



Family Planning NSW Ethics Committee (FPNSW Ethics Committee)

Standard Operating Procedures

STANDARD OPERATING PROCEDURES

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**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 001 **Date:** April 2010

Subject: FPNSW Ethics Committee function

Purpose: To describe the function of the FPNSW Ethics Committee

OVERALL FUNCTION

1. The primary objective of the FPNSW 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 FPNSW Ethics Committee are:
 - i) To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
 - ii) To provide ethical oversight, monitoring and advice for research projects involving humans.
 - iii) To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
 - iv) 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 FPNSW Ethics Committee where the research involves participants of any institutions governed by Family Planning NSW.

This operating procedure does not prohibit the institution from accepting an ethical approval undertaken 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.

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. The FPNSW Ethics Committee will assess projects submitted to it for review in accordance with the [National Statement](#) (and any other legal requirements) in order to determine their ethical acceptability.

5. The FPNSW Ethics Committee may review projects involving quality assurance when required. In determining whether or not quality assurance proposals require review, the FPNSW Ethics Committee will refer to the NH&MRC document ['When does quality assurance in health care require independent ethical review?'](#) and the ['Health Records and Information Privacy Act 2002: Statutory Guidelines on Management of Health Services'](#).

6. Family Planning NSW Ethics Committee (FPNSW Ethics Committee)

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Reference Number: SOP 002

Date: April 2010

Subject: Membership composition

Purpose: To describe the membership composition of the FPNSW Ethics Committee

1. The composition of the FPNSW 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 FPNSW 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 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.

2. To ensure the membership will equip the FPNSW 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 FPNSW Ethics Committee may seek advice and assistance from appropriate experts to assist with the review of a project. However, the FPNSW 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 FPNSW Ethics Committee has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the FPNSW 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 (FPNSW Ethics Committee)
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Reference Number: SOP 003

Date: April 2010

Subject: Appointment of Members

Purpose: To describe the procedure for the appointment of members to the FPNSW Ethics Committee

1. Members are appointed as individuals rather than in a representative capacity.
2. Prospective members of the FPNSW 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.
 - 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. The Family Planning NSW Human Resources Department will instigate a criminal record check of preferred applicants.
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 FPNSW, 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. The Chair and Deputy Chair will be appointed by the Board. In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair.

6. 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 FPNSW Ethics Committee member, and the conditions of their appointment.
7. 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 FPNSW Ethics Committee will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the FPNSW 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 FPNSW Ethics Committee member.
8. Members must agree to their name and profession being made available to the public, including being published on the Family Planning NSW website.
9. Upon appointment, members shall be provided with the following documentation:
 - FPNSW Ethics Committee Terms of Reference;
 - FPNSW Ethics Committee Standard Operating Procedures;
 - Calendar of meeting dates
 - Responsibilities of members of the Family Planning NSW Ethics Committee (Attachment A)
10. Details of the term of appointment are outlined in the Terms of Reference paragraph 6.3. 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 FPNSW 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 FPNSW Ethics Committee, and the regular input of fresh ideas and approaches.
11. The appointment of the Chair and Deputy Chair is reviewed every third calendar year by the Board.
12. New members are expected to attend NH&MRC education and training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by Family Planning NSW, where possible.
13. Members shall not be remunerated. Members may make an application for reimbursement of legitimate expenses incurred in attending FPNSW Ethics Committee meetings, such as travelling and parking expenses, at the discretion of the Chief Executive.
14. Members may apply to the Chair, in writing, for a leave of absence from the FPNSW Ethics Committee for extended periods. Steps shall be taken to fill the vacancy.
15. Membership will lapse if a member fails to attend three consecutive meetings of the FPNSW 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.

16. 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.
17. 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.
18. Members must provide current contact details to ensure that they can be contacted from time to time, including for times between meetings for expedited review.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 004

Date: April 2010

Subject: Orientation of new members

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

1. New FPNSW Ethics Committee members must be provided with adequate orientation.

2. Orientation may involve all or some of the following:
 - Introduction to other FPNSW Ethics Committee members prior to the FPNSW Ethics Committee meeting.
 - Informal meeting with Chair and Ethics Executive Officer to explain their responsibilities as an FPNSW Ethics Committee member, the FPNSW Ethics Committee processes and procedures.
 - An opportunity to sit in on FPNSW Ethics Committee meetings as an observer before their appointment takes effect.
 - ‘Partnering’ with another FPNSW Ethics Committee member in the same category.
 - Priority given to participate in training sessions.

3. New FPNSW Ethics Committee members will be provided with the following written information:
 - A list of the members’ names and their roles on the FPNSW Ethics Committee.
 - A copy of the *NH&MRC National Statement on Ethical Conduct in Human Research, 2007*.
 - up-to-date list of members’ names and email details including that of the Ethics Executive Officer;
 - any other relevant information about the FPNSW Ethics Committee’s processes, procedures and protocols.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 005

Date: April 2010

Subject: Training and Education of FPNSW Ethics Committee members

Purpose: To promote ongoing education and training opportunities for all members of the FPNSW Ethics Committee.

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.

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

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 006

Date: April 2010

Subject: Submission procedure for new applications

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

1. All applications for ethical review must be submitted to the Ethics Executive Officer of the FPNSW Ethics Committee, by close of business on the relevant closing date. The closing dates for applications should normally be no later than 21 days prior to each FPNSW Ethics Committee meeting.
2. Information regarding closing dates should be readily available to prospective applicants.
3. Applications must be submitted using the National Ethics Application Form (NEAF), and shall include all documentation as required by the FPNSW Ethics Committee. The procedures for application to the FPNSW Ethics Committee and the application can be accessed on www.neaf.gov.au

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 007 **Date:** April 2010

Subject: Processing of applications for review

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

All applications must be signed by the CEO, prior to submission to Ethics. 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 FPNSW Ethics Committee's 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 E). The ESSC will either:
 - a. 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 E)
 - 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 been certified as being scientifically sound, it will be listed on the agenda of the next FPNSW Ethics Committee meeting. If a substantial number of applications are received, some may be deferred until the following FPNSW 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 (FPNSW Ethics Committee)
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Reference Number: SOP 008

