**MIVF Human Research Ethics Committee**

**Guidelines for the Review of Quality Assurance, Negligible Risk & Low Risk Studies**

In most cases, research involving humans requires ethical review. The level of review will be proportionate with the level of risk to which participants are exposed. The MIVF Human Research and Ethics Committee (HREC) has outlined three processes for the review of projects relating to humans:

* exemption from ethical review,
* expedited review for low-risk projects, and
* full ethical review.

The processes reflect the risk to which participants are exposed.

The National Statement (S.2.1.6) identifies research as ‘low risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

Section 5.1.7 states that institutions may choose to establish other levels of ethical review (other than full review) for research that carries only low risk and does not include the following:

* Interventions and therapies, including clinical and non-clinical trials, and innovations
* Human genetics (with the potential to generate significant or sensitive information)
* Human stem cells
* Women who are pregnant and the human foetus
* Children and young people
* People highly dependent on medical care who may be unable to give consent
* People with a cognitive impairment, an intellectual disability, or a mental illness
* Aboriginal and Torres Strait Islander Peoples
* People who may be involved in illegal activities

Guidelines, checklists, and application forms have been compiled from the websites of a variety of healthcare settings in Victoria and based on the National Statement to guide our processes.

**EXEMPTION FROM ETHICAL REVIEW**

Quality Assurance (QA) activities that can be exempted from ethical review

QA activities that involve low-risk to participants do not require formal review by an HREC. There are circumstances where submission to the HREC is necessary to meet the requirements of external bodies, for example when there is the intention to publish the outcomes of a QA activity in a journal or via conference proceedings. In these circumstances, evidence of independent review is required and can be provided by the HREC via the Expedited Review Process (page 5 of this document).

The National Health and Medical Research Council document titled “When does QA in health require independent ethical review?” available at: <http://www.nhmrc.gov.au/publications/synopses/e46syn.htm> establishes the processes by which QA activities can be assessed in terms of risk.

The checklist appears on page 3 of this document.

QA projects can be an evaluation or monitoring of a current service or practice to improve that service or practice. Examples might include surveys of patient experiences with a particular program (e.g.: donor program).

QA projects that can be classified as low risk and therefore do not require ethical review are those activities that do not breach confidentiality or privacy and are non-interventional, or activities that do not breach confidentiality or privacy and are interventional. Examples of QA activities where evaluation is interventional but does not present ethical issues, include the use of brief anonymous questionnaires or surveys of patient satisfaction with services provided. Another example would be where a clinic has introduced a new intake program for patients commencing IVF. A nurse wishes to present the content and format of this program. As it is a description of clinical practice with no personal patient data being accessed, this research would not require HREC approval.

There are, however, QA activities that include elements that could warrant full ethical review because these elements elevate the project into the category of higher risk. These QA activities should be submitted for ethical review. Examples of projects that require ethical review include projects in which the National Privacy Principles (refer to Appendix 1) apply or projects where the evaluation of a practice or procedure requires additional invasive investigations such as the collection of an extra blood sample.

Research that can be exempted from ethical review

If the research has negligible risk **and** involves the use of totally non-identifiable data an ethical review may not be necessary.

Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk (NHMRC, *National Statement on Ethical Conduct in Human Research*, 2023, 2.1.7).

Non-identifiable data involves the use of existing collections of data or records about human beings (NHMRC, *National Statement on Ethical Conduct in Human Research*, 2023, 5.1.22). (EG: evaluation of OHSS incidence data from MPS).

Other research that would not require HREC approval would include a meta-analysis of published literature (eg: the data regarding blastocyst culture). This draws only on published data in the literature and contains no new data; HREC approval would therefore not be required.

With advances in genetic knowledge and data linkage, human tissue samples should always be considered re-identifiable data (NHMRC, *National Statement on Ethical Conduct in Human Research*, 2023, 3.2 Tissue and Data).

**QUALITY ASSURANCE STUDY CHECKLIST**

Terms such as ‘peer review’, ‘quality assurance’, ‘quality improvement’, ‘quality activities’, ‘quality studies’, and ‘audit’ are often used interchangeably. Quality assurance covers all these terms. The ethical principles of respect for persons, beneficence, and justice apply to quality assurance and research activities.

