Melbourne IVF Human Research Ethics Committee – Terms of Reference

Purpose

The Melbourne IVF (MIVF) Human Research Ethics Committee (HREC) has responsibility to consider the ethical implications of proposed human research studies conducted under the auspices of the organisation and determine whether or not they are acceptable on ethical grounds. These responsibilities include monitoring the ethical aspects of all research studies involving human participants undertaken by the staff of Melbourne IVF.

Guiding Ethical Principles

The Committee is concerned to ensure that a participant's inclusion in a research study complies with the Principles of Ethical Conduct set down in the *National Statement on Ethical Conduct in Human Research, [March 2007]*

The primary purpose of the ethical principles and associated guidelines for research involving humans is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

Reference: National Statement on Ethical Conduct in Human Research – March 2007, Section 1, pp. 11 – 13; Section 2, pp. 15-24.

In line with the National Statement, the Committee will not examine the issue of Research Merit and Integrity of individual projects. This will be undertaken prior to ethical review by peer review processes within the realm of the duly constituted Melbourne IVF Research Committee

The MIVF HREC will:

- abide by the Values and Principles of Ethical Conduct outlined in the National Statement on Ethical Conduct in Human Research *[March 2007]*, issued by the National Health and Medical Research Council (NHMRC) in accordance with the *NHMRC Act, 1992 (Cth.)* and all other relevant Acts and legislative requirements including the *Guidelines Under Section 95 of the Federal Privacy Act 1988* and the *VIC Privacy and Personal Information Protection Act, 1998*

- determine whether or not proposed research projects involving human participants are acceptable on ethical grounds - no research project may proceed without prior consideration and approval of a written protocol by the Committee

- monitor the progress of research projects to ensure continued compliance with approved ethical standards

- maintain a register of proposed research projects involving human participants and communicate information on request to appropriate national bodies

- implement (where necessary) policies of the NHMRC, develop policies and/or monitoring of clinical practice.

Membership of the Committee

Membership of the Committee shall be as follows:

- a Chairperson (either internal or external to the institution)
- at least one Laywoman (who has no affiliation with the institution)
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- a Religious representative or a person who performs a similar role in the community such as an Aboriginal Elder
- a Lawyer
- a Health Researcher
- a Health Professional – care, counselling or treatment
- a Medical Researcher with knowledge of Clinical Trials
- additional members may be appointed from time to time.

Members are appointed for their specific expertise not in a representative category. All appointments are for two years and may be renewable. No members will adjudicate on proposals in which they have an interest as researcher or supervisor or funder. Membership will reflect the National Statement minimal Membership requirements.

Scope of Responsibilities and Functions

To this end the MIVF HREC aims to:

- Provide balanced, independent and timely review of research protocols involving human participants in respect to their ethical acceptability and scientific merit.
- Oversee approved protocols during the course of the research until completion to ensure that they comply with approved ethical standards, legislation, codes of practice and policies.
- The HREC may obtain expert opinion or establish sub-committees to provide scientific/technical assessment and safety evaluation of research protocols along with compliance with regulatory requirements.
- The Research Ethics Manager will register all research protocols submitted to the MIVF HREC along with any monitoring and reporting requirements and approval of protocol amendments during the course of the research.

Committee Procedures

The MIVF HREC operates according to written standard operating procedures (SOP). These procedures shall be reviewed at least every three years and updated as required. All HREC members have access to copies of the SOP, and from time to time, will be consulted with regard to amendments.

(a) Protocol Submissions

The HREC require submissions to be in a standard format using the DHS application forms which can be downloaded from the following web address: http://www.health.vic.gov.au/ethics/single/common_app_form.htm

The HREC requires researchers to:

(i) submit hard copies of the protocol
(ii) submit hard copies of the relevant ethic modules

The Chair along with the Research Ethics Manager and members of the Committee will determine if any additional expert advice is required in relation to scientific review.