Date: April 2010

Subject: Preparation of agenda

Purpose: To describe the process and format of agenda for an FPNSW Ethics Committee meeting

1. The Ethics Executive Officer will prepare an agenda for each FPNSW 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 FPNSW 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 FPNSW Ethics Committee members at least 7 days prior to the next meeting. 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) apologies;
 - ii) minutes of the previous meeting;
 - iii) business arising from the previous minutes;
 - iv) new applications;
 - v) amendments to approved protocols;
 - vi) correspondence;
 - vii) adverse event notifications
 - viii) other business;
 - ix) close and next meeting.
6. The agenda and all documentation shall remain confidential.
7. All items provided by Chief Investigators for the Ethics Committee agenda will require correspondence advising any action required or that it was noted during the meeting.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 009

Date: April 2010

Subject: Conduct of meetings

Purpose: To describe the format of meetings of the FPNSW Ethics Committee

1. The FPNSW 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.
2. Members may attend FPNSW Ethics Committee meetings in person or via teleconference.
3. The Chair may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 7). Should this occur, the FPNSW Ethics Committee will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
4. The Chair may cancel a scheduled meeting if there is insufficient business to be conducted.
5. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the FPNSW 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.
6. The FPNSW 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.
7. Notwithstanding paragraph 6, the FPNSW Ethics Committee may agree to the presence of visitors or observers to a meeting.
8. 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.
9. A quorum must be present in order for the FPNSW 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 FPNSW 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 FPNSW Ethics Committee.

10. 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 FPNSW Ethics Committee must be ratified by at least one representative from those membership categories not present.
11. Any member of the FPNSW Ethics Committee who has any interest, financial or otherwise, in a project or other related matter(s) considered by the FPNSW Ethics Committee, should declare such interest. This will be dealt with in accordance with SOP 022.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 010

Date: April 2010

Subject: Consideration of applications for ethical review by the FPNSW Ethics Committee

Purpose: To describe the process of the FPNSW Ethics Committee's consideration of applications for ethical assessment

1. The FPNSW 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 FPNSW Ethics Committee present at the meeting or providing written comments in lieu of attendance.
3. The FPNSW Ethics Committee will ethically assess each application in accordance with the [NH&MRC National Statement](#). The FPNSW 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 FPNSW Ethics Committee will consider whether an advocate for any participant or group of participants should be invited to the FPNSW 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 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).
6. The FPNSW 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 FPNSW Ethics Committee.
 - It will request modification of the project.
 - It will reject the project.
7. The FPNSW Ethics Committee will endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the project, provided that the majority includes at least one layperson. Any significant minority view shall be noted in the minutes.

8. In order to facilitate consideration of an application, the FPNSW 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 FPNSW Ethics Committee has requested clarification, the provision of further information, or modification of the project, the FPNSW 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 where the Chair may consult, verbally or in writing, with one or more named members who were present at the meeting or who submitted written comments on the application;

In such circumstances, the FPNSW 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 FPNSW Ethics Committee may decide that the information should be considered at a further meeting of the FPNSW Ethics Committee.
11. The FPNSW Ethics Committee may conduct expedited review of projects in accordance with SOP 012.

Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 011

Date: April 2010

Subject: Preparation of minutes

Purpose: To describe the process and format for minutes of a meeting of the FPNSW Ethics Committee.

1. The FPNSW Ethics Committee Ethics Executive Officer will prepare and maintain minutes of all meetings of the FPNSW 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;
 - v) new applications;
 - vi) amendments to approved projects
 - vii) adverse event notifications
 - viii) correspondence;
 - 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Ethics Committee and the absence of the member concerned during the FPNSW Ethics Committee consideration of the relevant application will be minuted (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 FPNSW 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 signed by the Chair / Deputy Chair as formal ratification of true and correct proceedings, at the next FPNSW Ethics Committee meeting.
10. The original 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 (FPNSW Ethics Committee)
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Reference Number: SOP 012

Date: April 2010

Subject: Expedited review

Purpose: To describe the procedure for the expedited review of research by the FPNSW Ethics Committee.

1. To enable the Family Planning NSW Ethics Committee to assess Committee business, submissions and research proposals 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 FPNSW 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 section 5.

2. 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 other member.

3. 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. 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 FPNSW Ethics Committee at its next meeting.

5. **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 FPNSW Ethics Committee and cannot be dealt with by a sub-committee.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 013

Date: April 2010

Subject: Notification of decisions of the FPNSW Ethics Committee for new applications

Purpose: To describe the procedure for the notification of decisions of the FPNSW Ethics Committee concerning the review of new applications.

1. The FPNSW Ethics Committee will report in writing 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 FPNSW 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* 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. The FPNSW 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 FPNSW Ethics Committee may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant FPNSW Ethics Committee meeting.
5. The FPNSW 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 Chief Investigator(s);
 - unique FPNSW Ethics Committee project identification number;
 - the version number and date of all documentation reviewed and approved by the FPNSW 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 FPNSW Ethics Committee approval;

- duration of FPNSW Ethics Committee approval; and
- conditions of FPNSW 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.

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

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
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Reference Number: SOP 014

Date: April 2010

Subject: Submission of amendments and extensions to approved projects

Purpose: To describe the procedure for the submission and FPNSW 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 FPNSW Ethics Committee approval, are required to be reported by the Chief Investigator to the FPNSW 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 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 EERP or by the FPNSW 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 FPNSW 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 FPNSW Ethics Committee will review the decision at its next available meeting.
4. All other requests for amendments shall be reviewed by the FPNSW 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 FPNSW 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 FPNSW 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* or relevant pieces of legislation.
8. 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 FPNSW Ethics Committee's register of received and reviewed applications.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 015

Date: April 2010

Subject: Handling of adverse events

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

1. The FPNSW Ethics Committee shall require, as a condition of approval of each project, that researchers report serious or unexpected adverse events to the FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Ethics Committee.
4. The procedures and format for notification of adverse events to the FPNSW Ethics Committee shall be readily available to investigators.
5. Adverse events may be reviewed by an Executive of the FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 (FPNSW Ethics Committee)
Standard Operating Procedures

Reference Number: SOP 016

Date: September 2009

Subject: Monitoring of approved research projects

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

1. The FPNSW 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 FPNSW Ethics Committee will require applicants to provide a report at least annually, and at completion of the study. Continuing approval of the research will be subject to the Chief Investigator submitting an annual compliance report ([Attachment E](#)).
2. The FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Ethics Committee shall require, as a condition of approval of each project, that investigators inform the FPNSW Ethics Committee, giving reasons, if the research project is discontinued before the expected date of completion.