The following nine questions will help you determine if your project fits the criteria for a QA study.

1. Is the consent from participantsa inadequate, or is the activity inconsistent with the National Privacy Principal 2.1 (a)? Yes No

a Participants may include patients, carers, health care providers and the institution involved.

2. Does the proposed quality assurance activity pose any risksb for patients beyond those of their routine care? Yes No

b Risks include not only physical risks but also psychological, spiritual and social harm or distress.

3. Does the proposed quality assurance activity pose a burdenc on patients beyond that experienced in their routine care? Yes No

c Burdens may include intrusiveness, discomfort, inconvenience, or embarrassment, e.g. Numerous telephone calls, lengthy questionnaires, or additional hospital visits.

4. Is the proposed quality assurance activity to be conducted by a persond who does not normally have access to the patient’s record for clinical care or a directly related secondary purpose? Yes No

d The involvement of a clinical student or a research student who is a member of the team in any clinical setting or involvement of an authorised quality assurance officer would be acceptable.

Review of medical records by anyone who would not normally have access to information contained therein unavoidably compromises the privacy of individuals. However, authorised audit of records is an extremely valuable quality assurance activity. Provided the individual reviewing the records is bound by legislation or a professional code of ethics, the use is a directly-related secondary purpose and is within the expectations of the patient, this is acceptable.

5. Does the proposed quality assurance activitye breach the confidentiality of any individual’s personal information, beyond that experienced in the provision of routine care?

 Yes No

e A quality assurance activity that requires a letter, fax, or email to a patient, that includes sensitive health information, could lead to a breach of confidentiality if the communication is read by someone other than the proposed recipient.

6. Does the proposed quality assurance activity involve any clinically significant departure from the routine care provided to the participants? Yes No

(Application and evaluation of a new technology not previously used in the health service may need further consideration by an HREC).

7. Does the proposed quality assurance activity involve randomisation or the use of a control group or placebo? Yes No

(Proposals involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation).

8. Does the proposed quality assurance activity seek to gather information about the patient beyond that collected in routine care? Yes No

Information may include observations, blood samples, additional investigations etc. Genetic studies or others seeking information about family members, relatives, or contacts as well as the individual patient, require further consideration by the HREC.

9. Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of carers, health care providers, or institutions? Yes No

**If you answered NO to ALL the above questions, the proposal does not need consideration by HREC**

**If you answered YES to any of the above questions it does not mean that this is not at QA study. Please give further details for consideration as to the suitability for expedited ethical review.EXPEDITED ETHICAL REVIEW**

Expedited ethical review is available for projects that are low risk according to the National Statement on Ethical Conduct in Human Research (2023) Chapter 2.1: Risk and Benefit. The National Statement, section 2.1.6 holds that:

 *Research is “Low Risk” where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.*

Low-risk studies involve an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm. These studies must not present any more than what could be considered a minimal risk and/or burden to participants. Risks to participants include not only physical risks, but also risks of psychological, spiritual, and social harm or distress. Burdens may include research that is intrusive, and causes discomfort, inconvenience, or embarrassment for the participants.

If your QA activity or research proposal meets the criteria for low risk then please complete the Low-Risk Application form and attach relevant documents i.e., study protocol, data collection tools, questionnaires, and Plain Language Statements and Consent Forms.

Submit the application to: HREC Secretary

 Melbourne IVF

 344 Victoria Parade

 East Melbourne VIC 3002

 Phone: (03) 9473 4444

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Application for Ethical Review of Low-Risk Projects

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| **A. GENERAL INFORMATION** |
| **PROJECT TITLE** |  |
| **APPLICANT DETAILS** |  |
| **CHIEF INVESTIGATOR** |  |

**List the names of any additional investigator(s) (**Copy/paste cells as required for additional investigators/assistants)

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To assist in determining whether your research activity is Low or Negligible Risk, please select [X] any one or more boxes below applicable to your project: *[Double-click on check box “[ ] ” and select ‘checked’]*

