Institutional Review Board
Translator's Declaration

IRB#:
PI:

To the Institutional Review Board:

I, Sangya Mohanty declare that the linguist is fluent in and understands the English language and the Nepali language. To the best of my knowledge and belief, the attached translation(s) are true, accurate and correct.

Attached are (1) the original documents (In English) and (2) the Nepali - translated version(s).

Other than my role as a translator, I have no other involvement with the above-referenced research proposal.

Translator's Name (Print): Sangya Mohanty

Address: BNSPL, SDF-L(7/A), SEZ Phase II

Phone No.: (____) - ____ - ____ Fax No.: (____) - ____ - ____

E-mail: Pm@braahmam.net

Sangya Mohanty
PC, Braahmam — 30/6/2017

Signature — Date

Institutional Review Board
Consent to Participate in Research

Principal Investigator: **Version Date:**

Study Title:

Institution/Hospital:

छोटो रूप लिखित जानकारीयुक्त सहमति कागजात

यो कागजात विषयमा बुझ्न सक्ने भाषामा लेखिनुपर्छ र मौखिक रूपमा प्रस्तुत गरिने जानकारीको लिखित सारांशमा संलग्न गरिनुपर्छ।

तपाईँलाई अनुसन्धान अध्ययनमा सहभागी हुनको लागि अनुरोध गरिँदै छ।

तपाईँ सहमत हुनुअघि, अध्ययन डाक्टरले तपाईँलाई निम्नको बारेमा बताउनुपर्छ:

(i) अध्ययन गर्नुको कारण, काम गरिने कार्यहरू र तपाईँ कति समय अध्ययनमा रहनुहुनेछ;
(ii) प्रयोगात्मक भएका कुनै जाँचहरू वा उपचार;
(iii) अध्ययनबाट आउने तपाईँले आशा गर्न सक्ने कुनै जोखिम वा अन्य असर र राम्रा असर;
(iv) तपाईँले अध्ययनमा नबस्ने निर्णय गर्नुभएमा तपाईँले पाउन सक्ने अन्य उपचारहरू; र
(v) अध्ययन अभिलेखहरू कसरी राखिन्छन् र कसले तिनलाई हेर्न सक्छन्।

जब निम्नमध्ये कुनै कुरा लागु हुन्छ, अध्ययन डाक्टरले तपाईँलाई निम्न कुराहरू बताउनुपर्छ:

(i) अनुसन्धान अध्ययनको कारणले तपाईँलाई चोटपटक लागेमा रकम;
(ii) थाहा नभएका अन्य जोखिमहरूको सम्भावना;
(iii) अध्ययन डाक्टरले तपाईँलाई अध्ययनबाट हटाउन सक्ने कारणहरू;
(iv) तपाईँले अध्ययनमा भाग लिनुभएमा तपाईँलाई शुल्क;
(v) तपाईँले अध्ययनमा बस्नबाट रोकिने निर्णय गर्नुभएमा के हुनेछ;
(vi) तपाईँलाई नयाँ पत्ता लागेका कुराहरूको बारेमा कहिले भनिनेछ जसले अध्ययनमा बस्ने बारेमा तपाईँले गर्ने अनुभवमा असर गर्न सक्छ; र
(vii) अध्ययनमा कति मानिस हुनेछन्।

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] यु.एस. कानुनद्वारा आवश्यकीय रूपमा यस चिकित्सकीय परीक्षणको एक विवरण **www.clinicaltrials.gov** मा उपलब्ध हुनेछ। यस वेबसाइटले तपाईँको पहिचान गर्न सक्ने जानकारी समावेश गर्ने छैन। बढिमा वेबसाइटले परिणामहरूको एक सारांश समावेश गर्नेछ। तपाईँले कुनै पनि समयमा यो वेबसाइटमा खोज्न सक्नुहुन्छ।

यदि तपाईँले अध्ययनमा बस्ने सहमति गर्नुभएमा, अध्ययन डाक्टरले अध्ययनको एक लिखित सारांशसहित तपाईँले यस फाराममा हस्ताक्षर गर्नुभएपछि यसको एक प्रतिलिपी तपाईँलाई दिनुपर्छ।

Principal Investigator: **Version Date:**

Study Title:

Institution/Hospital:

यदि अनुसन्धानको बारेमा तपाईँसँग कुनै प्रश्न भएमा वा तपाईँले अध्ययनको कारणले आफूलाई चोट लागेको अनुभव गर्नुभएमा INSERT CONTACT'S NAME निम्नमा CONTACT'S PHONE NUMBER सम्पर्क गर्न नहिचकिचाउनुहोस्

