

21 June 2019

The Chief Investigator
 A/Prof Peter Illingworth
 IVFAustralia
 Greenwich NSW 2065

Dear A/Prof Peter Illingworth,

Project No. 155 “eValuating IVY Selection Ability. The VISA study”

Investigators : A/Prof Peter Illingworth, Dr Simon Cooke, Prof David Gardner, Mr Aengus Tran, Dr Christos Venetis

Thank you for submitting the above research project for single ethical review. This project was considered by the IVFAustralia Ethics Committee at its meeting held on 17 June 2019.

I am pleased to advise you that the above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval for this research project has been granted by IVFAustralia Ethics Committee.

The approved documents include:

Document	Version	Date
IVFA Research Proposal	V3.2	01/06/2019
Summary Info (to be used in emails/Ads & Fliers)	V1.0	01/06/2019
Participant Info Sheet & Consent Form	V1.1	04/06/2019
HREA online Application ID: PI00005	V1	30/05/2019

Please note the following standard requirements of approval:

1. Approval will be for a period of three years from 17/06/2019 until 16/06/2022. At the end of this period, if the project has been completed, abandoned, discontinued, or not commenced for any reason, you are required to submit a Final Report on the project. If you complete the work earlier than you had planned you must submit a Final Report as soon as the work is completed. The Final Report form is attached and will also be emailed to you.

If the project has run for 3 years and is not completed you must also submit a report. Should you wish to continue the project you must make an application to the IVFAustralia Ethics Committee (IVFA Ethics Committee) for extension of the approval, and provide reasons to justify the request for an extension. If such an application is not made the IVFA Ethics Committee approval will expire. The request for extension must be received by the IVFA Ethics Committee at least 3 months prior to expiration of the original approval expiry date. The reason for the three year limit on renewal of approvals is to allow the Committee to fully review progress of research in an environment where legislation, guidelines and requirements are continually changing.

2. In the interim you must submit a Progress Report every 12 months while the project is still proceeding. The form is attached and will also be emailed to you. If the project has run for more than three (3) years you will need to complete and submit a Final Report (see *Point 1* above) and submit a new application for the project.

3. Please remember the IVFA Ethics Committee must be notified of any alteration to the project.
4. You must notify the IVFA Ethics Committee immediately in the event of any adverse effects on participants or of any unforeseen events that might affect continued ethical acceptability of the project.
5. At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the IVFAustralia Research and Development Committee, supported by the IVFA Ethics Committee. The guidelines are attached for your information. You must ensure that the trial is conducted in compliance with the research protocols submitted. It would be deemed unethical for the trial to continue where there have been deviations from the protocol, unexpected severe side effects or one treatment is shown to be significantly better or worse such that some participants will be disadvantaged if the trial continues.
6. If you will be applying for or have applied for internal or external funding for the above project it is your responsibility to provide the R&D Committee with a copy of this letter as soon as possible. The R&D Committee will not inform external funding agencies that you have final approval for your project and funds will not be released by the IVFAustralia R&D Committee until it has received a copy of this final approval letter.
7. If your project is to be presented at a scientific meeting or published as an abstract, please forward a copy of this final publication to the Ethics Committee.
8. Please contact the IT Coordinator at IVFAustralia if you have received approval to use data in the former OMZ and current VPS database. You will need to advise:
 - The specifics of the data you are hoping to be able to get out from the IVFA database (ie the data set to be exported including, the IVFA site, database files and fields if possible)
 - When you need the data The required format of the export
 - Privacy and control of export (access) measures

You need to give the IT Department at least two weeks' notice for appropriate resource allocation. Data extraction can take anywhere from a number of hours to weeks depending on the requirements and usually involves our programmers as the relationships in the database are complex.

The IVFA Ethics Committee wishes you every success in your research.

Kind Regards



Nicole Aghabi
Chairperson
IVFAustralia Ethics Committee