APPENDIX K

CERTIFICATE OF TRANSLATION / INTERPRETER APPROVAL FORM

For research conducted in languages other than English, the DU IRB must have all versions of the research materials (e.g. recruitment, informed consent form(s), instruments, etc.) in both English and Non-English on file. This Certificate of Translation/Interpreter Approval Form must be submitted to verify that a translation from English to Non-English is accurate and to obtain approval for use of a qualified interpreter. Those who translate and/or serve as an interpreter for research study must provide a brief description of their qualifications, skills or experience for taking on this important responsibility and role. **All research subjects, regardless of their language/dialect, must be provided with appropriate information in their primary language to ensure their willingness to participate without bias or undue influence.**

**IMPORTANT CONSIDERATIONS**

**TRANSLATION OF RESEARCH DOCUMENTS:**
It is acceptable for investigators to “translate” the research documents (e.g., recruitment, consent, data collection instruments) if they provide adequate information that describes their qualifications, skills or experience to serve as a translator.

**TIMING OF THE TRANSLATION:**
The research investigator(s) may wish to delay initial translation from English into the Non-English version until after the IRB’s initial review of the application. Awaiting the IRB initial review comments will ultimately help researchers avoid unnecessary and additional work for a translator.

**INTERPRETER:**
If an interpreter will need to be used in a research project in order to recruit, administer appropriate consent, and implement research procedures (interviews, surveys, or focus groups, etc.) on behalf of the investigator, the IRB must review and approve the individual’s qualifications, skills and experience to serve as an interpreter.

**MODIFICATIONS:**
When a translation is carried out AFTER the research has been approved, a formal modification (amendment form) to the approved research must be submitted through IRBNet. The researcher must submit any modified materials along with the translated versions of these materials. The Certificate of Translation Form can be submitted as part of the formal modification process.
SECTION A: CHOOSE AN OPTION:

☐ Request initial review of Translator for translating documents from English to non-English for a research project

☐ Request initial review of Interpreter for recruiting, consenting and administering study interactions/interventions with research subjects who do not speak or read English as their native language.

SECTION B: GENERAL INFORMATION:

B.1 Translated language(s)/dialect(s) necessary for the research to be conducted:
Click here to enter text.

NOTE: The DU IRB requires forward- and back-translations of all study materials by a qualified translator (a certified translator or an individual who has the appropriate experience speaking and writing the language and/or dialect of the targeted research population).

B.2 Describe the qualifications and skills (either professional or through life experience) of the translator and/or interpreter to be used for the research project.
Click here to enter text.

For Initial Review of Interpreter Only:

B.3 Explain whether the proposed interpreter has had any experience working with individuals in a human subjects research project.
Click here to enter text.

B.4 What training/instruction will the investigator conduct with the interpreter to ensure that the research subject’s rights are respected and the Belmont Ethical Principles are followed?
Click here to enter text.

INVESTIGATOR CERTIFICATION STATEMENT:

By electronically signing your name below, you certify the research information will be translated/interpreted to individuals who may enroll in your research study who do not speak or read English as their primary
language. Translations and/or the use of an interpreter, will be conducted by the Principal Investigator or through the services of a translator/interpreter. To the best of your knowledge, the translator/interpreter will have the necessary qualifications and/or training to present the research information accurately without bias or undue influence. Furthermore, you agree to provide appropriate resources and contacts to subjects, who can speak and respond in the subject’s native language, to answer any research-related questions during and after the research has ended.

Investigator’s Name: Click here to enter text.,
Date of signature: Click here to enter a date.