FIU IRB Approval:	12/12/2018
FIU IRB Expiration:	12/12/2019
FIU IRB Number:	IRB-18-0451

FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Impact of Pillboxes on Medical Adherence.

PURPOSE OF THE STUDY

You are being asked to be in a research study. The purpose of this study is to understand the impact of different types of pillboxes on medication adherence and your satisfaction with the pillbox.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of 40 people in this research study.

DURATION OF THE STUDY

Your participation will require four interactions with research students, including, three face to face visits. Full participation in the study is anticipated to take no longer than 5 hours total across all interactions.

PROCEDURES

If you agree to be in the study, there will be a total of four interactions lasting approximately 5 hours over the course of approximately 3 months. If you agree to be in the study, we will ask you to do the following things:

1. Describe your background, health, medications, and daily routines related to talking medication in a series of audio recorded interviews and surveys.
2. Use a new pillbox over the course of 1 month.

RISKS AND/OR DISCOMFORTS

The following risks may be associated with your participation in this study:

- Loss of time – This study will take approximately 5 hours of your time.
- Boredom – You will be asked to complete a series of surveys and interviews, which some people may find boring.
- Invasion of privacy – Some of the interview and survey question may ask about your health and medications.
- Leakage of information – We store the information on computers and filing cabinets. While we do everything, we can to protect the data, there is always a risk of a data breach.
- Medication errors – In this study you will use a new pillbox. This may make you more likely to make a medication error. We will go over the new pillbox with you to make sure you know how to use it and reduce the likelihood of making a medication error.

BENEFITS

The following benefits may be associated with your participation in this study: First, you will receive a new pillbox. Second, your participation in this study will help us learn more about medication adherence and help us help others better take their medications as prescribed. Finally, you may enjoy sharing your story with the research team.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this study.

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CONFIDENTIALITY
The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only the researcher team will have access to the records. However, your records may be reviewed for audit purposes by authorized University or other agents who will be bound by the same provisions of confidentiality. All data related to this study will be stored on a secure, password protected, and locked devices and servers. Information you enter will not be associated with your identification unless you request to be contacted about future research opportunities. Although the information you share will be held as confidential, we will disclose to the proper authorities any information you share with us concerning abuse, neglect, or harming yourself or others.

COMPENSATION & COSTS
You will receive a payment of up to $20 gift cards for your participation. You may also keep the pillbox you receive. You will not be responsible for any costs to participate in this study.

RIGHT TO DECLINE OR WITHDRAW
Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION
If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Dr. Jaclyn Schwartz at 11200 SW 8th St., AHC 3, 420-A, Miami, FL 33199, (305) 348 - 3106, Jaclyn.Schwartz@fiu.edu.

IRB CONTACT INFORMATION
If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT
I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date