Promote and endorse ethical standards of research and information privacy in proposals referred to it, by provision of guidance to researchers and others as appropriate.

2. FUNCTIONS

- 2.1 The functions of the Ethics Committee are to:
 - 2.1.1 Provide independent, competent and timely review of research proposals submitted to it for approval, in respect of their ethical acceptability; and
 - 2.1.2 Act in accordance with NH&MRC guidelines pertaining to HREC, including the National Statement. The Committee will function as a properly constituted HREC in accordance with the National Statement.

3. SCOPE OF RESPONSIBILITY

- 3.1 Research proposals involving humans will be reviewed by the FPNSW Ethics Committee where the research involves patients or staff of FPNSW, or volunteers participating in projects being undertaken by FPNSW.

This term of reference does not prohibit the institution from accepting an ethical approval granted by another Ethics Committee as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other Ethics Committee is registered with the Australian Health Ethics Committee (AHEC).

- 3.2 The FPNSW Ethics Committee may from time to time grant ethical approval for research undertaken by external organisations or individuals. However, approval must first have been granted by FPNSW Board for the FPNSW Ethics Committee to provide this service.

In such circumstances, an agreement shall exist between FPNSW and the external institution/ organisation which defines the role of the FPNSW Ethics Committee in providing ethical approval and ethical monitoring of the research, and the role of the external institution in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the FPNSW Ethics Committee, and shall also specify that the external institution/ organisation (not FPNSW) is responsible for liabilities arising from the conduct of the research.

- 3.3 Research involving humans as outlined in the National Statement p8.

4. STATUS OF THE FPNSW ETHICS COMMITTEE

- 4.1 The FPNSW Ethics Committee is an advisory committee of the FPNSW Board of Directors with responsibility for granting ethical approval, withholding ethical approval and withdrawing ethical approval.
- 4.2 The CEO is responsible for granting the institutional approval for research to be conducted within its institutions giving due consideration to the advice of the FPNSW Ethics Committee. (Note: The Chief Executive may not give approval for research to be conducted unless ethical approval has been granted by the FPNSW Ethics Committee).
- 4.3 In accordance with the National Statement, the FPNSW Board has delegated to the FPNSW Ethics Committee the authority to:
- 4.3.1 give approval on behalf of the organisation to the conduct of ethically approved research at FPNSW.
 - 4.3.2 defer or reject research proposals
 - 4.3.3 request modifications to research proposals
 - 4.3.4 monitor approved research
 - 4.3.5 approve amendments to research
 - 4.3.6 suspend approval of research
 - 4.3.7 withdraw approval of research

5. ACCOUNTABILITY OF THE FPNSW ETHICS COMMITTEE

- 5.1 The FPNSW Ethics Committee is accountable to the Family Planning NSW (FPNSW) Board in the conduct of its business. The minutes of each FPNSW Ethics Committee meeting shall be signed by the Chair and forwarded to the FPNSW Board, following confirmation.
- 5.2 The FPNSW Ethics Committee shall provide an annual report to the FPNSW Board at the end of each financial year, which will include information on membership and the number of proposals reviewed. A copy of this report shall also be forwarded to the CEO, FPNSW.
- 5.3 The FPNSW Ethics Committee may from time to time bring to the attention of the CEO, FPNSW issues of significant concern.
- 5.4 The FPNSW Ethics Committee will provide reports:
- 5.4.1 to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NH&MRC)

- 5.4.2 to the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.
- 5.5 The FPNSW Ethics Committee Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be accessible on the FPNSW website.

6. MEMBERSHIP & MEETINGS

6.1 Composition

- 6.1.1 The composition of the FPNSW Ethics Committee shall include members of the general community as well as those with expertise in specific areas. Membership shall be in accordance with the National Statement and shall include at least:
- 6.1.1.1 a Chair with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations;
 - 6.1.1.2 at least two lay people, one man and one woman, who are not currently involved in medical, scientific, legal or academic work and have no affiliation with FPNSW;
 - 6.1.1.3 at least one person who performs a pastoral care role in a community, (eg. an Aboriginal elder, a minister of religion);
 - 6.1.1.4 a lawyer, where possible, one who is not engaged to advise FPNSW;
 - 6.1.1.5 at least two people with current research experience that is relevant to research proposals to be considered at the meeting they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise;
 - 6.1.1.6 A member with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, nurse, as appropriate).
- 6.1.2 The FPNSW Board may appoint a Board member to the Ethics Committee. Additional members with special expertise may be appointed by the Board in special categories. Alternate members may also be appointed.
- 6.1.3 To ensure the membership will equip the FPNSW Ethics Committee to address all 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.
- 6.1.4 A quorum shall exist when a representative of each of the categories listed in 6.1.1 is present. 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 FPNSW Ethics Committee.

