Tuesday, 21 September 2021

Prof Guy Marks
Woolcock Institute 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.

If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.

Protocol Number:	**2021/412**
Protocol Title:	**Test and Treat to End TB**
Sites Approved:	**Ca Mau Province, southern Vietnam**
Authorised Persons:	**Marks Guy; Britton Warwick; Fox Gregory; Nguyen Thu Anh; Toelle Brett; Graham Steve; Hill Philip C.; Khanh Luu Boi; Nguyen Binh Hoa; Nguyen Linh N.; Nguyen Viet Nhung; Thanh Nguyen Tat; Wood James;**
Approval Period:	**21 September 2021** to **21 September 2025**
First Annual Report Due:	**21 September 2022**

Documents Approved:

Date Uploaded	Version Number	Document Name
15/09/2021	Version 2	7a. PCF_1 Test_14Sep2021_V2.0_tracked
15/09/2021	Version 2	8a. PCF_1_Test_Child_14Sep2021_V2.0_Tracked
15/09/2021	Version 2	9a. PCF_2_Treat_14Sep2021_V2.0_tracked
15/09/2021	Version 2	7. PIS_1_Test_14 Sep2021_V2.0_Tracked
15/09/2021	Version 2	8. PIS_1 Test_Child_14Sep2021_V2.0_tracked
15/09/2021	Version 2	11a. PCF_3 Survey_Child_14Sep2021_V2.0_tracked
15/09/2021	Version 2	6. Medical assessment_baseline_V2.0_14Sep2021_tracked
15/09/2021	Version 2	1a.Protocol_V2_September 2021_tracked
15/09/2021	Version 2	10a. PCF_2Treat_Child_14Sep2021_V2.0_Tracked
11/08/2021	Version 2	12. PIS-4 SURVEY_CHILD_tracked
11/08/2021	Version 2	2. Withdrawal form
11/08/2021	Version 1	3a. Rifapentine and Isoniazid Product Information
11/08/2021	Version 2	3. Rifapentine and Isoniazid Product Information
11/08/2021	Version 1	4. PPD Product Information
11/08/2021	Version 1	5. COVID-19 Safety Protocol
11/08/2021	Version 1	1. Protocol
28/04/2021	Version 1	PCF-2 TREAT_CHILD
28/04/2021	Version 1	PIS-2 TREAT
28/04/2021	Version 1	11. Body Weight Measurement Form
28/04/2021	Version 1	4. Tuberculin Test Placement Form
28/04/2021	Version 1	15. Active TB Clinical Assessment Form - Visit 2
28/04/2021	Version 1	18. Symptom Screening Prior to Administration
28/04/2021	Version 1	19. Adverse Event Form
28/04/2021	Version 1	TST Appointment Card
28/04/2021	Version 1	Xray and Clinical Assessment Invitation

28/04/2021	Version 1	Guide for Sputum Collection
28/04/2021	Version 1	Banner
28/04/2021	Version 1	Flyers, Banner and PA announcements
28/04/2021	Version 1	Home Visit Safety Protocol
28/04/2021	Version 1	16. Sputum Culture Form
28/04/2021	Version 1	17. Drug dispensing fieldworker
28/04/2021	Version 1	20. Close Out Form
28/04/2021	Version 1	21. Pregnancy Reporting Form
28/04/2021	Version 1	Notification Letter by CPC
28/04/2021	Version 1	Standee Advertisement
28/04/2021	Version 1	PIS-2 TREAT_CHILD
28/04/2021	Version 1	PIS-4 SURVEY_CHILD
28/04/2021	Version 1	1. Household Enumeration Form
28/04/2021	Version 1	7. Pregnancy and Lactation Screening Form
28/04/2021	Version 1	8. Pre-treatement Assessment Form
28/04/2021	Version 1	12. Blood Pressure Measurement Form
28/04/2021	Version 1	13. Medical Assessment Baseline Form
28/04/2021	Version 1	PIS-3 SURVEY
28/04/2021	Version 1	2. Informed Consent Process Form
28/04/2021	Version 1	3. Symptom Screening Questionnaire
28/04/2021	Version 1	5. Tuberculin Test Reading Form
28/04/2021	Version 1	6. Sputum Xpert Form
28/04/2021	Version 1	9. Chest Radiograph Report Form
28/04/2021	Version 1	10. Blood Test Form
28/04/2021	Version 1	14. Active TB Clinical Assessment Form - Visit 1
28/04/2021	Version 1	22. Prevalence Survey Symptom Questionnaire
28/04/2021	Version 1	SMS Messages to participants
28/04/2021	Version 1	Medical Booklet
28/04/2021	Version 1	Screening Results Form

Special Condition/s of Approval

- It is a condition of approval that certified translations of the public documents (e.g. Participant Information Statement, Participant Consent Form) are made and provided to participants, once these documents have been approved in English. https://intranet.sydney.edu.au/research-support/ethics-integrity/human-ethics/guidelines.html#translated-documents

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,

Helen Mitchell

Associate Professor Helen Mitchell
Chair
Human Research Ethics Committee (HREC 1)

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 (2018) and the NHMRC's Australian Code for the Responsible Conduct of Research (2018).