**MELBOURNE IVF HREC**

**AMENDMENT SUBMISSION FORM**

**This form is to be used by researchers who are seeking approval of MINOR/MAJOR amendments to an already approved project.**

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| **HREC Reference Number** |  |
| **Full Project Title** |  |
| **Principal Investigator** |  |
| **Contact Details** |  |

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| **PLEASE INDICATE THE TYPE OF AMENDMENT** |
| **MINOR AMENDMENT**  **MAJOR AMENDMENT**  **A MINOR Amendment:** is where the change to the original submission is of an administrative nature (e.g. adding an investigator)  **A MAJOR Amendment:** is a substantial change made to the terms of the HREC submission, the protocol or any other supporting documentation, after the study has been approved which is likely to affect to a significant degree:  (a) the safety or physical or mental integrity of the subjects of the trial or research  (b) the scientific value of the trial or research  (c) the conduct or management of the trial, or research  (d) the quality or safety of any investigational medicinal product used in the trial  **PLEASE NOTE:** if you submit your project amendment as a ‘Minor Amendment’, the HREC are within their authority to request that the submission is not deemed minor and that a ‘Major Amendment’ submission is required. |

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| **SUBMISSION REQUIREMENTS** |
| **PLEASE PROVIDE:**  **PAPER COPIES**   * Please provide **ONE ORIGINAL COPY** (Track Changed and Clean Copy) and **5 HARD COPIES** (Track Changed and Clean Copy). * Each document in the submission **MUST** be individually stapled. * **COPIES** of the submission **MUST be COLLATED** into **INDIVIDUAL BUNDLES** and secured/clipped together using a ‘fold back clip’ to allow for distribution to each HREC member. * In the footer of all submitted documents the document name, version number, date and page number (in the format ‘x of y’ (eg. 1 of 8) must be included.   **ELECTRONIC COPIES**  **DOCUMENT NAME**   * Please name documents as per the following format:   **“HREC ID XX-XX- “<DOCUMENT NAME>” – <“PRINCIPAL INVESTIGATOR SURNAME”>**  e.g. 20-99 - “Study Protocol”- “SMITH”   * The document name must be consistent with the name on the footer of the document.   **TRACK CHANGES**   * Please provide an electronic copy of the submission (include all documents Track changed and Clean copy). * In the footer of all submitted documents the document name, version number, date and page number (in the format ‘x of y’ (eg. 1 of 8) must be included. * Again, name documents as per above instructions.   **IMPORTANT**  **ALL CHANGES MUST BE CLEARLY ‘TRACKED’ USING THE ‘TRACKED CHANGES’ FUNCTION**  Ensure that ‘Version Numbers’ and ‘Version Dates’ are updated in the footer and throughout the document. |

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| **SUMMARY OF THE PROJECT** (provide a brief lay summary) |
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| **APPROVED PROTOCOL** (include Version Number and Date) |
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| **AMENDMENT REQUEST**  Please detail ALL proposed changes to the approved protocol and provide justification for the requested changes.  If an investigator is being added please include the below:   1. Describe what this researcher will do in the context of this project. 2. Include a brief summary of relevant experience for this project. |
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| **DO THE PROPOSED CHANGES RAISE ANY ETHICAL ISSUES?** | **YES** **\*** **NO** |
| **\***If ‘YES’, identify the ethical issues and submit this as a ‘Major Amendment’ | |

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| **STUDY DOCUMENTS**  **Please list (and attach) ALL amended/new documents to be reviewed** (please add rows where necessary)**:**   * Ensure that ALL documents reflect the new ‘Version Number’ and ‘Version Date’ in the footer and throughout the document. * **New Documents MUST be submitted as ‘Version 1’** | | | |
| **DOCUMENT NAME** | **Version Number** | **Date** | **# of pages** |
| **Example:** *Participant Information and Consent Form (PICF)* | *2* | *25th June 2014* | *8* |
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**PLEASE ENSURE THAT YOU HAVE SATISFIED EACH OF THE SUBMISSION REQUIREMENTS BEFORE SUBMITTING YOUR APPLICATION**

**Incomplete applications WILL NOT be submitted for HREC review**

**DECLARATION**

I confirm that this project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).

I confirm that the project is being conducted in compliance with the NHMRC *National Statement on Ethical Conduct in Human Research* (NHMRC, 2023) or as amended.

I confirm that I have not received any information, in any form, from anyone involved in this research project, to suggest this report does not accurately reflect the progress of the project at the above site(s).

**INVESTIGATOR**

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| --- | --- | --- | --- |
| Name |  | | |
| Signature |  | Date |  |