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 Lao 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 Lao - 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: BNISPL, SDF - L(7/A), SEZ Phase II

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

E-mail: PM@ bnaahmam.net

Sangya Mohanty
PC, Braahmam

Signature

30/6/2017

Date

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ແບບຟອມສັ້ນສຳລັບເອກະສານຍິນຍອມ

ເອກະສານສະບັບນີ້ຕ້ອງຂຽນເປັນພາສາ ທີ່ເຂົ້າໃຈດີ ກ່ຽວກັບເນື້ອໃນ ແລະ ຈະຕ້ອງຄັດຕິດກັບບົດສະຫຼຸບຫຍໍ້ບັນດາຂໍ້ມູນທີ່ບັນຍາຍປາກເປົ່າ.

ທ່ານໄດ້ຖືກຮຽກຮ້ອງໃຫ້ເປັນສ່ວນໜຶ່ງໃນການສຶກສາຄົ້ນຄວ້າ.

ກ່ອນທ່ານຈະຕົກລົງເຫັນດີ, ທ່ານໝໍສຶກສາຄົ້ນຄວ້າຈະບອກທ່ານກ່ຽວກັບ:

(i) ເຫດຜົນໃນການສຶກສາ, ສິ່ງທີ່ຈະໄດ້ເຮັດ ແລະ ທ່ານຈະຢູ່ໃນການສຶກສາດົນປານໃດ;
(ii) ບັນດາການກວດ ຫຼື ຂັ້ນຕອນທີ່ຈະມີການທົດລອງ;
(iii) ບັນດາຄວາມສ່ຽງ ຫຼື ຜົນຂ້າງຄຽງທີ່ຄາດໄວ້, ແລະ ຜົນດີທີ່ອາດຈະໄດ້ຈາກການສຶກສາ;
(iv) ການຂັ້ນຕອນອື່ນໆທີ່ທ່ານອາດສາມາດໄດ້ຮັບ ຖ້າທ່ານຕັດສິນໃຈບໍ່ເຂົ້າໂຄງການສຶກສາ; ແລະ
(v) ການເກັບຮັກສາຂໍ້ມູນການສຶກສາແນວໃດ ແລະ ໃຜທີ່ສາມາດເບິ່ງໄດ້.

ໃນເມື່ອໃຊ້ໜຶ່ງໃນກໍລະນີຕ່າງໆດັ່ງຕໍ່ໄປນີ້, ທ່ານໝໍສຶກສາຍັງຕ້ອງບອກທ່ານກ່ຽວກັບ:

(i) ການຈ່າຍເງິນໃນກໍລະນີທີ່ທ່ານໄດ້ຮັບບາດເຈັບເນື່ອງຈາກການສຶກສາຄົ້ນຄວ້າ;
(ii) ຄວາມສ່ຽງອື່ນໆທີ່ອາດເປັນໄປໄດ້ທີ່ບໍ່ຄາດຄິດ;
(iii) ເຫດຜົນວ່າເປັນຫຍັງທ່ານໝໍສຶກສາອາດຈະເອົາທ່ານອອກຈາກການສຶກສາ;
(iv) ຄ່າໃຊ້ຈ່າຍທີ່ທ່ານຈະໄດ້ຈ່າຍຖ້າທ່ານເຂົ້າຮ່ວມໂຄງການສຶກສາ;
(v) ສິ່ງທີ່ຈະເກີດຂຶ້ນຖ້າທ່ານຕັດສິນໃຈທີ່ຈະຢຸດເຊົາກັບໂຄງການສຶກສາ;
(vi) ເມື່ອໃດທ່ານຈະໄດ້ຮັບການບອກກ່ຽວກັບສິ່ງທີ່ຄົ້ນພົບໃໝ່ ເຊິ່ງອາດຈະມີຜົນກະທົບ ເພື່ອຮູ້ວ່າທ່ານຢູ່ກັບການສຶກສາ; ແລະ
(vii) ຈະມີຈັກຄົນທີ່ເຂົ້າຮ່ວມການສຶກສາ.

