NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board

MEMORANDUM

To: Brianna Kent, Ph.D.
HPD – College of Health Care Sciences

From: Matthew Seamon, Pharm.D., JD
Chair, Institutional Review Board

WHS for Dr. Seamon

Date: July 13, 2016

Re: *Trauma Informed Health Care for Human Trafficking Victims* – NSU IRB No. 2016-272

I have reviewed the revisions to the above-referenced research protocol by an expedited procedure. On behalf of the Institutional Review Board of Nova Southeastern University, *Trauma Informed Health Care for Human Trafficking Victims* is approved in keeping with expedited review category #6 and #7. Your study is approved on **July 6, 2016** and is approved until **July 5, 2017**. You are required to submit for continuing review by **June 6, 2017.** As principal investigator, you must adhere to the following requirements:

1) CONSENT: You must use the stamped (dated consent forms) attached when consenting subjects. The consent forms must indicate the approval and its date. The forms must be administered in such a manner that they are clearly understood by the subjects. The subjects must be given a copy of the signed consent document, and a copy must be placed with the subjects' confidential chart/file.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair of any adverse reactions that may develop as a result of this study. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation.

4) CONTINUING REVIEWS: A continuing review (progress report) must be submitted by the continuing review date noted above. Please see the IRB web site for continuing review information.

5) FINAL REPORT: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended via the IRB Closing Report form.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) revised June 18, 1991.

Cc: Dr. Rose Colon
Mr. William Smith

3301 College Avenue • Fort Lauderdale, Florida 33314-7796
(954) 262-5369 • Fax: (954) 262-3977 • Email: *irb@nova.edu* • Web site: *www.nova.edu/irb*

Coalition for Research and Education Against Trafficking and Exploitation

Human Trafficking Training

Research Participants Needed!

Researchers at Nova Southeastern University in the College of Health Care Sciences are recruiting volunteers for a research study including training on trauma-informed care to victims of human trafficking.

Participants may choose to participate in the trauma-informed training, and will be asked to fill out surveys and may be invited to participate in an audio-recorded focus group.

In appreciation of your time, a light meal will be provided.

The training will be held on a day and time that is convenient to all participants. Please select your day and times on the Doodle invitation below:

http://doodle.com/poll/gm2ignrn3xzn7sep

For more information and to RSVP please contact:

Brianna Black Kent, Ph.D., Principal Investigator, College of Health Care Sciences, Nova Southeastern University at 954-262-1296 or brianna@nova.edu

CREATE
Coalition for Research and Education Against Trafficking and Exploitation

NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board
Approval Date: JUL 06 2016
Continuing Review Date: JUL 05 2017

NSU

NOVA SOUTHEASTERN UNIVERSITY
Institutional Review Board
Approval Date: JUL 0 6 2016
Continuing Review Date: JUL 0 5 2017

Consent Form for Participation in the Research Study Entitled Trauma-informed Health Care for Trafficking Survivors: Effectiveness of Training among Dentists, Psychologists, and Optometrists

Funding Source: Community Foundation of Broward.

IRB protocol #

Principal investigator
Brianna Black Kent, Ph.D.
Department of Health Science
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Co-investigator
Sandrine Gaillard-Kenney, Ed.D.
Department of Health Science
Nova Southeastern University
Fort Lauderdale, FL 33328

For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information
NSU Health Professions Division
Sanford L. Ziff Center
3200 S. University Drive
Davie, FL 33328

NSU North Miami Beach Health Care Center
1750 NE 167th Street
North Miami Beach, FL 33162
(954) 678-2273

Psychological Services
Maltz Building
3301 College Avenue
Ft. Lauderdale-Davie, FL 33314

What is the study about?
You are invited to participate in a research study. The goal of this study is to measure the effectiveness of a 90-minute human trafficking and trauma informed care training on your level of preparation to interact with, and provide care to victims of human trafficking.

