Stony Brook University

Committees on Research Involving Human Subjects

Registration Form for Expedited or Full CORIHS Review

[1255165-1] DrOTS: Drone Observed Therapy in Remote Nepal

I. Principal Investigator

Name:	Peter Small, MD	**Department:**	Global Health Institute
Email:	peter.small@stronybrookmedicine.edu	**Phone #:**	631-601-3513
Mailing Address:	z = 4364		
Currently CORIHS certified?	☐ No	☑ Yes	
Direct interaction with human subjects?	☑ No	☐ Yes	

II. Study Coordinator

Name:	Joe Brew	**Department:**	Economics
Email:	joebrew@gmail.com	**Phone #:**	+34 666 66 80 86
Mailing Address:	Institut de Salut Global de Barcelona Carrer del Rosselló, 132, 08036 Barcelona Spain		
Direct interaction with human subjects?	☑ No	☐ Yes	
Currently CORIHS certified?	☐ No	☑ Yes	

III. Co-Investigators/Additional Personnel

Please complete this section for each Co-investigator or Additional Personnel.

Name:	Maxine Caws	**Department:**	Liverpool School of Tropical Health and Medicine
SBU Status:	Other		
Direct interaction with human subjects?	☑ No	☐ Yes	
Currently CORIHS certified?	☐ No	☑ Yes	

IV. Research Funding

- ☐ Internal Funds
- ☑ External Funds
- ☐ No Internal or External Funds Required, but an unfunded agreement is being routed through COEUS.
- ☐ Seeking Funding
- ☐ No Internal or External Funds Required

Grant Title	Sponsor	Status	RF Account #
DrOTS: Drone Observed Therapy in Remote Nepal	Jim Simons	Awarded	- -

For all projects:
Do any individuals listed above, or members of their immediate families, have a vested personal interest in the future commercial success of the drug, device, etc. under study (e.g., was involved in discovery, patent, licensing, IND/IDE filings etc.)?

☑ No ☐ Yes ☐ Not Applicable (There is no drug, device, etc. under study.)

V. Research Locations

Campus locations used to conduct study procedures (including consent process):

- ☐ West Campus
- ☐ Dental School/Clinic
- ☐ Health Science Center
- ☐ LI Veterans Home
- ☐ BNL *
- ☐ University Hospital **
- ☐ Clinical Research Center, Technology Park **
- ☐ Cancer Center **
- ☐ Mod M (Metabolic Treatment Unit) **
- ☐ Other:

* Note: You must share your study with Darcy Mallon (full access).

** For these sites, additional approvals are required. You must share your study with UH individuals as outlined in Section IV of the Instructions for SBU or BNL Investigators. You must complete and upload the Application for Approval to Conduct Research Activities at Stony Brook University Hospital, available in the IRBNet Designer (Forms and Templates Library).

Activities conducted at another institution? ☐ No ☑ Yes

*If **no,** skip to Section VI.*

Multi-center clinical trial? ☑ No ☐ Yes

*If **yes,** skip to Section VI.*

Participating institution(s), FWA numbers, and role(s):

Birat Nepal Medicale Trust. Institute of co-investigator Maxine Caws. BNMT will provide in-country assistance and use of facilities for quality control testing of diagnostic technologies, and will manage human resources in Nepal.

Lead institution? ☑ SBU ☐ Other:

Note that *if SBU is the lead institution,* IRBNet must be used by all sites to keep them informed of study-related current information (protocols, amendments, consent documents, IRB status). The Principal Investigator will comply with this requirement:

☑ Yes ☐ No ☐ SBU is not the lead institution.

VI. Study Information

Investigator-initiated study? ☐ No ☑ Yes

Populations which will be utilized/recruited for this study:

- ☑ Children (0-17 years old)
- ☑ Females
- ☐ Pregnant women/fetuses
- ☐ Non-viable/questionably viable neonates (viable neonates are considered children)
- ☐ Minorities (including American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic)
- ☐ Cognitively-impaired adults
- ☑ Non-English speakers (must be offered inclusion in studies where there is a potential for [therapeutic] benefit that is not available outside of the research context - see SOPs Section 17.8)
- ☐ Any investigators named on this form, or relatives/subordinates/students thereof
- ☐ Prisoners
- ☐ Not Applicable

Obtaining informed consent (and/or permission, assent) from subjects?