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| **B. ACTIVITY RISK CLASSIFICATION CHECKLIST** |
| [ ]  Vulnerable participants, (children, those dependent on care, psychological/psychiatric condition, elderly, pregnant)# |
| [ ]  Genetic research (with the potential to generate significant or sensitive information)٭ |
| [ ]  Externally funded research requiring HREC-level clearance٭ |
| [ ]  Research conducted by a person not associated with the institution٭ |
| [ ]  Other sites requiring HREC-level approval or multi-centre study with Melbourne IVF as coordinating centre# |
| [ ]  Data access/use subject to statutory guidelines &/or reporting٭ |
| [ ]  Data access/use without an individual’s proper prior consent٭(excludes retrospective record reviews/appropriate secondary use#) |
| [ ]  Identification of participant groups/individuals in research outcomes without full consent or there is unclear consent٭ |
| [ ]  Sensitive information/impact (legal٭, regulatory compliance٭, commercial, Professional, cultural, etc) |
| [ ]  Personally intrusive/confronting or quite inconvenient/embarrassing questioning or other activity\* |
| [ ]  Physically confining/invasive techniques or significant physical contact/stimulation –TMS٭, X-ray٭, CT scan٭, MRI٭, clothing change |
| [ ]  Providing, or potential to provide, individual health/medical/psychiatric diagnosis٭ |
| [ ]  Screening for healthy participant inclusion/exclusion |
| [ ]  Providing individual health/medical/psychiatric therapy/treatment٭ |
| [ ]  Administration of other (non-medical) substances/treatments |
| [ ]  Non-minimal impact therapeutic or other devices٭/activity٭ |
| [ ]  Withdrawal of treatment/services or use of placebo |
| [ ]  Conflicts of interest or dual researcher-professional roles |
| [ ]  Research conducted overseas |
| [ ]  Serious psychological profiling, investigation, or exploration |
| [ ]  Deception or covert observation  |
| [ ]  Human research activity commenced or completed without ethical approval# |
| [ ]  Limited or non-disclosure of research information/procedures including deception or concealment |
| [ ]  Participant recruitment/selection via third party |
| [ ]  Qualitative research without experience |
| [ ]  Research involving family members of patient |
| [ ]  Participation incentives, prizes or significant payments |
| [ ]  Research placing researchers/assistants at risk |

PLEASE NOTE:

Selection of one or more boxes ordinarily requires full ethical review

Items above marked ٭ must be submitted for full ethical review. Do not complete this form.

Items above marked # may need to go for full ethical review or may qualify for low risk review depending on the context.

For all # or checked boxes please complete the expandable box below to justify why low risk review is applicable to your activity

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| **C. PROJECT DETAILS** |
| **1.** | **WHY?****Why are you undertaking this project?**Include the aims and intent of the project |  |
| **2.** | **WHAT AND HOW?****Brief description of project and procedures**Please detail clearly and sufficiently the proposed research procedures and outcome measures.Attach questionnaires, data collection sheets, cover letters, advertisements, flyers and brochures. |  |
| **3.** | **Possible risks to participants or investigators?**Please describe any risks you perceive and the measures to be taken to minimise these. |  |
| **4.** | **Anticipated benefits**Please describe the potential benefit/s to participants, profession, society, etc |  |
| **5.** | **Future use of data**Will any of these data be used by yourself or others for any purpose other than for this project? If so, please describe. |  |
| **6.** | **External involvement**Is a body external to MIVF involved in the initiation or support of the project? |  |
| **7.** | **Funding****How is the project funded?** |  |

