

## FAMILY PLANNING NSW ETHICS COMMITTEE TERMS OF REFERENCE

The Family Planning NSW Ethics Committee was established in May 2000 as a sub-committee of the Family Planning NSW Board of Directors to provide an independent review mechanism for all research proposals. The committee is a Human Research Ethics Committee (HREC) registered with the National Health and Medical Research Council (NH&MRC) and guided by rigorous standards, including those articulated in the National Statement on Ethical Conduct in Human Research (2007) (National Statement).

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

### 1. OBJECTIVES

- 1.1 To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability
- 1.2 Provide advice to the Board on issues relating to the ethical conduct of research that might arise from time to time;
- 1.3 To provide ethical oversight, monitoring and advice for research projects involving humans.
- 1.4 To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
- 1.5 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. SCOPE OF RESPONSIBILITY

- 2.1 Review proposals of research submitted by staff, students or external institutes to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
- 2.2 Grant approval for research proposals where this review has determined that the proposal is ethically acceptable and in accordance with relevant standards and guidelines.
- 2.3 Withhold ethical approval for research proposals where the review has determined that the proposal is not ethically acceptable and/or is not in accordance with relevant standards and guidelines.



2.4 Request amendments to research proposals in order for the proposal to be ethically acceptable and meet relevant standards and guidelines

2.5 Suspend or withdraw ethical approval for research proposals where this review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.

2.6 Monitor the conduct of proposals through the submission of annual and final reports.

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) and NH&MRC

The Family Planning NSW Ethics Committee may from time to time grant ethical approval for reproductive and sexual health research undertaken by external organisations or individuals. In such circumstances, an agreement shall exist between Family Planning NSW and the external institution/ organisation. This agreement should define the role of the

Family Planning NSW 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 Family Planning NSW Ethics Committee, and shall also specify that the external institution/ organisation (not Family Planning NSW) is responsible for liabilities arising from the conduct of the research

### **3. MEMBERSHIP**

#### **3.1 Composition**

The composition of the Family Planning NSW Ethics Committee shall be in accordance with the National Statement (2007) Section 5.1.30 and shall include; a Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations;

- at least two lay people, one man and one woman, who have no affiliation with Family Planning NSW and are not currently involved in medical, scientific, legal or academic work;
- at least one person who performs a pastoral care role in a community, (eg. an Aboriginal elder, a minister of religion);
- a lawyer, where possible, one who is not engaged to advise Family Planning NSW;
- 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;
- at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, nurse, as appropriate).

3.1.1 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. Alternate members may also be appointed.

3.1.2 To ensure the membership will equip the Family Planning NSW 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.

3.1.3 A quorum shall exist when a representative of each of the categories listed in National Statement (2007) Section 5.1.30 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 Family Planning NSW Ethics Committee.

## 3.2 Sub-committees

3.5.1 *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 or negligible) risk to participants. Membership of the Executive Committee shall be the Chair, the Ethics Executive Officer and one or more Committee members.

3.5.2 *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.

## 4. MEETING

4.1 The Family Planning NSW Ethics Committee shall meet on a regular basis, which will normally be at six weekly intervals. Meetings are held Tuesday evenings between 6.30 – 8.30pm at the discretion of the Chair. No meeting will be held in January.

4.2 Meeting dates and agenda closing dates will be published on Family Planning NSW website.

4.3 Minutes of the meeting shall be taken by the Ethics Executive Officer. A clean copy of the minutes will be forwarded to the chair for review and acknowledgment that it is a true record of that meeting. A copy of the minutes is to be distributed to all committee members prior to the next meeting. Following ratification, all minutes will be sent to the Family Planning NSW Board.

4.4 Any member of the Family Planning NSW Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the Family Planning NSW 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.

4.5 The Family Planning NSW 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.

4.6 The Family Planning NSW 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.

4.7 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.

## 5. RECORDS RETENTION

5.1 The Ethics Executive Officer, or delegate, will prepare and maintain electronic records of the Family Planning NSW Ethics Committee's activities, including agendas and minutes of all meetings.

5.2 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 Family Planning NSW Ethics Committee.

5.3 Files shall be kept securely and confidentially in accordance with the requirements of Schedule 1 of Health Records and Information Privacy Act 2002.  
[http://www.austlii.edu.au/au/legis/nsw/consol\\_act/hraipa2002370/sch1.html](http://www.austlii.edu.au/au/legis/nsw/consol_act/hraipa2002370/sch1.html)

5.4 Records 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>.

5.5 The Family Planning NSW Ethics Committee will maintain a register of all the applications received and reviewed in accordance with the National Statement.

## 6. REPORTING RESPONSIBILITIES AND INSTITUTIONAL ACCOUNTABILITY

6.1 The Family Planning NSW Ethics Committee is accountable to the Family Planning NSW Board in the conduct of its business. The Family Planning NSW Ethics Committee shall provide an annual report to the Family Planning NSW 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, Family Planning NSW.

6.2 The Family Planning NSW Ethics Committee may from time to time bring to the attention of the CEO, Family Planning NSW issues of significant concern.

6.3 The ratified minutes of each Committee meeting shall be forwarded to the Family Planning NSW Board.

6.4 The Family Planning NSW Ethics Committee will provide annual reports to NH&MRC and the NSW Privacy Commissioner in accordance with their reporting requirements.

6.5 The Family Planning NSW Ethics Committee Terms of Reference, Standard Operating Procedures and membership is available to the general public on the Family Planning NSW website.

## **7. REMUNERATION**

Membership of the Family Planning NSW HREC is on a voluntary basis.

## **8. AMENDMENT TO THE TERMS OF REFERENCE**

These Terms of Reference will be reviewed every three years and may be amended in consultation with the Family Planning NSW Ethics Committee and approved by the Family Planning NSW Board.