[**IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING:** तपाईँले मेरो सङ्काय सल्लाहकारलाई पनि (**INSERT NAME OF FACULTY ADVISOR**) निम्नमा (**INSERT FACULTY ADVISOR'S NUMBER**)] सम्पर्क गर्न सक्नुहुन्छ।

[**IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING:** यदि तपाईँ अनुसन्धान कर्मचारीसम्म पुग्न सक्नुहुन्न भने, कृपया अध्ययन डाक्टरलाई निम्नमा लेख्नुहोस् (**INSERT INVESTIGATOR'S PAGER NUMBER**)]।

सहमति दिने बारेमा वा यस अध्ययनको सहभागीको रूपमा तपाईँको अधिकारको बारेमा थप जानकारीको लागि संस्थागत समीक्षा कार्यालयलाई (Institutional Review Board Office) (615) 322-2918 मा वा टोल फ्रीमा (866) 224-8273 मा सम्पर्क गर्नुहोस्।

तपाईँ यस अनुसन्धान अध्ययनमा हुनु पर्ने छैन। तपाईँले आफ्नो स्वास्थ्यहेरचाह, सुविधाहरू वा अन्य अधिकारहरू परिवर्तन नगरी यस अध्ययनमा नबस्ने र अन्य उपचार पाउने छनोट गर्न सक्नुहुन्छ। तपाईँले कुनै पनि समयमा यस अध्ययनमा बस्नबाट रोकिन सक्नुहुन्छ।

Institutional Review Board
Consent to Participate in Research

Principal Investigator: **Version Date:**

Study Title:

Institution/Hospital:

यस अध्ययनमा हुनु पर्ने व्यक्तिको स्वीकृतिद्वारा कथन

अनुसन्धान अध्ययनले मलाई शाब्दिक रूपमा बताएको छ। मेरा सबै प्रश्नहरूको जवाफ पाएको छु, र म स्वतन्त्र र स्वेच्छिक रूपमा यस अध्ययनमा सहभागी हुने छनोट गर्दछु।

_____ _____

सहभागीको हस्ताक्षर Signature of Participant मिति Date

_____ _____

साक्षीको हस्ताक्षर Signature of Witness मिति Date

_____ _____

अनुवादकको हस्ताक्षर (लागु भएमा) मिति Date

Signature of Interpreter (if applicable)

9/20/17

Institutional Review Board
Consent to Participate in Research

Principal Investigator: **Version Date:**
Study Title:
Institution/Hospital:

SHORT FORM WRITTEN INFORMED CONSENT DOCUMENT

This document must be written in a language understandable to the subject and should be attached to a written summary of the information that is presented orally.

You are being asked to take part in a research study.

Before you agree, the study doctor must tell you about:

(i) the reason for doing the study, the things that will be done and how long you will be in the study;
(ii) any tests or treatments that are experimental;
(iii) any risks or side effects you can expect, and good effects that might come from the study;
(iv) other treatments you could get if you decide not to be in the study; and
(v) how the study records will be kept and who can see them.

When any of the following things apply, the study doctor must also tell you about:

(i) payment in case you are injured because of the research study;
(ii) the possibility of other risks that are not known;
(iii) reasons why the study doctor may take you out of the study;
(iv) costs to you if you take part in the study;
(v) what will happen if you decide to stop being in the study;
(vi) when you will be told about new findings which may affect how you feel about staying in the study; and
(vii) how many people will be in the study.

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you agree to be in the study, the study doctor must give you a copy of this form after it is signed along with a written summary of the study.

If you have any questions about this research study or if you feel you have been hurt because of this study, please feel free to contact **(INSERT NAME OF CONTACT)** at **(CONTACT'S PHONE NUMBER).**

[IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING: You can also contact my Faculty Advisor**, (INSERT NAME OF FACULTY ADVISOR)** at **(INSERT FACULTY ADVISOR'S NUMBER)].**

[IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING: If you cannot reach the research staff, please page the study doctor at **(INSERT INVESTIGATOR'S PAGER NUMBER)]**.

For additional information about giving consent or your rights as a participant in this study, contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Institutional Review Board
Consent to Participate in Research

Principal Investigator: **Version Date:**
Study Title:
Institution/Hospital:

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
The research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Signature of Participant Date

_____ _____
Signature of Witness Date

_____ _____
Signature of Translator (if applicable) Date