Institutional Review Board
Translator's Declaration

IRB#:
PI:

To the Institutional Review Board:

I, Bayan Tech (on Behalf of the Translator) declare that the linguist used is fluent in and understands the English language and the Somali language. To the best of our knowledge and belief, the attached translation(s) are true, accurate and correct.

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

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

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Ahmed Fathy

Signature

Rec'd 7/2017

Date

Institutional Review Board
Consent to Participate in Research

Principal Investigator: **Version Date:**

Study Title:

Institution/Hospital:

WARQADDA FOOM GAABAN OO OGGOLAANSHAHA KA WARQABO AH.

Warqadda waa inay ku qornaataa luqadda <u>la fahmi karo</u> mowduuca oo waa in lagu lifaaqaa macluumaadka qoran ee kooban ee af ahaan loo soo bandhigay.

Waxaan lagu waydiisanayaa inaad ka qayb qaadato daraasad cilmi baadhis ah.

ka hor inta aanad aqbalin, dhakhtarka daraasada waa inuu wax kaaga sheegaa:

(i) sababta loo samaynayo daraasada, waxyaabaha la samayn doono iyo ilaa inta aad daraasada ku jiri doonto.
(ii) wixii baadhitaano ah ama daawayn ah ee tijaabo ah,.
(iii) Wixii khataro ah ama saamaynta xun ee dawada ah ee la fili karo, iyo natiijooyinka wanaagsan ee ka iman karta daraasada.
(iv) daawaynta kale ee aad ka heli karto haddii aad go'aan ku gaadho daraasada; iyo
(v) Sida diiwaanada daraasada waa la hayn doonaa iyo cida arki karta.

Marka shay kasta oo soo socdaa uu habboonyahay, dhakhtarka daraasada waa inuu sidoo kale wax kaaga sheegaa:

(i) lacag bixinta xaalada lagu dhaawacay sababtoo ah daraasada cilmi baadhida;
(ii) suuragal ahaanshaha khataraha kale ee aan la aqoon;
(iii) sababaha dhakhtarka daraasadu uu kaaga saari karo daraasada;
(iv) kharashka ay kugu tegayso haddii aad ka qayb qaadato daraasada;
(v) waxa dhici doonaa haddii aad go'aan ku gaadho inaad ku jirto daraasada;
(vi) marka wax lagaaga sheegi doono natiijooyinka cusub kaas oo saamayn doona sida aad ka dareento ku jirida daraasada; iyo
(vii) inta ay leegyihiin dadka ku jiri doona daraasada.

[Insert if your study is using an investigational drug, device or biologic, otherwise please delete] Faahfaahinta daraasad kasta oo caafimaad waxaa laga heli doonaa www.clinicaltrials.gov, sida uu ubaahanyahay Sharciga Maraykanku. Barta internatka kuma jiri doonto macluumaadka ku aqoonsan kara adiga. Ugu badnaan, Barta internatka waxaa ku jiri doono natiijooyinka oo kooban. Waxaad ka raadin kartaa Bartan iternatka wakhti kasta.

Haddii aad aqbasho inaad ku jirto daraasadan, dhakhtarka daraasada waa inuu ku siiyaa nuqul foomkan ah marka la saxeexo ee la raaciyo daraasada kooban ee qoran.

Haddii aad hayso wax su'aalo ah oo ku saabsan daraasadan cilmu baadhida ama haddii aad dareento in lagu waxyeeleeyay iyaddoo sabablu tahay daraasada, fadlan dareen xoriyada aad kula xidhiidho INSERT NAME OF CONTACT xaga CONTACT'S PHONE NUMBER .

[IF THE STUDY INCLUDES A FACULTY ADVISOR, INSERT THE FOLLOWING: Waxaad sidoo kale la xidhiidhi kartaa La taliyaha Kulliyaday , (INSERT NAME OF FACULTY ADVISOR) aga (INSERT FACULTY ADVISOR'S NUMBER)].

[IF THE STUDY DOCTOR HAS A PAGER, INSERT THE FOLLOWING: Haddii aanad gaadhi karayn shaqaalaha cilmi baadhida, fadlan eeg dhexda bogga daraasada dhakhtarka xaga (INSERT INVESTIGATOR'S PAGER NUMBER)].

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Wixii macluumaadka dheeraadka ah ee ku saabsan oggolaanshaha ama xuquuqdaada sidii ka qayb gale daraasadan ah, kala xidhiidha Xafiiska Machadka Guddida Dib u eegida (Institutional Review Board Office) (615) 322-2918 ama lambarka bilaashka ah (866) 224-8273.

Waa in aanad ku jirin daraasadan cilmi baadhida. Waxaad dooran kartaa daraasadan oo waxaad heli kartaa daawayn kale iyaddoon la beddelin daryeelkaaga caafimaad, adeegyada ama xuquuqaha. Waxaad joojin kartaa ku jirida daraasada wakhti kasta.

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WARBIXINTA QOFKA AQBALAYA INUU KU JIRO DARAASADAN
Daraasada cilmi baadhida waxaa la iigu sharaxay hadal ahaan. Dhammaan su'aalaha waa laga jawaabay, oo si xor ah oo aan khasab ahayn ayaan u doortay inaan ka qayb galo daraasadan,

_____		_____	
Saxeexa ka qayb galaha	Signature of Participant	Taariikhda	Date
_____		_____	
Saxeexa markhaatiga	Signature of Witness	Taariikhda	Date
_____		_____	
Saxeexa turjubaanka (haddii la heli karo)		Taariikhda	Date

Signature of Interpreter (if applicable)

Institutional Review Board
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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