6. Where the FPNSW 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 FPNSW Ethics Committee may withdraw approval. In such circumstances, the FPNSW 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 FPNSW Ethics Committee will give consideration to the degree of risk to participants in the research project.

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 017

Date: April 2010

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 FPNSW Ethics Committee.

1. The FPNSW 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 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 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 FPNSW 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 FPNSW 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 FPNSW Ethics Committee); and
 - the FPNSW Ethics Committee Ethics Executive Officer.
10. The panel will afford the FPNSW 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 (FPNSW Ethics Committee)
Standard Operating Procedures

Reference Number: SOP 018

Date: April 2010

Subject: Complaints concerning the FPNSW Ethics Committee's review process

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

1. In accordance with paragraph 8 of the Terms of Reference, any concern or complaint about the conduct of a project should be directed to the attention of the FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Ethics Committee).

8. The panel will afford the FPNSW 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 FPNSW Ethics Committee acted in accordance with the NH&MRC *National Statement on Research Ethical Conduct in Human Research*, 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 FPNSW 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 FPNSW Ethics Committee including such actions as:
 - Review Terms of Reference and Standard Operating Procedures;
 - Review committee membership;
 - Take other such action as appropriate.
- 13 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.
- 14 The approval of the Board, its delegate or the panel cannot be substituted for the approval of the FPNSW Ethics Committee.

Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures

Reference Number: SOP 019

Date: April 2010

Subject: Record keeping

Purpose: To describe the procedure for the preparation and maintenance of records of the FPNSW Ethics Committee's activities.

1. The Ethics Executive Officer will prepare and maintain written records of the FPNSW Ethics Committee's activities, including agendas and minutes of all meetings of the FPNSW 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 FPNSW 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 FPNSW Ethics Committee, all approved documents and other material used to inform potential research participants.

3. All relevant records of the FPNSW 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 FPNSW 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 ['Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records \(GDA 17\)'](#).

6. A register of all the applications received and reviewed shall be maintained in accordance with the [NH&MRC National Statement](#).

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 020

Date: April 2010

Subject: Special Access Scheme applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via the Special Access Scheme

FPNSW Ethics Committee responsibilities in relation to the Special Access Scheme (SAS)* are primarily concerned with the granting of approvals under section 19(1)(a) of the Therapeutic Goods Act by 'external delegates'. In accordance with Regulation 47A(6)(b) of the Act, all special access scheme applications approved by an external delegate must be approved by an FPNSW Ethics Committee.

There is currently no external delegate at Family Planning NSW.

*Refer to the [Therapeutic Goods Administration Access to Unapproved Therapeutic Goods via the Special Access Scheme, October 2004](#).

Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures

Reference Number: SOP 021

Date: April 2010

Subject: Authorised Prescriber applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via Authorised Prescribers.

1. Authorised prescriber applications need to be considered by the full Ethics Committee.
2. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the FPNSW Ethics Committee shall undertake an assessment of the following, in accordance with the *Therapeutic Goods Act 1989* and associated regulations*:
 - The safety of the product in relation to its proposed use;
 - The suitability of the medical practitioner; and
 - Information to be given to the patient about the product and the informed consent form.
3. If endorsed, the FPNSW Ethics Committee shall provide a letter of endorsement to the applicant in the format suggested by the Therapeutic Goods Administration [Note: Refer to Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004]. The FPNSW Ethics Committee may impose any conditions on the endorsement such as:
 - a requirement that regular reports be provided to the FPNSW Ethics Committee containing such information as the number of patients for whom the unapproved product has been prescribed;
 - requirements for reporting of any adverse events.
4. The FPNSW Ethics Committee shall review its endorsement of the Authorised Prescriber if it becomes aware of:
 - inappropriate use of the product by the Authorised Prescriber;
 - a concern about the safety of the product;
 - failure of the Authorised Prescriber to comply with conditions imposed by the FPNSW Ethics Committee; or
 - failure of the Authorised Prescriber to comply with State/Territory legislation
5. The FPNSW Ethics Committee may withdraw its endorsement of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected. The FPNSW Ethics Committee shall advise the medical practitioner and the Chief Executive of its concerns in the first

instance. The Chief Executive and the Chair of the FPNSW Ethics Committee shall jointly determine whether to contact the Therapeutic Goods Administration.

6. Applications for authorised prescriber status regarding mifepristone should be processed using documents in Attachment

*Refer to the Therapeutic Goods Administration *Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004.*

**Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 022

Date: April 2010

Subject: Handling of conflicts of interest

Purpose: To describe the procedure for the handling of conflicts of interest of FPNSW Ethics Committee members.

1. A FPNSW Ethics Committee member shall, as soon as practicable during the FPNSW 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 FPNSW Ethics Committee.

2. If a FPNSW 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 (FPNSW Ethics Committee)
Standard Operating Procedures**

Reference Number: SOP 023

Date: April 2010

Subject: FPNSW Ethics Committee reporting requirements

Purpose: To describe the reporting requirements of the FPNSW Ethics Committee.

1. The minutes of each FPNSW Ethics Committee meeting will be forwarded to the Board through the - Chief Executive, following confirmation.

2. The FPNSW 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 FPNSW 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.

3. The FPNSW Ethics Committee will provide reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NH&MRC.

4. 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)*.

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 posted on the website.