Before giving a favourable opinion, the HREC should be adequately reassured about the following issues, as applicable:

- Scientific design and conduct of the study:
- Recruitment of research participants
- Care and protection of research participants
- Protection of research participants' confidentiality
- Informed consent process
- Local community considerations

These should follow the values and principles of ethical conduct as described in the National Statement on Ethical Conduct in Human Research (2007):

- Research merit and integrity
- Justice
- Beneficence
- Respect

Levels of ethical review

Low & negligible risk research (National Statement Section 2 & Section 5.1.20-5.1.23)

Research that carries only negligible risk and involves the use of existing collections of data or records that contain only non-identifiable data about human beings may be exempted from full ethical review. The National Statement recognises that the levels of ethical review for low risk and negligible risk research may include, but need not be limited to:

(a) review or assessment at departmental level by the head of department;
(b) review or assessment by a departmental committee of peers (with or without external or independent members);
(c) delegated review with reporting to an HREC; or
(d) review by a subcommittee of an HREC.

In keeping with the National Statement the MIVF HREC provides review of low risk research protocols via a subcommittee/panel comprised of the Chair and two nominated HREC

members with expertise/understanding relevant to the nature and scope of the research and participants to be recruited. The Chair will recommend approval of the low risk protocol, to be ratified by the HREC at the next meeting and final approval will be signed off by MIVF Managing Director.

Research idenitifed as higher than low risk
Any research identified as involving more than low risk must be referred to the HREC for full review except in exceptional circumstances as stated below.

Multicentred research studies reviewed and approved by another HREC
The HREC may approve a protocol without further ethical review, which another ethics committee has approved and the protocol appears to conform to the requirements of the HREC. The HREC reserves the right to ratify the previous decision, request amendments or clarification or reject the protocol.

Exceptional circumstances exempt from full ethical review
In exceptional circumstances, where as a matter of public policy, and in the national interest, it is essential that an application should be reviewed urgently to allow health related research to commence as quickly as possible, MIVF Managing Director may grant approval under exceptional circumstances for a protocol where:

- Another Committee has approved the protocol and the protocol appears to conform to the requirements of the HREC.
- Clinical need necessitates urgent approval of the protocol.

(b)* Meetings (*National Statement sections 5.1.37 and 5.2.28)

- Meetings will be held every second month.
- Meeting dates are available on the MIVF website.
- Notice of meetings will be given to members for the current year and at least two (2) weeks before any meeting.
- A hard copy of the agenda, previous minutes, new protocols for consideration, including the ethics application forms, patient information & consent form, questionnaires or other relevant correspondence and the written advice for any meeting will be forwarded to all members 2 weeks before the meeting.

(c)* Meeting Protocol *(National Statement sections 5.2.1-5.2.4, 5.2.28 – 5.2.31)

- Decisions by the HREC about whether the research protocol meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the HREC.
- Where there is less than full attendance of the minimum membership at a meeting, the Chair must be satisfied, before a decision is reached, that those members unable to attend the meeting have received all papers and have had an opportunity to contribute their views and that the views of all members have been recorded and considered. Members who are unable to attend a meeting are thereby asked to contribute and advise their opinion via submission to the Research Ethics Manager prior to the meeting.
- Meetings are held in the Conference Room, Ground Floor, 320 Victoria Parade, East Melbourne.

- The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting to discuss a proposal but would be required to leave the meeting before any decision is taken.
- Members of the Committee will be required to declare any conflict of interest prior to or at any time during a meeting, such as where the member is associated with a research protocol under review by the Committee.
- In general, decisions of HREC will be reached by general agreement rather than simple voting majorities.
- The appointed Chair will chair every meeting when present. On occasions when the Chair is absent or excluded because of a conflict of interest, the meeting will appoint a chair.

***(d)* Secretariat Support**

Secretariat support will be provided by the Managing Director's executive assistant. This will include:

- Manage project submissions to the HREC and associated correspondence/communication
- Draft and distribute meeting agendae and correspondence arising out of meetings and subsequent HREC activities
- Provide all research project documentation for the committee within deadlines
- Properly maintain files, records
- Coordinate with researchers, study coordinators, other HREC staff
- Record receipt of documents, progress of project review/approval/monitoring and other matters as appropriate in the databases in a timely fashion
- Respond to administrative queries from researchers, staff and committees

***(e)* Decisions from HREC meetings**

Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol and where necessary link those reasons to the National Statement. Notification of the Committee's deliberations will be made directly to the Principal Investigator.