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] ລາຍລະອຽດການທົດລອງທາງຄລີນິກນີ້ຈະມີໃຫ້ຢູ່ທີ່ www.clinicaltrials.gov ຕາມກົດໝາຍຂອງສະຫະລັດກຳນົດ. ເວັບໄຊນີ້ຈະບໍ່ປະກອບມີຂໍ້ມູນທີ່ສາມາດລະບຸຕົວທ່ານ. ຫຼາຍສຸດນັ້ນແມ່ນເວັບຈະມີຂໍ້ສະຫຼຸບສັງລວມຂອງຜົນໄດ້ຮັບນັ້ນ. ທ່ານສາມາດຄົ້ນຫາທີ່ເວັບໄຊໄດ້ຕະຫຼອດເວລາ.

ຖ້າທ່ານຕົກລົງເຫັນດີທີ່ຈະເຂົ້າຮ່ວມການສຶກສາ,
ທ່ານໝໍສຶກສາຕ້ອງໃຫ້ສຳເນົາແບບຟອມນີ້ຫຼັງຈາກເຊັນພ້ອມກັບຂໍ້ສະຫຼຸບສັງລວມກ່ຽວກັບການສຶກສາ.

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ຖ້າທ່ານມີຄຳຖາມກ່ຽວກັບການສຶກສາຄົ້ນຄວ້ານີ້ ຫຼື ຖ້າທ່ານຮູ້ສຶກວ່າ ທ່ານໄດ້ຮັບບາດເຈັບເນື່ອງຈາກການສຶກສານີ້, ກະລຸນາຢ່າລັງເລທີ່ຈະຕິດຕໍ່ຫາ INSERT NAME OF CONTACT ທີ່ CONTACT'S PHONE NUMBER

[IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING:
ທ່ານຍັງສາມາດຕິດຕໍ່ຫາທີ່ປຶກສາຂອງຄະນະ (INSERT NAME OF FACULTY ADVISOR) ໄດ້ທີ່ (INSERT FACULTY ADVISOR'S NUMBER)].

[IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING:
ຖ້າທ່ານບໍ່ສາມາດເຂົ້າເຖິງພະນັກງານຄົ້ນຄວ້າໄດ້, ກະລຸນາຕິດຕໍ່ຫາທ່ານໝໍໄດ້ທີ່ (INSERT INVESTIGATOR'S PAGER NUMBER)].

ສຳລັບຂໍ້ມູນເພີ່ມເຕີມກ່ຽວກັບການການຍິນຍອມ ຫຼື ສິດທິຂອງທ່ານໃນນາມຜູ້ເຂົ້າຮ່ວມການສຶກສານີ້, ຕິດຕໍ່ຫາຫ້ອງການຄະນະກຳມະການກວດກາສະຖານບັນທີ່ເບີ (Institutional Review Board Office) (615) 322-2918 ຫຼື ໂທບໍ່ເສຍຄ່າໄດ້ທີ່ (866) 224-8273.

ທ່ານບໍ່ຈຳເປັນຕ້ອງຮ່ວມກັບການສຶກສາຄັ້ງນີ້. ທ່ານອາດຈະເລືອກບໍ່ໃຫ້ເຂົ້າຮ່ວມການສຶກສານີ້ ແລະ ໄດ້ຮັບການປິ່ນປົວອື່ນໆ ໂດຍບໍ່ມີການປ່ຽນແປງການດູແລສຸຂະພາບຂອງທ່ານ, ການບໍລິການ ຫຼື ສິດທິອື່ນໆ. ທ່ານສາມາດຢຸດການເຂົ້າຮ່ວມການສຶກສາໄດ້ທຸກເວລາ.

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ເອກະສານວ່າດ້ວຍການຕົກລົງເຫັນດີເຂົ້າຮ່ວມການສຶກສານີ້
ການສຶກສາໄດ້ມີການອະທິບາຍໃຫ້ຂ້ອຍຟັງແບບປາກເປົ່າ. ຄຳຖາມທັງຫມົດຂອງຂ້າພະເຈົ້າໄດ້ຮັບຄຳຕອບ, ແລະ ຂ້າພະເຈົ້າບໍ່ມີຫຍັງ ແລະ ສະຫມັກໃຈເລືອກທີ່ຈະເຂົ້າຮ່ວມການສຶກສາຄັ້ງນີ້.

_____ _____

ລາຍເຊັນຜູ້ເຂົ້າຮ່ວມ Signature of Participant ວັນທີ Date

_____ _____

ລາຍເຊັນພະຍານ Signature of Witness ວັນທີ Date

_____ _____

ລາຍເຊັນນາຍພາສາ (ຖ້າມີ) ວັນທີ Date

Signature of Interpreter (if applicable)

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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.

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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