Mr Arthur Hui
Manager
Research and Ethics Secretariat
Tel: +61 3 8345 3720
Fax: +61 3 8345 3702
Email: arthur.hui@thewomens.org.au

the women's
the royal women's hospital

ABN 62 787 822 077
Locked Bag 300
Cnr Grattan St & Flemington Rd
Parkville VIC 3052 Australia
Tel +61 3 8345 2000
www.thewomens.org.au

20.12.18

Dr E Twidale
Principal Gynaecology Registrar
RWH

Dear Dr Twidale,

Re: Project 18/37 –Methoxyflurane for intrauterine device insertion in conscious patients: An open, single arm pilot study testing feasibility and medication acceptability

Thank you for submitting the clarification and amendments as requested by the RWH Human Research Ethics Committee.

I confirm the project is now approved.

Enclosed please find Project Approval and Notification of Project Commencement Forms for your record.

Please note that the RWH Human Research Ethics Committee has now agreed that GCP training should be mandatory for all principal investigators. The Committee also strongly encourages GCP training for other associate investigators and student researchers.

Please return the completed Notification of Project Commencement Form to me when the project begins.

Yours sincerely,

A. C. B. Hui
Manager
Research and Ethics Secretariat

Encl:

THE ROYAL WOMEN'S HOSPITAL

RESEARCH AND HUMAN RESEARCH ETHICS COMMITTEES

PROJECT APPROVAL

PROJECT NO:	**18/37**
PROJECT TITLE:	Methoxyflurane for intrauterine device insertion in conscious patients: An open, single arm pilot study testing feasibility and medication acceptability
INVESTIGATOR (S):	E Twidale, C Streeton, D Devonshire, P Moore
DATE OF APPROVAL:	20 December 2018
ANTICIPATED DURATION:	Five (5) months

SIGNED ……
Secretary, Research & Human Research Ethics Committees DATE

CONDITIONS OF APPROVAL

The Principal Investigator is reminded of the following:-

1. ***GCP training is mandatory for all principal investigators. The Human Research Ethics Committee also strongly encourages GCP training for other associate investigators and student researchers.***

2. ***Prior to commencement of the project, you must contact the relevant RWH Divisional Directors / Department Heads to confirm your actual commencement date. Failure to inform these RWH personnel may jeopardise their approval and support for your project.***

3. ***A Project may commence once the Principal Investigator has received written confirmation that the Human Research Ethics Committee has approved the Project.***

4. ***Substantial changes in protocols must be submitted to the Research/Human Research Ethics Committees for approval.***

5. ***Progress reports must be submitted annually. A request will be forwarded to the Principal Investigator. If no report is supplied, permission to continue the project may lapse.***

6. ***The Research/Human Research Ethics Committees must be notified IMMEDIATELY of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise.***

7. ***Consent forms must be available for audit and retained on file for at least five (5) years.***

8.. ***Raw data and details of analysis must be retained by the Principal Investigator for at least five (5) years.***

9. ***Principal Investigator MUST upon leaving the Institution, inform the Human Research Ethics Committee as to the nominated person to replace him/her.***

PLEASE QUOTE PROJECT NO. AND TITLE FOR ALL CORRESPONDENCE

RWH PROJECT NUMBER 18/37

THE ROYAL WOMEN'S HOSPITAL

RESEARCH AND HUMAN RESEARCH ETHICS COMMITTEES

NOTIFICATION OF PROJECT COMMENCEMENT

PROJECT TITLE:	Methoxyflurane for intrauterine device insertion in conscious patients: An open, single arm pilot study testing feasibility and medication acceptability
INVESTIGATOR (S):	E Twidale, C Streeton, D Devonshire, P Moore
DATE OF APPROVAL:	20 December 2018
ANTICIPATED DURATION:	Five (5) months

DATE OF COMMENCEMENT ……...../……...../….....

PRINCIPAL INVESTIGATOR:

NAME.....
(PLEASE PRINT)

SIGNATURE..... **DATE**……...../..…….../.....