Family Planning NSW Ethics Committee (FPNSW Ethics Committee)
Standard Operating Procedures

Reference Number: SOP 024

Date: April 2010

Subject: Review of Standard Operating Procedures and Terms of Reference

Purpose: To describe the procedure for the approval of amendments to the FPNSW 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 FPNSW Ethics Committee member:

- The proposal must be in writing and circulated to all FPNSW Ethics Committee members for their consideration.
- 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.
- 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 to the FPNSW Board for review and/or approval.

For those proposals made by the Chief Executive:

- The Chief Executive will send the proposal to the FPNSW 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 (FPNSW Ethics Committee)

In line with the *National Statement* members of the Family Planning NSW Ethics Committee are asked to acknowledge acceptance of the following matters:

Confidentiality

Members of the FPNSW 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 FPNSW 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 FPNSW 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 Secretariat 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 FPNSW Ethics Committee should:-

- address all matters through the Chair;
- remember the need to ensure all participants in the meeting can hear any discussion;
- endeavour 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 FPNSW Ethics Committee member. I have consented to a criminal record check, as required by NSW Health.

I will keep confidential all matters discussed at FPNSW 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.
Fax: (02) 8752 4396

Attachment B
Standard Letter for FPNSW Ethics Committee Approval of New Application

[On letterhead]

Date
Dear (Chief Investigator)

Re: **R2008-xx Protocol Title: [insert study title]**

The Family Planning NSW Ethics Committee, at its meeting of **xx/xx/200x**, first reviewed the proposal named above. APPROVAL has now been given for the **xxxx**-sponsored trial to be conducted by: (insert name of chief investigator) at Family Planning NSW.

The following documents for the above study have been approved by the Ethics Committee:

Protocol Identification Number: xxxxx	Version: xx	Date: xxx 200x
Investigator's Brochure	Version: xx	Date: xxx 200x
Amendment	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)		

Please quote the File No. **R20xx-xx** in all correspondence to the Ethics Committee.
(All further documentation addressed to this office *must include* the above approval number).

Expiry of Approval: xx/xx/2000x

Conditions Applying:

1. Submission of an annual compliance report to the Family Planning NSW Ethics Committee.
2. **xxxx**

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'.

Should you require further information please contact **xxx**, Ethics Executive Officer, on (02) **xxxxxxxx**.

Yours sincerely
[Chair's signature]

Chair's name printed

Attachment C
Standard Response Letter for FPNSW 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 FPNSW 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 FPNSW Ethics Committee's review of your project, please contact [insert name and contact details of FPNSW Ethics Committee Ethics Executive Officer or Chair].

Yours sincerely

[insert name of Chair or delegate FPNSW Ethics Committee]
[insert FPNSW Ethics Committee address]

Attachment D
Standard Letter for FPNSW Ethics Committee Approval of Amendment

[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]**

- **Amendment x dated xxxx 200x**
- **Revised Protocol No. xxxx dated xxxx 200x.**
- **Revised Patient Information Sheet and Consent Form Version x dated xxxx 200x.**

Thank you for submitting the above documents which were approved by the FPNSW Ethics Committee at its meeting of xxxxx 200x.

Please quote the above File No. in all correspondence.

Yours sincerely

[insert name of Chair or delegate of FPNSW Ethics Committee]
[insert FPNSW Ethics Committee address]

Attachment E

FAMILY PLANNING NSW ETHICS COMMITTEE Annual Report / Final Report (Please Circle)



Title of Project:
.....
.....

Reference File No: R20xx-xx

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 multicentre study? Yes No

If yes, please indicate the number of subjects enrolled at FPNSW

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

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: Paper / Computer Disk / Microfiche / Film /.Memory Stick / Other

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 (FPNSW) Ethics Committee assesses each application in accordance with the NH&MRC National Statement. The FPNSW 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 FPNSW Scientific Advisory Group is to provide advice to the FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Scientific Advisory Group in instances where the expertise of the FPNSW Ethics Committee is insufficient to appraise the scientific validity of a study.

4.4. Matters referred to the FPNSW 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 FPNSW Scientific Advisory Group.

4.6. Matters of statistical analysis may also be referred to the FPNSW 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 FPNSW Scientific Advisory Group.

5. Membership & process of consultation

5.1. Composition:

The composition of the FPNSW 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 FPNSW 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, FPNSW Scientific Advisory Group members may consult one another or engage directly with the relevant Chief Investigator if the proposal warrants discussion. FPNSW Scientific Advisory Group members will provide documentary advice to the FPNSW 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 FPNSW Board shall appoint members to the FPNSW Scientific Advisory Group, in consultation with the Chair of the FPNSW 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 FPNSW Ethics Committee, 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.

6.4. Appointments will allow for continuity, the development of expertise within the FPNSW 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 FPNSW Scientific Advisory Group members will be by application to the Chair of the FPNSW Ethics Committee.

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

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

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

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

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

9. Conduct of business

Procedures

9.1. A sub-group of the FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Scientific Advisory Group with an Assessment Checklist and Certification of Scientific Review for completion.
- 9.13. The member or members of the FPNSW Scientific Advisory Group will review the study and apply the Assessment Checklist.
- 9.14. The member or members of the FPNSW Scientific Advisory Group is encouraged to seek clarification of research details from the Chief Investigator as necessary.
- 9.15. FPNSW Scientific Advisory Group members may confer with one another as necessary regarding the rigour of research proposals.
- 9.16. FPNSW 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 FPNSW 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 FPNSW 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 FPNSW Scientific Advisory Group are not received four days prior to the next FPNSW Ethics Committee Meeting, the proposal will be deferred to a subsequent meeting.

Attachment G
Applications for mifepristone authorised prescriber status
**AGREEMENT TO UNDERTAKE ETHICAL REVIEW FOR AN
EXTERNAL ENTITY¹**

BETWEEN

Family Planning NSW, 328-336 Liverpool Rd, Ashfield, NSW 2131, ABN 75 000 026 335,
("FPNSW").

AND

[Insert name of private organisation/hospital/individual], [insert ACN if applicable] of
[Insert Address] (the "External Entity").