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| **D. ETHICAL ISSUES CHECKLIST** *[Double-click on YES or NO check box ”* [ ] ” *and select ‘checked’]* | **YES** | **NO** |
| **1.** | Does the activity seek to gather information beyond that collected in routine care or service? | [ ]  | [ ]  |
| **2.** | Does the proposal involve any significant alteration to the routine care or service provided to the individuals? | [ ]  | [ ]  |
| **3.** | Does the data collection process involve access to confidential personal data (including access to data provided for a purpose other than this particular research project) without the prior consent of subjects? | [ ]  | [ ]  |
| **4.** | Does the project pose any risks for participants beyond those of their routine care, treatment, or activity? | [ ]  | [ ]  |
| **5.** | Does the project impose a burden on participants beyond that experienced in their routine care, treatment, or activity? | [ ]  | [ ]  |
| **6.** | Is the proposed activity to be conducted by a person who may not normally have access to the patient’s health or other records for care or a directly related secondary purpose? | [ ]  | [ ]  |
| **7.** | Will information that can identify individuals be collected, used, or disclosed? | [ ]  | [ ]  |
| **8.** | Will participants have pictures taken of them, e.g., photographs, or video recordings?If Yes, please explain, in the space below, how you intend to maintain confidentiality and ultimately dispose of the material | [ ]  | [ ]  |
| **9.** | If interviews are to be conducted, will they be record by electronic device?If Yes, please explain, in the space below, how you intend to retain confidentiality and ultimately dispose of the material. | [ ]  | [ ]  |
| **10** | Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability (not just immediately or directly)? | [ ]  | [ ]  |
| **11.** | Might any aspect of your project risk damage to the participant’s professional/social/cultural/ financial standing or employability? | [ ]  | [ ]  |
| **12.** | Will the research involve access to data banks or intend to access or establish a registry? | [ ]  | [ ]  |
| **13.** | Is any aspect of the activity likely to breach the confidentiality of an individual’s personal information, beyond that experienced in the provision of routine care or service? | [ ]  | [ ]  |
| **14.** | Will any treatment be used with potentially unpleasant or harmful side effects? | [ ]  | [ ]  |
| **15.** | Does the research involve any stimuli, tasks, investigations, or procedures which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the research procedures? | [ ]  | [ ]  |
| **16.** | Will the research involve the use of randomisation, placebo control or the withholding/substitution of treatment, programs or services (health, educational, commercial, other)? | [ ]  | [ ]  |
| **17.** | Will any samples of body fluid or body tissue be required specifically for the research which would not be required in the case of ordinary treatment? | [ ]  | [ ]  |
| **18.** | Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health providers or institutions | [ ]  | [ ]  |
| **19.** | Are there any other ethical issues involved in the research? | [ ]  | [ ]  |

**NOTE**: If the answer to any of the above questions is "Yes", please **explain** and **justify** below in sufficiently clear detail. The box below will expand to fit your response.

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| **E. PARTICIPANT DETAILS & CONSENT** |
| **1.** | **Participant details**Please include age, gender, diagnostic category, number of participants and the method of recruitment/ selection |  |
| **2.** | **Disclosure and informed consent** | **(a) How will participants be informed about the project in order to give valid consent and what method of consent is to be used?**Please check the box that applies and attach any information sheets and consent forms to application:**[ ]**  Information Statement(s)/Letter(s) and Signed Consent Form(s) will be used[ ]  Information Statement(s)/Letter(s) and consent implied by return of anonymous questionnaire[ ]  Verbal advice and verbal consent Please explain how and why:[ ]  Consent as part of routine clinical care in projects where no additional procedures are performed[ ]  No additional consent as project involves secondary use of previously collected data[ ]  Previously provided consent for future use of data for research[ ]  Other (Please explain how and why): |
| **(b.) If a waiver of consent is required, please explain, and justify why:** |
| **3.** | **Privacy and access to external data**Does the research involve access to data which was collected by an organisation for its own purposes (i.e.: not specifically collected for *this* project) such as data banks or diagnostic specimens provided by an institution? |  |

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| **F. DATA & PUBLICATION** |
| **1.** | **Data collection and use** | 1. **Who will access the data and how or in what form will data be accessed?**
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| 1. **In what form with data be collected / recorded?** (*eg, notes; verbatim, audio and/or video recordings; transcripts of recordings; recorded or signed consents; etc*)