- 6.1.5 The FPNSW Ethics Committee shall be free to consult any person(s) considered to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

6.2 **Appointment**

- 6.2.1 The FPNSW Board shall appoint members to the FPNSW Ethics Committee, in consultation with the FPNSW Ethics Committee, and other senior organisational officers, as appropriate.
- 6.2.2 Prospective members may be recruited by direct approach, nomination or by advertisement, or by other means as deemed appropriate.
- 6.2.3 A selection committee, consisting of the Chair, the Ethics Executive Officer and any other interested FPNSW Ethics Committee member shall interview prospective applicants, consult with the FPNSW Ethics Committee members and make a recommendation to the FPNSW Board.
- 6.2.4 Appointments will allow for continuity, the development of expertise within the FPNSW Ethics Committee, and the regular input of fresh ideas and approaches.

6.3 **Term of Appointment**

- 6.3.1 Membership will be reviewed every third calendar year, regardless of the fraction of the term already served by each member.
- 6.3.2 Reappointment of FPNSW Ethics Committee members will be by application to the Chair of the FPNSW Ethics Committee who will then make a recommendation to the FPNSW Board prior to an offer of appointment being made.
- 6.3.3 Membership will lapse if a member fails without reasonable excuse or without notifying the Chair to attend three consecutive meetings of the FPNSW Ethics Committee, unless exceptional circumstances exist. The Chair will notify the member in writing of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.
- 6.3.4 A member may resign from the FPNSW 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.
- 6.3.5 The FPNSW Board may terminate the appointment of any member of the FPNSW Ethics Committee if the FPNSW Board is of the opinion that:
- 6.3.5.1 it is necessary for the proper and effective functioning of the FPNSW Ethics Committee;
 - 6.3.5.2 the person is not a fit and proper person to serve on an FPNSW Ethics Committee;

6.3.5.3 the person has failed to carry out their duties as an FPNSW Ethics Committee member.

6.3.6 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 FPNSW Ethics Committee member, FPNSW Ethics Committee meeting attendance responsibilities and general responsibilities as a FPNSW Ethics Committee member.

6.4 Conditions of appointment

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

6.4.2 Members are not offered remuneration. However, reimbursement for legitimate transport expenses incurred in attending FPNSW Ethics Committee meetings (eg taxi vouchers) will be considered after discussion with the Chair.

6.4.3 Members will be required to sign a statement undertaking:

6.4.3.1 that all matters of which he/she becomes aware during the course of his/her work on the FPNSW Ethics Committee will be kept confidential;

6.4.3.2 that any conflicts of interest, which exist or may arise during his/her tenure on the FPNSW Ethics Committee will be declared; and

6.4.3.3 that he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a FPNSW Ethics Committee member.

6.5 Education for Ethics Committee members

6.5.1 Newly appointed members shall be provided with adequate orientation.

6.5.2 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the FPNSW Ethics Committee, at the expense of FPNSW, where possible in accordance with the National Statement.

6.6 Sub-committees

6.6.1 The FPNSW Board may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the FPNSW Ethics Committee. The Chair of any such sub-committee will be appointed by the FPNSW Board. Members of the sub-committee need not be members of the FPNSW Ethics Committee.

6.7 Liability coverage

6.7.1 The FPNSW provides indemnity for members of the FPNSW Ethics Committee for any liabilities that arise as a result of the member exercising his or her duties as a member, in good faith.

6.7.2 Where research is sponsored by an outside organisation, this body will provide indemnity for research participants, and will be required to confirm this in the application to the Ethics Committee.

6.8 Meetings

6.8.1 The FPNSW Ethics Committee shall meet on a regular basis, which will normally be at six weekly intervals. Meetings are held Tuesday between 6.30 – 9.30pm at the discretion of the Chair. No meeting will be held in January.

6.8.2 Meeting dates and agenda closing dates will be published.

6.8.3 Minutes of the meeting shall be taken by the Ethics Executive Officer. A copy of the minutes is to be distributed to all committee members prior to the next meeting. A clean copy of the minutes is to be signed by the Chair and filed as a true record of that meeting. A copy of the minutes shall be forwarded to the FPNSW Board.

6.8.4 Any member of the FPNSW Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the FPNSW Ethics Committee, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, 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.

All declarations of interest will be minuted.

6.8.5 The FPNSW Ethics Committee will endeavour to reach a decision concerning the ethical acceptability of a proposal 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 proposal, provided that the majority includes at least one layperson. Any significant minority view shall be noted in the minutes.