WHEREAS

- A. FPNSW appoints the members of, and administers a Human Research Ethics Committee to provide ethical approval of human research in accordance with the National Statement on Ethical Conduct in Research Involving Humans and endorsement of applications for Authorised Prescriber status in accordance with TGA Legislation.
- B. The External Entity conducts or hosts human research which requires approval by a human research ethics committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans or employs medical practitioners who wish to apply for Authorised Prescriber status, but it is not practicable for the External Entity to appoint and maintain its own ethics committee.
- C. The External Entity wishes to submit applications for research involving humans or endorsement of Authorised Prescriber applications to the human research ethics committees appointed and administered by FPNSW for the purposes of obtaining ethical approval in accordance with the National Statement on Ethical Conduct in Research Involving Humans and TGA legislation.

IT IS HEREBY AGREED AS FOLLOWS

1. Interpretation

1.1. Definitions

"Acceptable Clinical Trial Register" means the Australian Clinical Trials Registry or another clinical trial register that meets the requirements of the International Committee of Journal Editors;

"Application for Ethical Review" means an application submitted to the HREC by the External Entity for review of a human research project that:

- (a) is to be conducted at premises under the direction and control of the External Entity; and/or;
- (b) involves patients or clients of the External Entity as participants in the research; and/or

¹ This agreement is based on the NSW Health *Pro Forma* Agreement to Undertake Ethical Review for an External Entity – Policy Directive PD2008_046.

- (c) uses the resources or staff of the External Entity (including visiting medical officers and independent contractors of the External Entity acting in that capacity);

“Application Form” means any application form for ethical review accepted by the HREC;

“Approved Research Project” means any human research project described in an Application for Ethical Review submitted to the HREC by the External Entity and which has been given ethical approval by the HREC;

“Authorised Prescriber” means a medical practitioner granted authority by the TGA to prescribe a specified unregistered therapeutic good or class of goods to specified recipients or classes of recipients Under subsections 19(5)-(9) of the Therapeutic Goods Act.

“Authorised Prescriber Endorsement” means evidence of endorsement from the HREC in the form of a letter giving a clear statement that endorsement is being given for the purpose of the medical practitioner becoming an authorised prescriber under Section 19(5) of the Therapeutic Goods Act, including the name of the medical practitioner, the product and indication for which endorsement has been given, the site(s) of practice covered by the endorsement and any conditions the ethics committee has imposed on the endorsement;

“HREC” means the Human Research Ethics Committee listed in Annexure A, that is appointed and administered by Family Planning NSW;

“Clinical Trial” means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include any intervention used to modify a health outcome and include drugs, surgical procedures, devices, behavioural treatments etc;

“CTN Form” means the form “Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme” published by the Therapeutic Goods Administration;

“CTX Form” means the form “Supply of Unapproved Therapeutic Goods under the Clinical Trial Exemption (CTX) Scheme” published by the Therapeutic Goods Administration;

“Matters of ethical approval” means matters to be reviewed by a human research ethics committee pursuant to the National Statement and which are relevant to whether the conduct of a research project is ethically acceptable;

“Matters of research governance” means matters, excluding Matters of Ethical Approval, which must be considered by the External Entity to determine whether it is a suitable site at which an Approved Research Project should be conducted, including, but not limited to: the proposed cost of the project; the proposed budget; the availability of appropriate equipment, drugs and other resources; and the skills and availability of clinical and non-clinical personnel;

“National Statement” means the National Statement on Ethical Conduct in Research Involving Humans 1999, published by the National Health and Medical Research Council, or any replacement thereof;

“Privacy Legislation” means the Privacy and Personal Information Protection Act 1998 (NSW), the Health Records and Information Privacy Act 2002 (NSW) and the Privacy Act 1988 (Cth) and any statutory instruments made pursuant thereto;

“**Sponsor**” means a sponsor within the meaning of the TGA legislation;

“**Standard Medicines Australia Indemnity**” means the current “Medicines Australia Form of Indemnity for Clinical Trials – Standard” as published by Medicines Australia from time to time;

“**Standard Medicines Australia Indemnity – HREC Review**” means the current “Medicines Australia Form of Indemnity for Clinical Trials – HREC Review only” as published by Medicines Australia from time to time;

“**TGA**” means the Therapeutic Goods Administration of the Commonwealth of Australia or any successor body;

“**TGA legislation**” means the Therapeutic Goods Act 1989 (Cth) and any statutory instruments made pursuant thereto;

- 1.2. A reference to this Agreement or another instrument includes any variation or replacement of them.
- 1.3. A reference to all clauses, exhibits, annexures or schedules shall, unless otherwise provided, be a reference to the clauses, exhibits, annexures or schedules of or to this Agreement.
- 1.4. Except where the context otherwise requires:
 - (a) clause headings are for convenient reference only and are not intended to affect the interpretation of this Agreement;
 - (b) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
 - (c) any reference to a person or body includes a partnership and a body corporate or body politic;
 - (d) words in the singular include the plural and vice versa.

2. Term

- 2.1. This Agreement applies only to the following application for endorsement for mifepristone Authorised Prescriber status:

Medical Practitioner:
Clinic Address:*

*Where medication will be provided.

3. Provision of HREC services

- 3.1. The HREC will accept and review Applications for Ethical Review and Authorised Prescriber endorsement from the External Entity in accordance with the National Statement and TGA Legislation.
- 3.2. FPNSW will only accept and review such Applications for Ethical Review where:
 - (a) the External Entity has endorsed the Application for Ethical Review in writing (either by covering letter on the External Entity's letterhead or on the Application Form); and
 - (b) the Application for Ethical Review is submitted on an Application Form and in compliance with all the HREC's Standard Operating Procedures.
- 3.3. The HREC will review the Application according to its usual procedures including, in the HREC's discretion, referral of the Application for expert scientific or other advice.
- 3.4. The HREC will monitor the conduct of any Approved Research Project or Authorised Prescriber endorsement in accordance with the requirements of the National Statement and in its usual monitoring practices.