**In relation to data access, please acknowledge whether one or both of the following apply:****[ ]**  An individual can be identified; if so, explain why this is necessary?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**[ ]**  Is potentially identifiable / re-identifiable / coded; if so, explain how patient confidentiality will be maintained?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**[ ]**  An individual is not identifiable |
| **2.** | **DATA SECURITY** Please indicate **how** **data** (all types of data, including, eg, signed consent forms, questionnaires, electronic data) **will be securely stored** (eg, electronic form in password-protected disk drive, locked filing cabinet, etc). With more than one type of data, will the types be separately stored? | **(a Following completion of study, including length of time data will be stored after completion of the study:**  |
| **3.** | **PUBLICATION / OUTCOMES**Please explain in sufficient detail | 1. What, if any, publication (conference, news media, academic journal, other journal, etc) is envisaged following on or in relation to this project, both in terms of data proper and/or analysis of data?
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| 1. Will participants be informed about any envisaged research publication/outcome?
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| Would any participants be able to be identified through the publication of data proper or research findings? If so, explain why this is necessary. |

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| **G. DECLARATIONS** |
| **I/We agree to undertake the research activity and handle data confidentially in accordance with the requirements of Melbourne IVF, the National Statement on Ethical Conduct in Human Research 2023 and the MIVF Ethics Committee, including any special ethical conditions.** |
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| **NAME: (block letters)** |  | **SIGNATURE:** |  | **DATE:** |
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| **NAME: (block letters)** |  | **SIGNATURE:** |  | **DATE:** |
| **ENDORSEMENT OF HEAD OF UNIT (OR DELEGATE)****I declare that this project has been developed and will be conducted in accordance with relevant MIVF standards, policies, and codes of practice, has research merit, adequate resources and appropriate leadership/supervision.** |
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| **NAME & POSITION: (block letters)****Chair, MIVF Research Committee** |  | **SIGNATURE:** |  | **DATE:** |

**APPENDIX 1: The National Privacy Principles (NPP’s)**

**A Summary**

This is a summary of the NPP’s. It is a guide only and we recommend that you read the entire text of the NPP’s which is available on line at: www.privacy.gov.au

**NPP1 – Collection**

* Must only collect personal information that is necessary for the purpose
* Collection of personal information must be fair and not intrusive
* Must take reasonable steps to ensure the person from whom personal information is collected is aware:
* of the identity of the organisation
* that they can access information
* why the information is being collected
* to whom the information will be disclosed
* the consequences if they do not provide the requested information
* Must be collected from the individual directly if reasonable and practicable.
* If personal information is collected from a third party, reasonable steps must be taken to ensure the individual is aware of the items identified under bullet point three.

**NPP2 – Use and Disclosure**

Use and disclosure of personal information must only be for the purpose that it was intended for, or for strongly related secondary purposes, or for specified direct marketing, public interest, law enforcement or public safety purposes.

In direct marketing the customer must be given the option not to receive further communications both at the time of first contact and at any time afterwards.

**NPP3 – Data Quality**

Data quality must be good and reasonable steps must be taken to ensure personal information is accurate, complete and up to date when collected and used.

**NPP4 – Data Security**

Data must be kept safe from misuse, loss and unauthorised access. Personal information that is no longer needed must be destroyed or permanently de-identified.

**NPP5 – Openness**

A clear Privacy Policy statement must be available outlining the organisations personal information handling practices. On request, reasonable steps must be made to let a person know what personal information it holds, for what purposes, how it collects, holds, uses and discloses that information.

**NPP6 – Access and Correction**

Access to and correction of personal information must be made available on request by the individual. A reasonable fee may be charged for providing access. Reasonable steps must be taken to correct information.

**NPP7 – Identifiers**

Commonwealth Government identifiers (such as TFN ‘s) cannot be adopted, used or disclosed.

**NPP8 – Anonymity**

Where lawful and practicable, individuals have a right not to identify themselves.

**NPP9 – Trans-border Data Flows**

Transfer may only occur to a foreign country if the recipient is subject to a law similar to the NPP’s; or the individual has consented; or the transfer is necessary for the performance of the contract between the individual and the organisation.

**NPP10 – Sensitive Information**

Sensitive information must not be collected unless the individual has consented or in some special circumstances as required by law such as public health and safety.