

**RESEARCH CONSENT FORM**

**DrOTS: Drones Observed Therapy in Remote Nepal**  
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**You are being asked to be a volunteer in a research study.**

**Common abbreviations:**

TB = tuberculosis

DrOTS = Drone Observed Therapy System

MERMS = Medication Event Reminder Monitor Systems

**PURPOSE**

The purpose of this study is to assess two new technologies in the DrOTS program for diagnosis and treatment of tuberculosis (TB), a potentially fatal infectious disease. The two technologies are:

1. Drones, which will fly testing specimen and medicine to and from the health clinic;
2. A medication reminder box (Medication Event Reminder-Monitor; MERM), which stores your daily medicine, reminds you to take them, and records when the box is opened;
3. A training video, which explains what TB is and how it is best treated and prevented.

You are eligible for this study because, in accordance with the Nepali National TB Program, you have exhibited symptoms of non-drug-resistant tuberculosis. If you choose to take part in this study, you will be one of approximately 115 subjects, all living in Pyuthan, Nepal.

**PROCEDURES**

The study will last for six (6) months. If you choose to take part in the study, your part will involve the following:

1. Allow your sputum to be flown in a drone to the nearest TB lab. Once a month, you will also be asked to provide urine samples to make sure that you are taking the medicine and it is not harming your body. You may also be asked to provide a blood sample to make sure the medicine is not harming your body;
2. Store your daily TB medication in the MERMs. This box will remind you to take  your medicine by flashing lights and making sounds, and it will record when it is opened. The medication will be provided by the National TB Program;
3. Watch a series of short videos on a mobile phone with the research team. The videos will explain what TB is and how it is best treated and prevented;
4. Complete short interviews to give us feedback about the technologies.

**Please Note:** If you participate in this study, you agree to use the above technologies without tampering, e.g. removal of batteries or misuse of the mobile phone.

**RISKS / DISCOMFORTS**

There are no foreseeable risks or discomforts associated with your participation in this study.

**BENEFITS**

The following benefits may occur as a result of participating in this study:

1. The use of drones to transport treatment materials will eliminate the need for travel to health clinics except in the case of serious complications. This means that medicine will reach you faster and it will be easier to complete all 6 months of the treatment protocol.
2. The MERM will remind you to take your daily medications; The MERM will give your doctor a summary of when you have opened the box and taken your medicine. This information will help him/her to give you unique treatment based on your habits.
3. The video training system will help you understand the treatment protocols and provide tips to complete your treatment effectively.

**PAYMENT TO YOU**

You will not be paid for participating in this study. The TB drugs will be provided to you free of charge.

**PAYMENT TO THE INSTITUTION**

This project is funded by the Simons Foundation, awarded to Dr. Peter Small at the Stony Brook Global Health Institute.

**CONFIDENTIALITY**

We will take steps to help make sure that all the information we get about you is kept confidential. A code number will be assigned to you and used in place of your name wherever possible. All the study data and your identification code will be kept locked up and/or password protected. Your name will not be used in any papers and talks are given about this research.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will only share the data we get from you in this study with the study team, the Nepali National TB Program, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices. However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this. In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above as well as your medical doctor and a board that reviews the safety of the study on an on-going basis.

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by signaling to a study coordinator, who will make the necessary arrangements to contact Dr. Peter Small. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means

* That you have read this section.
* That you will allow the use and reporting of your health data as described above.

**COSTS TO YOU**

There are no costs to you as a participant in this study. You will not be reimbursed for your participation in this study.

**ALTERNATIVES**

You can decide to not participate in this study, to withdraw from it, or to avoid the use of a specific technology at any time. In such case, you will nonetheless be offered standard care. Alternatives are as follows:

1. Drone: You can choose to walk to the health clinic monthly to deliver diagnostic samples and receive medication;
2. MERM: You can remove your medication from the box and turn off the pillbox at any time. If you choose not to use the MERM at any point in the study, you can be enrolled in a TB treatment facility.
3. Video training system: You can ask a health care worker to explain the information to you, and turn off the mobile device displaying the video at any time.

**IN CASE OF INJURY**

If you are injured as a result of being in this study, please contact Suman Chandra Gurung at telephone +977 1-4436434, 442824 at Birat Nepal Medical Trust. The health care facilities at Pyuthan District Hospital will be open to you in case of such injury. Additional complications can be reported to PI Dr. Peter Small through email at peter.small@stonybrookmedicine.edu.

**YOUR RIGHTS AS A RESEARCH SUBJECT**

* Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
* You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
* Any new information that may make you change your mind about being in this study will be given to you.
* You will get a signed and dated copy of this consent form to keep upon request.
* You do not lose any of your legal rights by signing this consent form.

**QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT**

* If you have any questions, concerns, or complaints about the study, you may contact Suman Chandra Gurung at telephone +977 1-4436434, 442824 or Birat Nepal Medical Trust. You may also refer to the Pyuthan District Hospital, where staff can address or direct your inquiry.
* Visit Stony Brook University’s Community Outreach page, [http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research](http://research.stonybrook.edu/orc/community.shtml" \l "overview-of-volunteering-in-research) for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

**If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.**

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Printed Name of Subject

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Signature of Subject Date Time

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Printed Name of DrOTS Team Member Obtaining Consent

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Signature of DrOTS Team Member Obtaining Consent Date Time