4. Fee

- 4.1. The External Entity will pay FPNSW the fees set out in Annexure A. The fee is non-refundable even if an Application for Ethical Review or Authorised Prescriber endorsement is unsuccessful with the FPNSW HREC or the TGA or is withdrawn prior to consideration or determination.

5. Records

- 5.1. The HREC will forward to the External Entity extracts of its HREC Minutes that relate to Applications for Ethical Review, Authorised Prescriber endorsement and Approved Research Projects on an annual basis.

6. Clinical Trials

- 6.1. Where the Approved Research Project is a Clinical Trial, the External Entity will ensure that the trial is registered on an Acceptable Clinical Trial Register.
- 6.2. FPNSW does not become a Sponsor of any Approved Research Project merely by virtue of this Agreement or by virtue of the HREC reviewing or approving an Approved Research Project. FPNSW shall not be named as a Sponsor on a CTN Form or a CTX Form relating to an Approved Research Project, without the prior written approval of the Chief Executive of FPNSW or his or her delegate.
- 6.3. Where the Approved Research Project is an industry sponsored Clinical Trial, the External Entity shall ensure that the Sponsor provides:
 - (a) the Standard Medicines Australia Indemnity in favour of the External Entity; and
 - (b) the Standard Medicines Australia Indemnity – HREC Review in favour of FPNSW.

7. Co-operation by the External Entity

- 7.1. The External Entity shall co-operate fully with the HREC and FPNSW acting in accordance with the National Statement, TGA Legislation, its standard operating procedures or its authorised policies, in relation to the conduct of any investigation into any complaint arising out of an Approved Research Project or Authorised Prescriber endorsement, or into any examination of any appeal from any decision of the HREC arising out of an Application for Ethical Review.
- 7.2. The External Entity shall immediately notify the HREC of any matter which affects the ethical approval of any Approved Research Project or Authorised Prescriber endorsement or may be relevant to any future decision of the HREC regarding Applications for Ethical Review, including but not limited to: any findings of misconduct or disciplinary action taken against any investigator or medical practitioner; or any breach of any statutory requirement regarding the conduct of research by the External Entity or adherence to the requirements for Authorised Prescription.

8. Responsibilities and Indemnities

- 8.1. The HREC is responsible for reviewing Matters of Ethical Approval in relation to any Application for Ethical Review, and is not responsible for reviewing Matters of Research Governance or for the conduct of an Approved Research Project or provision of medication as an Authorised Prescriber. It is a matter for the External Entity to authorise the commencement of, and ensure the proper conduct of, an Approved Research Project or endorsed Authorised Prescriber.
- 8.2. The External Entity, the investigators, the medical practitioners, the sponsors or any other persons taking part in the conduct of an Approved Research Project or as endorsed Authorised Prescribers (as the case may be) remain responsible for any liabilities which arise from the conduct of an Approved Research Project or Authorised Prescription, including but not limited to any injury to any person (including death), any actions, proceedings, claims, demands, costs, losses, damages and expenses (including any legal costs and expenses) arising directly or indirectly as a result of any unlawful, negligent or criminal act or omission of any person involved in the conduct of the Approved Research Project or the Authorised Prescriber, and the external entity hereby indemnifies FPNSW against any such liabilities.
- 8.3. The External Entity warrants that it has insurance or other indemnity arrangements sufficient to cover the conduct of all Approved Research Projects and endorsed Authorised Prescription. The External Entity warrants that where any investigator, medical practitioner or person involved in the conduct of an Approved Research Project or Authorised Prescription is not an employee of the External Entity, that person has sufficient insurance (including professional indemnity insurance) or other indemnity arrangements to cover any liabilities that may arise to them as a result of the conduct of an Approved Research Project or Authorised Prescription.
- 8.4. In the case of any Application for Ethical Review where a Standard Medicines Australia Indemnity – HREC Review is not provided pursuant to clause 6.3, the External Entity hereby indemnifies FPNSW and each member of the HREC against any actions, proceedings, claims, demands, costs, losses, damages and expenses (including any legal costs and expenses) made or prosecuted in any manner, arising directly or indirectly from the HREC's review of any Application for Ethical Review or Authorised Prescriber endorsement pursuant to this Agreement.
- 8.5. This clause survives the termination or expiration of this Agreement.

9. Termination

- 9.1. Either party may terminate this Agreement by giving fourteen (14) days written notice.
- 9.2. Upon termination, the FPNSW shall;
- (a) withdraw from consideration any Applications for Ethical Review for which the HREC has not yet issued a final decision; and
 - (b) continue to monitor any Approved Research Projects or Authorised Prescribers in accordance with the requirements of the National Statement and TGA Legislation.
- 9.3. The parties acknowledge that no damages are payable by either party for termination of this Agreement.

10. Confidentiality

The External Entity notes that the HREC may be required to disclose information included in an Application for Ethical Review, in appropriate circumstances permitted by Privacy Legislation, including the following:

- (a) to deal appropriately, in its discretion, with any complaints made regarding an Approved Research Project or endorsed Authorised Prescriber;
- (b) to report to any FPNSW officer regarding the activities of the HREC;
- (c) to supply any information to the NSW Department of Health in relation to any audit or survey of the HREC's activities;
- (d) to report any incident or adverse event to the Department of Health or any regulatory authority;
- (e) to report to, and as required by, the NSW Privacy Commissioner, the National Health and Medical Research Council, the Australian Health Ethics Committee, or any other statutory body;
- (f) in any circumstance required or permitted by law.

11. Amendment

- 11.1. This Agreement may be amended, assigned or novated only in writing signed by both parties.

12. Governing Law

- 12.1. This Agreement is governed by the law in force in New South Wales and the parties submit to the jurisdiction of the Courts of New South Wales.

13. Entire Agreement

- 13.1. This document contains the entire agreement between the parties about its subject matter. Any previous understanding, agreement, representation or warranty relating to that subject matter is replaced by this Agreement and is of no effect.

