Tuesday, 16 July 2019

Prof Guy Marks
Woolcock Inst. of Medical Research; Faculty of Medicine and Health
Email: guy.marks@sydney.edu.au

Dear Guy,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Protocol Number:	**2019/515**
Protocol Title:	**Test and Treat to End TB: A Pilot Study**
Sites Approved:	Ca Mau, Vietnam
Authorised Persons:	**Marks Guy; Fox Gregory; Graham Stephen; Nguyen Hoa; Wood James;**
Approval Period:	**16 July 2019** to **16 July 2023**
First Annual Report Due:	**16 July 2020**

Documents Approved:

Date Uploaded	Version Number	Document Name
09/07/2019	Version 2	Flyer, Banner and PA Announcement text_clean
09/07/2019	Version 2	PCF-1 for TEST component_clean
09/07/2019	Version 2	PIS-1 for TEST component_clean
09/07/2019	Version 2	PIS-2 for TREAT component_clean
09/07/2019	Version 2	PCF-2 for TREAT component_clean
24/05/2019	Version 1	Adverse Drug Reaction Form
24/05/2019	Version 1	Severe Adverse Event Form
24/05/2019	Version 1	Severe Adverse Event Detail Form
24/05/2019	Version 1	Chest Radiograph Report Form
24/05/2019	Version 1	Liver Function Test Results
24/05/2019	Version 1	Mantoux Test Form
24/05/2019	Version 1	Medical Assessment - During Treatment
24/05/2019	Version 1	Study Protocol
24/05/2019	Version 1	Isoniazid Product Information
24/05/2019	Version 1	Rifampicin Product Information
24/05/2019	Version 1	Rifapentine Product Information
24/05/2019	Version 1	Adverse Drug Reaction Detail Form
24/05/2019	Version 1	Full Blood Count Results Form
24/05/2019	Version 1	Medical Assessment - Baseline
24/05/2019	Version 1	Pregnancy Screening Form
24/05/2019	Version 1	Pre-treatement Assessment form for fieldworker
24/05/2019	Version 1	Sputum Culture Form
24/05/2019	Version 1	Sputum Xpert Form
24/05/2019	Version 1	Symptom Screening Prior to Administering Medications
24/05/2019	Version 1	Symptom Screening Questionnaire

Special Conditions of Approval for Clinical Trials

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with

additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinical-trials.research@sydney.edu.au

- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

R. L. Shackel

Associate Professor Rita Shackel
Chair
Human Research Ethics Committee (HREC 3)

cc. Clinical Trial Governance (only where relevant)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).