Human Research Ethics Committee (HREC) Submission Checklist

Melbourne IVF HREC Submission Checklist (New submission to full HREC)		
• Meeting dates and submission deadlines are listed on the Melbourne IVF website. • Applications must be received by close of business on the deadline day. • If this study is a clinical trial, you must register the study on the ANZCTR site (or equivalent, if a multi-site study).		
Documents Required	**Notes and Guidance**	**Submitted**
MIVF HREC Submission Form	• All HREC submission forms (new submission form, amendments, annual/final reports) should be accessed from the internet only as these will be the most current forms. **DO NOT** use previous submissions forms when submitting any new submission as these may be outdated https://www.mivf.com.au/ethics-committee	☐Yes
Cover letter signed by the Principal Investigator	• Nominate a short title for the project • Indicate the risk category for the project (i.e.: 'low risk' or 'high risk'). • List all sites for which HREC approval is being sought • List all documents submitted, including version control and dates • Only business/institutional emails and mailing addresses should be listed • Indicate if this is a student project • CTN reference where applicable • Clinical Trial Registration Number ANZCTR or clinicaltrials.gov	☐Yes
'High' Risk projects – Human Research Ethics Application (HREA) form	• HREA form can be found at: Welcome - NHMRC Portal (hrea.gov.au) • Ensure only business/institutional emails and mailing addresses are listed on the HREA.	☐Yes
'Low' Risk projects	• Please use the Low risk application form which can be accessed on the internet at: https://www.mivf.com.au/ethics-committee	☐Yes

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Approval Letters	• Letter of approval from a Research Committee or other entity Attesting to the scientific merit of the project	☐Yes
Study Protocol	• Submission of a study protocol is mandatory • HREA should reference relevant sections of the Protocol. • Ensure the description of the experimental design is clear. • Ensure sponsorship and financial support is clear • Ensure each section of the study protocol is answered. If any section is not applicable, provide a reason. • Clearly describe how patient confidentiality will be assured, explaining more specifically the security methods employed for the study records.	☐Yes
Participant Information Sheet and Consent Form (PICF)	• Ensure the PICF is written in terms able to be understood by a layperson • Ensure an accurate reflection of what is involved of participants is clearly stated. • Provide a lay explanation of any technical terms. • Fully describe any abbreviation or acronym the first time it is mentioned. • Do not bias or overstate the benefits of the study. • Ensure adequate description of risks and possible consequences of participation • Include a clear statement as to whom adverse events, questions, concerns, or complaints should be directed. • A "Withdrawal of Consent Form" must accompany the PICF. • For multisite/interstate studies, use the NHMRC templates • For single-site studies, insert the relevant site logo in the document header. • All study documents must have the correct institutional logo.	☐Yes ☐N/A

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Any other relevant study Documents	• For example: Investigator Brochures, questionnaires, patient cards/diaries, intended advertisement material, Social Media content, letter of invitation, interview questions, telephone scripts • All study documents must include the version number/date in the footer • All study documents must have the correct institutional logo	☐Yes ☐N/A
Therapeutic Goods Administration Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) form, if applicable	• CTNs must be submitted through the TGA's online portal. You must not submit a CTN to the TGA until HREC approval is granted. • Include CTN reference in the cover letter	☐Yes ☐N/A
Additional Documents for commercially sponsored studies		**Submitted**
Certificate of Insurance	• The insurance certificate must specifically name the Australian Corporate entity acting as a commercial sponsor as a named insured under the relevant insurance policy • If the certificate is provided in the name of an overseas parent company, it must name the Australian entity as a subsidiary • The insurance certificate must include a valid coverage period for the policy • The insurer providing the cover must be approved by the Australian Prudential Regulation Authority and must have a minimum financial strength rating of A- or above • The insurance certificate must provide coverage of AUD$20 million for every occurrence and AUD$20 million in the annual aggregate against a class of insurance appropriate for the risk associated with the research.	☐Yes ☐N/A
Financial Summary	• Please provide a full budget, and source of funding.	☐Yes
Conflict of Interest	• Declare any conflicts of interest. Refer to policy Virtus Conflicts of Interest Policy 20220920 v1.1.pdf	☐Yes ☐N/A

Research Agreement/Contract (usually where a third party is involved)	• For Australian studies, the Medicines Australia contract is preferred (Clinical-Trial-Research-Agreement-Medicines-Australia-Standard-Form-8-March-2017-b-2.doc (live.com) • This form will require legal sign-off	☐Yes ☐N/A