- ☑ YES, I will be obtaining documented, informed consent/permission/assent.
- ☐ YES, but I will be requesting a waiver from the documentation of consent/permission/assent in the Application for Expedited or Full CORIHS Review.
- ☐ NO, I will be requesting a waiver from the requirement of informed consent/permission/assent for this study in the Application for Expedited or Full CORIHS Review.

Collecting health information (e.g., from medical records, health care providers, or direct interaction with the subjects)?

- ☐ NO
- ☐ YES, data are de-identified or constitute a limited data set.
- ☑ YES, subjects' authorization will be obtained, or a waiver of authorization will be requested in the Application for Expedited or Full CORIHS Review.

Drugs or biologics used in this study? ☑ No ☐ Yes

VII. Investigational Drugs and Biologics

Drugs or biologics not FDA-approved? ☐ No ☐ Yes (upload IBs)

Trade Name: **Generic:**

IND/BB-IND #: **IND Holder:**

If the SBU investigator is the holder of the IND/BB-IND, will the investigator comply with the applicable FDA regulations and will the investigators ensure that the research is conducted according to the signed agreement and approved protocol?

☐ Yes ☐ No ☐ The SBU Investigator is not the IND/BB-IND Holder.

If no IND/BB-IND number, justify the use of the drug or biologic:

VIII. FDA-Approved Drugs and Biologics

Drugs or biologics FDA-approved and used according to label? ☐ No ☐ Yes (upload IBs)

Trade Name	Generic Name

IX. Off-Label Use of FDA-Approved Drugs and Biologics

Drugs or biologics used off-label? ☐ No ☐ Yes (upload IBs)

Trade Name: **Generic:**

IND/BB-IND #: **IND Holder:**

How does use of this drug/biologic differ from approved indication?

If the SBU investigator is the holder of the IND/BB-IND, will the investigator comply with the applicable FDA regulations and will the investigators ensure that the research is conducted according to the signed agreement and approved protocol?

☐ Yes ☐ No ☐ The SBU Investigator is not the IND/BB-IND Holder.

If no IND/BB-IND number, justify why an IND/BB-IND number is not needed:

X. Medical Devices

Medical devices used? ☑ No ☐ Yes (upload IDBs)

Trade Name: **Generic:**

IDE #: **IDE Holder:**

FDA-approved device? ☐ No ☐ Yes

If the SBU investigator is the holder of the IDE, will the investigator comply with the applicable FDA regulations and will the investigators ensure that the research is conducted according to the signed agreement and approved protocol?

☐ Yes ☐ No ☐ The SBU Investigator is not the IDE Holder.

Device risk?

Off-label use? ☐ No ☐ Yes ☐ Not Applicable - Experimental Device

If no IDE number and device is not approved or is being used off-label, justify use:

XI. Radiation Exposure

Exposure to radiation? ☑ No ☐ Yes

Forms of radiation that will be involved:

- ☐ Diagnostic X-Rays
- ☐ Radiation Therapy
- ☐ Radioisotopes
- ☐ Other:

Amounts and schedule of administration:

INSTRUCTIONS TO RESEARCHERS

Review the contents of this form for accuracy and completeness before submitting this package to CORIHS.

If you are submitting a new project in IRBNet:

- Complete the "Application for Expedited or Full CORIHS Review", located in the CORIHS Office Forms and Reference Library in IRBNet.
- Continue adding documents for your submission, in accordance with the requirements outlined in the CORIHS Submission Requirements for New, First Time Submissions, also available in your Forms and Templates Library.
- Obtain appropriate signatures and submit the package to the CORIHS office, in accordance with the Instructions for SBU or BNL Investigators.

If you are submitting continuing review materials into IRBNet and you have not previously submitted a copy of this electronic Registration Form for your study:

- Complete the continuing review application appropriate for your study (i.e., either "Application for Continued CORIHS Approval"), located in the CORIHS Office Forms and Reference Library in IRBNet.
- Continue adding documents for your submission, in accordance with the requirements outlined in the CORIHS Submission Requirements for Continuing Reviews also available in your Forms and Templates Library.

- Obtain appropriate signatures and submit the package to the CORIHS office, in accordance with the Instructions for SBU or BNL Investigators.

SUBMISSIONS TO THE CORIHS OFFICE THAT DO NOT INCLUDE THE REGISTRATION FORM, THE APPROPRIATE APPLICATION, AND ALL OTHER REQUIRED MATERIALS WILL BE CONSIDERED INCOMPLETE AND WILL NOT BE FORWARDED TO THE CORIHS COMMITTEES FOR ACTION. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE OFFICE OF RESEARCH COMPLIANCE AT 631-632-9036.