7. CONDUCT OF BUSINESS

7.1 Procedures

7.1.1 The FPNSW Ethics Committee will perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every three years and amended and updated as necessary. All FPNSW Ethics Committee members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to changes thereto.

7.2 Submissions, notifications and approvals

- 7.2.1 In accordance with NSW Health policy (PD2007-026) all submissions to the FPNSW Ethics Committee will be completed on a National Ethics Application Form (NEAF). All applications for ethical approval must be submitted to the Ethics Executive Officer of the FPNSW Ethics Committee, in the manner prescribed by the relevant SOP by the relevant closing date, in writing in the format approved by the FPNSW Ethics Committee and shall include such documentation as the FPNSW Ethics Committee may specify.
- 7.2.2 Guidelines will be issued to assist applicants in their preparation of applications.
- 7.2.3 The FPNSW Ethics Committee may request the applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the FPNSW Ethics Committee at which the application will be considered for the purpose of providing information to and answering questions from the FPNSW Ethics Committee members.
- 7.2.4 Applications received in accordance with the SOPs will be considered by the FPNSW Ethics Committee at its next available meeting following receipt. The Ethics Executive Officer shall circulate the completed application and associated documents received with a meeting agenda to all members of the FPNSW Ethics Committee at least 7 days prior to the next meeting.
- 7.2.5 The FPNSW Ethics Committee may delegate consideration of certain scientific/technical matters to an FPNSW Ethics Committee member or sub-committee of members. The FPNSW Ethics Committee may also obtain expert scientific/technical advice, subject to paragraph 6.6.1.
- 7.2.6 The FPNSW Ethics Committee will take into account the views or opinions of another Ethics Committee in relation to a research protocol.
- 7.2.7 The FPNSW Ethics Committee will promptly notify the applicant in writing, advising whether the application, which it has considered, has received ethical approval and any conditions of that approval.

7.3 Expedited review

- 7.3.1 The FPNSW Ethics Committee may establish and convene an Expedited Ethical Review Panel to discuss:
 - 7.3.1.1 amended proposals
 - 7.3.1.2 serious adverse event reports
 - 7.3.1.3 expedited proposals (minimal risk): eg Quality Control projects; Medical Records research
 - 7.3.1.4 authorised prescriber
 - 7.3.1.5 advertisements
 - 7.3.1.6 annual reports and on-going approvals
 - 7.3.1.7 final reports
 - 7.3.1.8 grievances

7.3.1.9 review of policies and practices with regard to Ethics.

7.3.2 The proceedings of the Expedited Ethical Review Panel (EERP) are ratified by the full FPNSW Ethics Committee at its meeting of the following month.

7.3.3 Membership of the EERP shall be open to anyone on the FPNSW Ethics Committee who wishes to attend. The minimum membership shall comprise the Chair of the Ethics Committee, Deputy Chair and a member with current research experience that is relevant to research proposals to be considered at the meeting. The Ethics Executive Officer will attend to take minutes, and to assist in providing corporate memory and advice.

7.4 Interpreters

7.4.1 Where research involves the participation of persons unfamiliar with the English language, the FPNSW 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 FPNSW Ethics Committee).

7.5 Logistic Support for the Ethics Committee

7.5.1 The Ethics Committee will be supported by an Ethics Executive Officer.

7.5.2 This Ethics Executive Officer will be responsible for day-to-day management of Ethics Committee business, preparation and circulation of meeting papers, minutes of meeting, correspondence, monitoring, storage or records, etc.

7.5.3 The Ethics Executive Officer will attend meetings of the Ethics Committee as a non-voting member.

7.6 Records

7.6.1 The Ethics Executive Officer, or delegate, will prepare and maintain written records of the FPNSW Ethics Committee's activities, including agendas and minutes of all meetings. The minutes of these meetings will be retained for State Archiving.

7.6.2 The Ethics Executive Officer, or delegate, will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the FPNSW Ethics Committee.

7.6.3 Files shall be kept securely and confidentially in accordance with the requirements of *Health Records and Information Privacy Act 2002*.

7.6.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is 5 years from the date of completion of a project but for specific types of research, such as clinical research, retention of 15 years shall apply in accordance with *NSW Health policy PD2005-127*. Files may be kept indefinitely, at the discretion of the Ethics Committee, subject to the agreement of the FPNSW.

7.6.5 The FPNSW Ethics Committee will maintain a register of all the applications received and reviewed in accordance with the National Statement.