Why are you asking me?
We are inviting you to participate because you are a full-time faculty, post-doctorate, resident, or intern in the College of Dental Medicine, College of Psychology, or College of Optometry who will mostly likely participate in

Initials _____ Date _____

providing health care services to victims of human trafficking as part of the new NSU SMILES (Services Making Individual Lives Economically Sustainable) research study. This study will provide dental, psychological, and optometry services at no cost to victims of human trafficking. The health care services will be provided at the Sanford L. Ziff Center at the NSU Ft. Lauderdale campus, the NSU North Miami Beach Health Care Center, and the Psychological Services at the Ft. Lauderdale campus.

What will I be doing if I agree to be in the study?
If you agree to be in the study, you will engage in a few simple steps. You will attend one, 90-minute training on trauma-informed care for human trafficking victims. Before, and right after the training, you will be asked to answer a 5-minute survey about your knowledge of human trafficking and of trauma-informed care for these victims. The questions will also assess your perceived level of preparedness to interact with these victims in the clinical environment. Approximately three months after the training, you will be invited to participate in a focus group about the effectiveness of the training. The focus group should take no longer than 90 minutes.

Is there any audio or video recording?
Only the focus group discussion will be audio recorded. This audio recording will be available to be heard by the principal and co-principal investigators, the research assistant, the IRB, and no one else. The research assistant will transcribe the recording. The recording will be kept securely in a locked cabinet in the principal investigator's office. The recording will be kept for 36 months and destroyed after that time by erasing the audio file. Because your voice may be potentially identifiable by anyone who hears the recording, your confidentiality for things you say on the recording cannot be guaranteed, although the researcher will limit access to the tape as described in this paragraph.

What are the dangers to me?
There is a minimal risk associated with possible breach/loss of confidentiality as it relates to the completion of the pre-post surveys. Although identifying information is not asked directly, demographic data will be collected and it is possible that some identities could be reconstructed. Your name will not be linked to your survey answers and there are no identifiers on the surveys.

During the focus group, answering questions or talking with others may be difficult. You may choose not to answer any discussion question and you can stop your participation in the focus group at any time. There is a risk associated with possible breach/loss of confidentiality as it relates to the focus group, because members of the group may share information with others outside of the group. Because your voice will be potentially identifiable by anyone who hears the recording, your confidentiality for things you say on the recording cannot be guaranteed although the researcher will limit access to the audio recording to the PIs and the Research Assistant. Upon commencing the focus group, confidentiality of the group and the need for participants to respect the privacy of all group members will be emphasized.

If you have questions about the research, your research rights, or have a research-related injury, contact Dr. Brianna Kent or Dr. Sandrine Gaillard-Kenney. You may also contact the IRB at the numbers indicated above with questions as to your research rights.

Are there any benefits to me for taking part in this research study?
There are no direct benefits. However, the information gained from the trauma-informed care for victims may increase awareness of the health care needs and improve the quality of health care provided to human trafficking victims.

Will I get paid for being in the study? Will it cost me anything?
There are no costs to you or payments made for participating in this study. In appreciation of your time a light lunch will be offered.

How will you keep my information private?
Your identity will not be included in any report or publication resulting from this research study. The principal investigator will store all collected paper and electronic data in a locked cabinet in the principal investigator's office to ensure security and confidentiality. The recordings from the focus group will be saved on an encrypted and password protected laptop that will be locked in the PI's file cabinet. Only the principal investigators and research assistant will have access to these data. The data will be retained for 36 months from the conclusion of the study. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB or regulatory agencies may review research records.

What if I do not want to participate or I want to leave the study?
You have the right to leave this study at any time or refuse to participate. If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research

records for 36 months from the conclusion of the study and may be used as a part of the research.

Other Considerations:
If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Voluntary Consent by Participant:
By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled, *Trauma-informed Health Care for Trafficking Survivors: Effectiveness of Training among Dentists, Psychologists, and Optometrists.*

Participant's Signature: _____ Date: _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____