Stony Brook University Institutional Review Board (IRB)

DATE:	September 21, 2018
TO:	Peter Small, MD
FROM:	Stony Brook University IRB (CORIHS A)
SUBMISSION TYPE:	New Project
STUDY TITLE:	[1255165-2] DrOTS: Drone Observed Therapy in Remote Nepal
CORIHS#:	2018-4648-F
ACTION:	DEFERRED
REVIEW TYPE:	Full Committee Review

The New Project referenced above was reviewed by Stony Brook University IRB (CORIHS A) (FWA #00000125) on September 13, 2018 and was deferred pending receipt of the following:

While many of the issues have been resolved with this submission, the following remain:

1) The protocol says that the study will rely on local health-care workers to consent subjects and carry out the protocol. The training for local health-care workers is not described. Training must include consenting and assessing the capacity to consent as well as training in the details of the protocol and health education, which has been added to the protocol.

2) Application and Supplemental Form C still contradict each other, and Application also contradicts itself. Application Section VII #3 states that consent will take place in private tents and huts both before and after diagnosis of TB and before treatment. Supplemental C Forms states that consent will be obtained prior to sputum collection and diagnosis. The process must be reconciled on all documents.

3) The inconsistency remains about whether parental consent will be obtained (Supplemental Form F says yes, and the cover letter states no, and the parental consent has been removed from this submission) and there is an assent form. The response indicated that study population will consist of only 16 year olds and above, all considered adults in Nepal. If this is accurate, please revise all study documents to reflect this. No parent permission or assent from minors would therefore be required.

4) Incomplete or contradictory information in the Application persists. Section II. 9B is answered "NO" to "will you obtain parental permission?", but the "Justification" that is required has not been provided. Section III question 8 is not answered. Section VII question 1 is answered YES, but "Confirmed" is not checked. Section VII question 3: the answer contradicts itself as to when consent will be obtained

Additionally, the answer to the IRB request for more detail on how a potential subject's capacity will be assessed, was put in the wrong place on the application. It is currently in Section II question 10D; should be added to answer in Section VII question 5.

5) Inexplicably, two different consent forms have been included with several differences. The wording (AND MEANING) of the "Alternatives" section is completely different for MERMS: consent "E" says "you

can choose to enroll in a TB treatment facility, rather than using a MERM; consent "D" says "you can remove your medication from the box and turn off the pillbox at any time." Consent "E" gives Dr Small's email; consent D does not. Consent "E" does not have Stony Brook University logo; "D" does. It is not clear why there are two forms; this must be explained or resolved.

ALL consents/assent still have Judy Matuk's telephone number and email to contact if any questions. There needs to some contact information that can be used by participants in Nepal.

6) Previous IRB review requested the questionnaires that will be used to determine if the study goals are met. While these questionnaires have been submitted, if possible please submit as Word documents for easier review.

7) NTP must be defined.

8) Please clarify the role for Maxine Caws, PhD. What tasks are associated with an "implementing partner"?

9) Protocol should include the type of statistical analysis that will be used.

10) Request for a conditional SBU IRB approval can be granted once these issues have been clarified and CORIHS approves the study. Once ethical approval from the Nepali Ministry of Health has been obtained, study can commence.

YOUR RESPONSE TO THESE CONDITIONS WILL BE CONSIDERED COMPLETE, AND FORWARDED FOR FINAL REVIEW, IF ALL OF THE FOLLOWING STEPS ARE TAKEN:

1. A cover letter is submitted that addresses, point by point, your response to each of the CORIHS questions/comments in the letter.
2. Study documents that are submitted in response to this letter have all revisions highlighted.
3. PI must sign the response package (and, for responses to deferrals, so must the department chair).
4. All study personnel listed on the registration form/renewal application have reviewed the applicable certification section at the end of the CORIHS application, and have electronically signed either the current package, or the package to be submitted in response to this letter, to confirm their compliance. Note that signatures may be provided on locked and submitted studies.
5. Required CITI and research HIPAA training for all personnel is up to date.

If the submission is not complete, as outlined above, you will receive notice that you have one week to complete the package or it will be withdrawn from consideration by CORIHS. Thank you.

Note:

- **In order to reply to this letter using IRBNet, please follow the section titled "How do you respond to CORIHS, post-review (i.e., modifications required, deferrals etc)?" in the Instructions for SBU and BNL Investigators available here:** http://research.stonybrook.edu/sites/default/files/IRBNet%20for%20SBU%20BNL%20Researchers_2.pdf

Your response will need to be reviewed by Stony Brook University IRB (CORIHS A) at a convened meeting. Please review the CORIHS Deadlines available at: http://www.stonybrook.edu/research/orc/human-subjects.shtml#deadlines-tab.

You are reminded that this activity must not be initiated until CORIHS sends written confirmation to you that full approval has been granted.

If you have any questions or comments about this correspondence, please contact:

      Office of Research Compliance
      Division of Human Subject Protections

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Stony Brook, NY 11794-3368.
Phone: 631-632-9036
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Please include your study title and CORIHS # in all correspondence with this office.