***(f)* Post HREC Approval Process**

- ***Progress reports***

Progress reports on all approved research protocols are to be submitted to the HREC at least annually. The first annual report should be submitted 12 months after the date on which the approval was given. The Committee may request more frequent progress reports, primarily based on the level of risk associated with the particular research protocol.

- ***SAE reporting***

All researchers must comply with the NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials May 2009 for the reporting of SAEs and SUSARS in clinical trials.

***(g)* Insurance and indemnity for HREC members**

As per the National Statement on Ethical Conduct in Human Research Section 5.1.9 MIVF provides HREC members with indemnity under MIVF insurance policy, insured by Vero Insurance limited.

Monitoring (National Statement Chapters 5.5 & 3.3)

- The Institution and the HREC acts in accordance with the National Statement in relation to monitoring approved research and requires the Principal Researcher (including co-ordinating principal investigator for multi-centre research) to:
- Keep adequate records (hard copy and/or electronic) and provide access to the HREC when requested.
- The Principal Investigator must annually provide the HREC with a written report using the on-line form provided on the MIVF website. The object of the report is to verify that the conduct of research confirms to the approved process.
- Notify and provide reports, in a timely fashion, to the HREC of significant events (including SAEs and SUSARs), complications and protocol deviations that occur at any time during the conduct of research, detailing the course of action taken. Where relevant, Principal Investigators will notify the outcome of monitoring visits by trial sponsors. In relation to sponsored clinical trials and investigator initiated trials involving drug or device interventions this notification of adverse events should be in keeping with the NHMRC Safety Monitoring Position Statement (May 2009).
- Provide prospective advice of any proposed changes to be made to the protocol and approval of these prior to implementation.
- Notify the HREC if the research is to be discontinued before the expected date of completion (detailing a justification for the termination of the trial, such as closure of the trial by the pharmaceutical sponsor).
- Notify the HREC of any complaints received from participants, staff, observers or the community.
- Provide documents of the outcomes of the research to the HREC.
- The HREC may:
    (a) Request an interview with the researchers if required.
    (b) Request access to research data and records (including consent documentation as part of a random audit).
    (c) Request the opinion of external experts if considered necessary.

Complaints and Procedures

Complaints from Researchers

Consistently with the National Statement, MIVF provides for complaints about the process of ethical review, but does not provide for an appeal against a final decision to reject a proposal.

If an application is being considered for rejection, the Researcher/s must have had an opportunity to address the HREC's concerns at an interview. The decision by the HREC to reject an application is final and may not be appealed.

Researchers have the right to attend one meeting of the HREC to present their complaint in person.

Complaints from research participants

Complaints by research participants will be made normally to the Principal Investigator or to the Chairperson of the relevant Ethics Committee.

The Chairperson will consider the complaint and will take what action he/she deems appropriate, as soon as possible. This action may include a direct discussion with the relevant research participant and/or direct contact with the Principal Investigator. The process will usually involve verification that the protocol approved by the Committee has

been followed and subsequent action may include temporary withholding of ethics approval. All discussions will be conducted in a confidential manner.

Complaints from other parties

Any complaint from other interested parties will be managed normally according to the procedure set out above: 'Complaints from research participants'.

Suspension or Discontinuation of Research

If an 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 protocol and that, as a result, the welfare and rights of the research participants are not, and will not be protected, the Committee may withdraw approval, inform the Principal Investigator of such withdrawal, and advise that the research project has been discontinued, suspended or other steps be undertaken.

KEY DOCUMENTS AND WEBSITES

National Statement on Ethical Conduct in Human Research (2007)
http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf
Australian Code for the Responsible Conduct of Research (2007)
http://www.nhmrc.gov.au/publications/synopses/r39syn.htm
Note for Guidance on Good Clinical Practice (CPMP/ ICH / 135 / 95)
http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf
World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
http://www.wma.net/e/policy/b3.htm
Ethics Application Forms
http://www.health.vic.gov.au/ethics/single/common_app_form.htm