**MELBOURNE IVF HREC**

**ANNUAL REPORT/FINAL REPORT**

**SUBMISSION FORM**

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

**PLEASE ENSURE THAT YOU HAVE SATISFIED EACH OF THE FOLLOWING BEFORE SUBMITTING YOUR APPLICATION**

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| **SUBMISSION REQUIREMENTS****\*\*DO NOT DELETE any text in the footer of this document (this is a quality document)\*\*** |
| **PLEASE PROVIDE:****PAPER COPIES*** Please provide **ONE ORIGINAL COPY** and **5 HARD COPIES**.
* 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.

**ELECTRONIC COPIES****DOCUMENT NAME** * Please name electronic files as per the following format:

**HREC ID <XX-XX>- <YEAR, ANNUAL/FINAL REPORT> – <PRINCIPAL INVESTIGATOR SURNAME>****e.g.** 20-99 - 2024 ANNUAL REPORT- SMITH **e.g.** 20-99 - 2024 FINAL REPORT- SMITH **ABSTRACTS AND PUBLICATIONS** Please include any abstract or publication arising from the project.  **FOR ABSTRACTS*** Please name the electronic file in the following format:

**HREC ID <XX-XX> – <ABSTRACT *(insert Conference Acronym and YEAR>* – PRINCIPAL INVESTIGATOR SURNAME****e.g.** 20-99 – ABSTRACT (ESHRE 2024) – SMITH* Please also add the electronic file name in the footer of the abstract

**FOR PUBLICATIONS**Please name the electronic file in the following format: **HREC ID <XX-XX> – <PUBLICATION> – <PRINCIPAL INVESTIGATOR SURNAME>** **e.g.** 20-99 – PUBLICATION - SMITH |
| **PLEASE INDICATE THE TYPE OF REPORT BEING SUBMITTED** |
| **Annual Progress Report** [ ]  **Final Report** [ ] **\*****\*Final Reports:** Investigators are required to complete ALL sections of this form, due on completion of the study, or if the research is discontinued before the expected date of completion. |

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| **SUMMARY OF THE PROJECT** (provide a brief lay summary) |
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| **PROJECT’S PROGRESS TO DATE** (provide a brief lay summary) |
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| **PROJECT PROGRESS** |
| **Current Status of Project** [ ]  Ongoing [ ]  Not yet commenced**\*** [ ]  Abandoned**\*** [ ]  Completed |
| \*Please provide explanation |
| **Expected Date of Completion**  |  |

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| **PROJECTS WHICH INVOLVE RECRUITMENT OF PARTICIPANTS** |
| **Recruitment target** |  |
| **Number of participants consented to date:**  |  |
| **Number of participants withdrawn to date:** |  |
| Provide reason(s) for participant withdrawal  |
| **Have patient numbers proceeded as planned?**  |  **YES[ ]  NO[ ] \***  |
| \*If ‘NO’, please explain |
| **Is recruitment complete?**  |  **YES[ ]  NO[ ]**  |
| **Is data analysis:**  **[ ]  Not started [ ]  In progress [ ]  Completed**  |

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| **PROJECTS WHICH INVOLVE THE USE OF PATIENT SAMPLES**  |
| **Recruitment target of samples** |  |
| **Actual number of samples/records accessed at this site**  |  |
| **Have samples/records accessed proceeded as planned?**  |  **YES[ ]  NO[ ] \***  |
| \*If ‘NO’, please explain |
| **Is recruitment complete?**  |  **YES[ ]  NO[ ]**  |
| **Is data analysis:**  **[ ]  Not started [ ]  In progress [ ]  Completed** |

