Thursday, 13 June 2019

Dr Gregory Fox
Woolcock Inst. of Medical Research; Faculty of Medicine and Health
Email: gregory.fox@sydney.edu.au

Dear Gregory,

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:	**2019/384**
Protocol Title:	**The effectiveness of a self-stigma and shame reduction intervention upon stigma measures for patients with TB and MDR-TB in Vietnam: a randomised controlled trial**
Sites Approved:	**Hanoi in northern Vietnam**
Authorised Persons:	**Fox Gregory; Redwood Lisa; Viney Kerri A; Mitchell Ellen;**
Approval Period:	**13 June 2019** to **13 June 2023**
First Annual Report Due:	**13 June 2020**

Documents Approved:

Date Uploaded	Version Number	Document Name
28/05/2019	Version 3	RCT PIC V3
28/05/2019	Version 13	Protocol_V13
28/05/2019	Version 3	Pilot PIS V3
26/04/2019	Version 1	CV
13/04/2019	Version 3	Consent_RCT_V3
11/04/2019	Version 2	Consent_Pilot_V2
11/04/2019	Version 1	Safety Protocol_V1
11/04/2019	Version 1	Logbook_MDR-TB_V1
11/04/2019	Version 1	Logbook_TB_V1
11/04/2019	Version 1	Patient Survey_V1
11/04/2019	Version 1	Post intervention patient review_V1
11/04/2019	Version 1	Facilitator feedback of pilot intervention_V1

Special Condition/s of Approval

- It is a condition of approval that certified translations of all public documents be made and provided to participants, once final approval of English versions have been obtained from the HREC. Please refer to the ethics office intranet page for further information.

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/).

THE UNIVERSITY OF SYDNEY

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,

Dr Helen Mitchell
Chair
Human Research Ethics Committee (HREC 1)

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).