EXECUTED as an Agreement

SIGNED for and on behalf of

Family Planning NSW
in the presence of:

SIGNED for and on behalf of

Family Planning NSW
in the presence of:

_____/_____/_____
Chief Executive Date Witness _____/_____/_____ Date

SIGNED for and on behalf of

[insert name of External Entity]

_____/_____/_____
Director Date

_____/_____/_____
Director/Secretary Date Witness _____/_____/_____ Date

ANNEXURE A

1. Human Research Ethics Committees appointed and administered by Family Planning NSW to which the External Entity may submit Applications for Ethical Review or endorsement for Authorised Prescriber application.

Family Planning NSW Human Research Ethics Committee

2. Fees

Include details of the fees to be paid by the Entity to FPNSW. This may be the HREC's standard schedule of fees (based on Departmental Policy Directive PD2005_628),

OR

a set fee per annum,

OR

a combination of both.

Note: Fees should only be waived where the Chief Executive of the Family Planning NSW considers there are appropriate reasons for providing the services of the HREC to the External Entity free of charge. This would generally only be the case where the Entity is a charitable or not-for-profit organisation whose aims and objectives are consistent with those of FPNSW.

INFORMATION FOR APPLICANTS REQUESTING HREC ENDORSEMENT FOR MIFEPRISTONE AUTHORISED PRESCRIPTION

Background

Family Planning NSW affirms the rights of women to have control over and decide freely on all matters related to their sexual and reproductive health. Family Planning NSW supports access to safe abortion choices, medical or surgical, within the bounds of applicable legislation.

Legislation

Mifepristone is currently not registered in Australia. Use of unregistered therapeutic goods requires authorization by or notification to the Therapeutic Goods Administration. See “Access to Unapproved Therapeutic Goods - Authorised Prescribers. Therapeutic Goods Administration, 2004.” for a summary of the relevant legislation and requirements for supply.

Assessment of Applications for Authorised Prescription Endorsement by the Family Planning NSW Human Research Ethics Committee (HREC)

Following the TGA guidelines, assessment of applications for endorsement of Authorised Prescribers includes but is not limited to the following criteria. Applications should clearly address how these criteria are met:

- Patient: is use of the product adequately clinically justified
- Product: does the safety and efficacy profile of the product justify the risks of use
- Prescriber: does the applicant clinician have the appropriate qualification, specialist expertise and experience, and clinical infrastructure to undertake the proposed use of the product

Application Requirements

Please see the Family Planning NSW Mifepristone Authorised Provider – HREC Endorsement Application Form. Completion of this form will provide guidance on the documentation and information required by the Committee.

Owing to the controversial and legislative issues surrounding the use of mifepristone in termination in Australia, a full Committee HREC review and approval is required for endorsement of Authorised Prescribers wishing to prescribe mifepristone. Endoresment cannot be provided by an Executive or sub-Committee.

If your application is urgent, you should discuss this with the HREC Chair through the Executive Officer prior to making your submission. If urgency can be demonstrated, the Chair may convene a special meeting of the Committee.

Requirements of the HREC if your Application is Approved

If you receive approval you will be required to provide the following:

1. Reports of any adverse events recorded in patients receiving mifepristone under this endorsement. These may be provided on ADRAC Blue Cards, or standard Medwatch or CIOMS forms.
2. 6-monthly reports to the February and July HREC meetings showing the number of patients who have received Mifepristone under this endorsement, the stage of their pregnancy at termination and the outcome of the procedure. These requirements will ensure that the HREC meets its monitoring obligations to the TGA.

Important Conditions

All approvals for the Authorised Prescription of mifepristone will include the following conditions (unless clearly specified otherwise in your approval letter). If you wish to discuss these conditions or are concerned that you may not be able to meet these conditions, you should arrange to discuss this with the HREC Chair through the Executive Officer prior to making your submission. Failure to demonstrate adherence to these and any other specified conditions may result in the HREC withdrawing endorsement.

- All patients/clients must be under the direct care of the clinician listed as the Authorised Prescriber
- Medical termination with mifepristone is restricted to pregnancies of less than nine weeks gestation
- Prompt reporting of SAEs and other medical events to the HREC
- Six-monthly reports to the HREC

Other Considerations:

Endorsement of your application by the FPNSW HREC does not permit you to prescribe mifepristone. You must:

- a. Submit an application to the TGA to become an Authorised Prescriber, and
- b. May be required to seek approval from your Institution, local pharmacy, etc.

Applications from Clinicians Outside of NSW

The HREC will review applications from outside of NSW. Applicants should be aware of all relevant State or Territory legislation governing pregnancy termination.

Contact Details

Family Planning NSW Human Research Ethics Committee – Executive Officer

Phone:

Email:

Fax:

Mailing Address:

3. You must notify the HREC immediately if you become aware of any of the following:
 - The TGA revokes your Authorised Prescriber status
 - Emerging safety concerns over the use of the unapproved therapeutic good, either in Australia or globally, including significant changes to information submitted by you in making this application
 - Addition of the therapeutic good or equivalent good to the Australian Register of Therapeutic Goods (ARTG)

Reporting Requirements:

Please provide the HREC with the following:

3. Reports and if requested follow-up of any adverse events recorded in patients receiving mifepristone under this endorsement. These may be provided in the form of ADRAC Blue Cards or Medwatch or CIOMS Forms and should be provided as promptly as possible but within 15 days².
4. 6-monthly reports to be submitted for the February and August HREC meetings showing:
 - A listing of women who have received mifepristone under this endorsement
 - Gestation at termination, outcomes and a summary of reported adverse events
 - Confirmation of currency of your medical registration
 - CV update if significant, notably any additional relevant publications

Notes:

1. The FPNSW HREC review of your application for Authorised Prescription of mifepristone does not imply FPNSW endorsement of the use of mifepristone, or of other medical or pregnancy termination procedures in any specific patient or client.
2. Appropriate care and management of individual patients and clients remains the responsibility of you as treating clinician and Authorised Prescriber.
3. You may further require approval to prescribe the unapproved therapeutic good from your Institution.

The FPNSW HREC is duly constituted, operates, complies with and is conducted according to the National Health and Medical Research Council (NHMRC) 'National Statement on Ethical Conduct in Human Research' (2007).