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| **HAVE PROBLEMS BEEN ENCOUNTERED IN THE FOLLOWING AREAS?** |
| **Study Design** | **YES** [ ]  **NO** [ ]  |
| **Ethics** | **YES** [ ]  **NO** [ ]  |
| **Finance** | **YES** [ ]  **NO** [ ]  **N/A[ ]**  |
| **Staffing**  |  **YES** [ ]  **NO** [ ]  |
| **Facilities, equipment** | **YES** [ ]  **NO** [ ]  **N/A[ ]**  |
| **Are signed Consent Forms available for inspection?** (If requested by Ethics Committee) | **YES** [ ]  **NO** [ ]  |
| **Is appropriate security maintained for records?** | **YES** [ ]  **NO** [ ]  |

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| **AMENDMENTS** |
| **In this reporting period have there been changes made to the:** | Protocol **YES** [ ]  **NO** [ ]  |
| Participant Information and Consent Form (PICF) **YES** [ ]  **NO** [ ]  |
| Recruitment material/methods **YES** [ ]  **NO** [ ]  |
| Financial arrangements **YES** [ ]  **NO** [ ]  |
| Staffing  **YES** [ ]  **NO** [ ]  |
| Resources **YES** [ ]  **NO** [ ]  |
| Other **YES** [ ]  **NO** [ ] If ‘YES’, please specify |
| **Have these changes been submitted to the Melbourne IVF HREC for review?**  | **YES** [ ]  **NO** [ ] **\*** |
| \*If ‘NO’, please explain why not and forward to the HREC immediately |  |

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| **CLINICAL TRIALS N/A[ ]**  |
| **In this reporting period, have there been any Adverse Events, Serious Adverse Events or Suspected Unexpected Serious Adverse Reactions that have raised safety issues in relation to the research project, which occurred in the past 12 months (or since previous report) and are yet to be reported to the HREC?** |  **YES** [ ] **\*** **NO** [ ]  |
| **\***If ‘YES’, please forward to the HREC immediately  |  |

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| **Has data been presented at a Scientific Meeting?** | **YES** [ ] **\*** **NO** [ ]  |
| **\***If ‘YES’, * list ALL conferences, presentations, seminars etc. at which findings from the research project have been presented **AND** **attach all abstracts.**
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| **Has a paper been published in a Referred journal?** | **YES** [ ] **\*** **NO** [ ]  **Publication pending**  [ ] **\*** |
| **\***List ALL publications to date, and those submitted for publication, which contain findings from the research project***Please also forward any publications arising from this research to the Melbourne IVF HREC Secretariat*****It is understood that this is an annual report, and therefore the study is yet to be completed, however sometimes study protocols are published, if this is the case, please provide a copy of all study related publications.**  |

**PLEASE ENSURE THAT YOU HAVE SATISFIED EACH OF THE SUBMISSION REQUIREMENTS BEFORE SUBMITTING YOUR APPLICATION**

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

**ANNUAL PROGRESS REPORT 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**

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

**FINAL REPORT N/A**  [ ]

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| **Project Completion Date** |  |

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| **Provide a ‘lay’ summary of the results, outcomes and any conclusions of the research** |
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| **Has data been presented at a Scientific Meeting?** | **YES** [ ] **\*** **NO** [ ]  |
| **\***If ‘YES’, * list ALL conferences, presentations, seminars etc. at which findings from the research project have been presented **AND attach any abstract**
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| **Has a paper been published in a Referred journal?** | **YES** [ ] **\*** **NO** [ ]  **Publication pending**  [ ] **\*** |
| **\***List ALL publications to date, and those submitted for publication, which contain findings from the research project**It is an expectation, and a condition of HREC study approval, that a copy of any publications arising from this study are provided to the HREC. Please forward any publications arising from this research to the Melbourne IVF HREC Secretariat** |

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| **If publication of findings is NOT planned, please explain why** |
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| **Is it planned that the participants will be informed of the research project results?\*** \**In accordance with the principles of the National Statement on Ethical Conduct in Human Research (NHMRC, 2023)* | **YES** [ ]  **NO** [ ]  |
| **If ‘YES’** - how?**If ‘NO’** - provide an explanation  |

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

**FINAL REPORT DECLARATION**

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

I confirm that the project was 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 completion or closure of the project at the above site(s).

**INVESTIGATOR**

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