7.7 Post approval responsibilities

- 7.7.1 The FPNSW Ethics Committee will monitor approved projects in terms of compliance with the FPNSW Ethics Committee's ethical approval. In doing so, the FPNSW Ethics Committee may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the FPNSW Ethics Committee will require applicants to provide a report at least annually, and at completion of the study.
- 7.7.2 The FPNSW 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:
 - 7.7.2.1 proposed changes in the research protocol or conduct;
 - 7.7.2.2 unforeseen events that might affect continued ethical acceptability of the project;
 - 7.7.2.3 serious or unexpected adverse events; and
 - 7.7.2.4 if the project is abandoned for any reason.
- 7.7.3 The FPNSW Ethics Committee may adopt any additional appropriate mechanism for monitoring, as deemed necessary.

8 COMPLAINTS AND REVIEW

8.1 Complaints concerning the conduct of a project

- 8.1.1 Any concern or complaint about the conduct of a project should be directed to the attention of the FPNSW Ethics Committee Ethics Executive Officer, who shall notify the Chair as soon as possible after a complaint is received. The Chair of the FPNSW Ethics Committee will instigate an investigation of the complaint and make a recommendation on the appropriate course of action. The complainant will receive a written response, if appropriate, from the FPNSW Ethics Committee. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the Chairperson of the FPNSW Board, or request the Chair to do so.

8.2 Complaints concerning the Ethics Committee's review process

- 8.2.1 Any concern or complaint about the FPNSW Ethics Committee's review process or rejection of an Ethics Application should be directed to the attention of the Chair of the FPNSW Ethics Committee, detailing it in writing. Complaints may also be made to the Chairperson of the FPNSW Board. The Chair may at his/her discretion notify the FPNSW Board of any complaints received by him/her. The Chairperson of the FPNSW Board will inform the Chair of any complaints received by him/her as soon as possible.

The Chair will instigate an investigation of the complaint and its validity, and make a recommendation to the FPNSW Ethics Committee on the appropriate course of action. The complainant will receive a written response, if appropriate, from the FPNSW Ethics Committee. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the FPNSW Board, or his/her

nominee, or request the Chair to do so. The Chair will provide to the FPNSW Board all relevant information about the complaint/concern. The FPNSW Board will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the Chairperson of the FPNSW Board will convene a suitable panel to review the complaint, ensuring that both the complainant and the FPNSW Ethics Committee are afforded the opportunity to make submissions.

The outcomes of this process may include:

8.2.1.1 The complaint/concern is dismissed.

8.2.1.2 The complaint/concern is referred back to the FPNSW Ethics Committee for consideration, bearing in mind the findings of the panel.

Should the FPNSW Ethics Committee be requested to review its decision, then the outcome of this review by the FPNSW Ethics Committee will be final. In accordance with point 4.2, the panel or FPNSW Board cannot substitute its approval for the approval of the FPNSW Ethics Committee.

8.2.2 In conducting its review, the panel shall be concerned with ascertaining whether the FPNSW Ethics Committee acted in accordance with the National Statement, its Terms of Reference and its Standard Operating Procedures.

9. AMENDMENT TO THE TERMS OF REFERENCE

9.1 These Terms of Reference will be reviewed every three years and may be amended by following the procedure below:

9.1.1 For proposed amendments to the Terms of Reference made by a FPNSW Ethics Committee member:

9.1.1.1 The proposal must be in writing and circulated to all FPNSW Ethics Committee members for their consideration.

9.1.1.2 The views of the members should be discussed at the next scheduled meeting of the FPNSW 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.

9.1.1.3 The proposal shall be ratified if two thirds of the members agree to the amendment.

9.1.1.4 The Chair shall send the amendment to the CEO.

9.1.1.5 The CEO shall send the updated Term of Reference to the FPNSW Board for review and/or approval.

9.1.2 For proposed amendments to the Terms of Reference made by the FPNSW Board and/or CEO:

9.1.2.1 The FPNSW Board and/or CEO will send the proposal to the FPNSW Ethics Committee and seek the views of any relevant person.

- 9.1.2.2 The proposal must be in writing and circulated to all FPNSW Ethics Committee members for their consideration.
- 9.1.2.3 The views of the members should be discussed at the next scheduled meeting of the FPNSW 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.
- 9.1.2.4 The proposal shall be ratified if two thirds of the members agree to the amendment.
- 9.1.2.5 The Chair shall send the amendment to the CEO.
- 9.1.2.6 The CEO, FPNSW shall send the updated Term of Reference to the FPNSW Board for review and/or approval.

10. APPLICATION FEES

A fee may be charged for applications submitted for assessment by the FPNSW Ethics Committee in the case of commercially-sponsored clinical trials.