² This reporting timeline follows TGA reporting requirements.

INDEMNITY FOR AUTHORISED PRESCRIBER ENDORSEMENT HREC REVIEW ONLY

(For use where the Indemnified Party is providing HREC review ONLY)

This Form has been developed from the Medicines Australia Form of Indemnity for Clinical Trials and is an adaptation of the form used by The Association of the British Pharmaceutical Industry (ABPI).

To: Family Planning NSW, 328-336 Liverpool Rd, Ashfield, NSW 2131, ABN 75 000 026 335, ("the Indemnified Party").

From: [Name, registered address and Australian Business Number of Institution] ("the Indemnifying Party").

Re: Authorised Prescriber Endorsement – Mifepristone, Medical Practitioner: Dr [Insert Name].

- 1 The Indemnified Party agrees to undertake ethical review of the request for Authorised Prescriber endorsement by [name of Medical Practitioner] ("the Medical Practitioner") in accordance with the submission documents annexed. The Indemnifying Party confirms that it is a term of its agreement with the Medical Practitioner that the Medical Practitioner shall obtain all necessary approvals from the applicable Human Research Ethics Committee ("HREC") and the Indemnified Party, where appropriate.
- 2 The Indemnified Party agrees to participate by making its HREC available to provide review, endorsement and oversight of the conduct of the Authorised Prescription, in accordance with the requirements of the *NHMRC National Statement on Ethical Conduct in Human Research (2007)* and the Therapeutics Goods Administration *Access to Unapproved Therapeutic Goods – Authorised Prescribers (2004)*.
- 3 In consideration of such participation by the Indemnified Party, subject to paragraph 4 below, the Indemnifying Party indemnifies and holds harmless the Indemnified Party and its employees, agents and members of and advisors to its HREC in respect of and against all claims and proceedings (including any settlements or *ex gratia* payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Patients or Clients of the Medical Practitioner (including their dependants and children injured *in utero* through the participation of the child's mother) against the Indemnified Party or any of its employees, agents or members of and advisors to its HREC for personal injury (including death) to Patients or Clients (and children injured *in utero* through the participation of the child's mother) arising out of or relating to the administration and/or use of the product(s) included under this Authorised Prescriber endorsement or any clinical intervention or procedure provided for or required to which the Patients or Clients would not have been exposed but for treatment with the product(s) under this Authorised Prescriber approval.

- 4 The above indemnity by the Indemnifying Party will not apply to any such claim or proceeding referred to in paragraph 3 above:
- (1) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified Party or any of its employees, agents or members of or advisors to the HREC.
 - (2) unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Indemnified Party notifies it to the Indemnifying Party in writing and at the Indemnifying Party's request, and cost, has permitted the Indemnifying Party to have full care and control of the claim or proceeding using legal representation of its own choosing.
 - (3) if the Indemnified Party, its employees, agents, or members of and advisors to its HREC have made any admission in respect of any such claim or proceeding or taken any action relating to any such claim or proceeding prejudicial to the defence of any such claim or proceeding without the written consent of the Indemnifying Party. Such consent will not be unreasonably withheld. This condition will not be treated as breached by any statement properly made by members of and advisors to the HREC in connection with the operation of the Indemnified Party's internal complaint procedures, accident reporting and quality assurance procedures or disciplinary procedures or where such statement is required by law.
- 5 The Indemnifying Party will keep the Indemnified Party and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Indemnified Party on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Indemnified Party which approval is not to be unreasonably withheld.
- 6 Without prejudice to the provisions of paragraph 4(2) and 4(3) above, the Indemnified Party will use reasonable endeavors to inform the Indemnifying Party promptly of any circumstances of which it has knowledge and which may reasonably be thought likely to give rise to any such claim or proceeding and will keep the Indemnifying Party informed of developments in relation to any such circumstances even where the Indemnified Party decides not to claim indemnity from the Indemnifying Party. Likewise, the Indemnifying Party will use reasonable endeavors to inform the Indemnified Party of any such circumstances and will keep the Indemnified Party informed of developments in relation to any such claim or proceeding made or brought against the Indemnifying Party alone.
- 7 The Parties will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Patients or Clients (including their dependants and children injured in utero through the participation of the child's mother).
- 8 Without prejudice to the foregoing, The Indemnifying Party and Medical Practitioner will maintain insurance or appropriate medical indemnity with respect to its activities and indemnity obligations under this Agreement. This insurance is to be evidenced by a certificate of currency of insurance, as requested by the Indemnified Party from time to time.

9 For the purpose of this indemnity, the expression “agents” is deemed to include, but is not limited to any health professional providing services to the Indemnified Party under a contract for services or otherwise.

10 This indemnity will be governed by and construed in accordance with the laws applicable in the State or Territory in which the Indemnified Party is established.

DATED the day of in the year

SIGNED by a duly authorised representative of the Indemnifying Party

.....
(Signature)

.....
(Name)

.....
(Position)

SIGNED by the Chief Executive or a duly authorised representative of the Indemnified Party

.....
(Signature)

.....
(Name)

.....
(Position)

Mifepristone Authorised Prescriber – Six-Monthly Report

Please submit to the Executive Officer, Family Planning NSW HREC to meet the deadlines for the February and July Meetings.

Clinician:		HREC Endorsement Reference:	
Site:		Submission Period	____/____/____ to ____/____/____

Number of medical terminations in reporting period:		
Were any medical terminations after 9 weeks gestation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, please provide case details
Number of procedures requiring surgical intervention:		
Number of procedures with at least one adverse event:		
Number of procedures with a serious adverse event: Death, immediately life-threatening, hospitalisation or prolongation of hospitalisation, disability, congenital abnormality, requiring intervention to prevent one of the above		
Were all adverse events reported to the HREC?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If No, please provide update
Your TGA Authorised Prescriber Status:	<input type="checkbox"/> Current <input type="checkbox"/> Revoked	Date revoked: ____/____/____
Are you aware of any global safety updates regarding mifepristone that affect your use as an Authorised Prescriber?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, please provide details