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Protocol Title: Testing Adaptive Interventions to Improve Physical Activity for Sedentary Women; "Working Women Walking"
Sponsor: National Institute of Health (NIH), Washington, DC

Name of Participant: _____

RUSH

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Key Information about this research study
You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future. You are being asked to participate in this study because you have expressed an interest in this study. Also, from an initial phone or in-person interview, you have conveyed that you have met the following eligibility criteria (requirements) for this study: you are a female employee at Rush University Medical Center aged 18-70, speak and read English, own a smartphone device with text messaging capability, are willing to receive texts as part of the study procedures, and are insufficiently physically active

Taking part in this research study is voluntary
You do not have to participate in this study or may choose to leave the study at any time. If you decide not to participate in this study or leave the study later, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected. No promises can be made about the outcome of this as far as your current condition, either positive or negative.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the study. More detailed information about the study will follow later in the document.

Why is this research being done?

The purpose of this study is to determine the most effective intervention to increase physical activity and improve cardiovascular (heart and blood pressure) health among sedentary (inactive) women. Compared to men, women continue to be at greater risk for failing to meet aerobic physical activity guidelines compared to men (46% vs 54% respectively). Addressing

health promotion, which includes promoting physical activity, continues to be a priority of the National Institutes of Health (NIH).

If you participate, how long will the study last?

Your participation in this study may last up to 52 weeks. You will be asked to complete 6 study visits, including one initial screening visit, one program orientation visit and four study visits, over the course of one year. Each visit will last approximately one hour.

What will happen to you during the study?

Should you be considered eligible for the study, research staff members will work closely with you to set personally tailored goals to gradually increase your walking frequency, duration and intensity. As part of the study, you will wear physical activity monitors that will keep track of your activity. You will receive the physical activity monitor or the monitor and motivational text messages, and later you may possibly also receive personal calls or group meetings to help you meet your physical activity goals. For more information, please see the "*What are the activities you will be doing if you participate in this study?"* section below.

Will you benefit from the study?

You may benefit from taking part in this study, but there is no guarantee that it will help you. For more information, please see the *"What are the benefits of participating in the study?"* section below.

Is there any risk to you in participating in this study?

This study includes little risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. For details and a list of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?"* section below.

Do you have other options besides taking part in this study?

Instead of participating in this study, you can explore other opportunities for increasing your level of exercise and activity.

Will you be paid to participate in this study?

Payment for your time or travel is available if you decide to take part in this study. For more information, please see the "*Will you be paid for your participation in this study?"* section below.

Will it cost you anything to participate in this study?

There is no cost to you for taking part in this study.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this study.

General Information
You are being asked to participate in this study because you are a female employee at Rush University Medical Center aged 18-70, read and speak English, own a smartphone device with text messaging capability that is compatible with Fitbit software, are willing to receive texts as part of the study procedures, and are considered insufficiently physically active.

This study is being conducted at Rush University, along with the help of Dr. Spyros Kitsiou at University of Illinois at Chicago (UIC). Dr. Kitsiou will be involved in data management and related procedures pertaining to the software used in this study that will track physical activity and dissemination of text-messages should you be randomized (assigned by chance, similar to a coin toss) to that part of the treatment condition.

How many people will take part in this study?
Approximately 312 participants are expected to take part in this study over four waves of recruitment.

What are the activities you will be doing if you participate in this study?
At this point, you will have already provided verbal consent for a brief initial eligibility screener completed over the phone, and confirmed your interest as well as base eligibility for participation in the study.

If you agree to continue in this study, you will be asked to participate in the following activities:

All research-related visits will be offered at Rush University Medical Center. You will also have the option for research-related visits to be at a convenient location of your choosing (such as your home) if necessary. For appointments, you will be given an Appointment Reminder form with the date, time and location of your appointment.

<u>Consent and Health Screening Appointment (D0):</u>

Interested women will be consented for the study, and then screened for additional inclusion criteria with the following:

1) You will be asked a series of questions regarding your physical readiness (PAR-Q & You Questionnaire)
2) Research staff will ask you a series of questions regarding your health history
    a. This will include questions about hypertension (high blood pressure), diabetes (high blood sugar), chronic disease, smoking, drinking and women's health
3) Research staff will complete height, weight and waist measurements
4) Research staff will complete three blood pressure readings

5) You will be asked about any A1C tests (a measure of your blood sugar over time) completed within the past 30 days
    a. Should you not recall or not have any such test results, you will be provided with A1C testing using self-monitoring kits to determine your A1C level for screening, at no cost to you using a A1CNow+ monitor which is approved by the FDA for self-monitoring A1C

You will be given a Physical Measures handout with the results of these measures. It is possible that, based on some of your data collected during this visit, you may need to see your healthcare provider for sign-off on your participation in the study. If this is the case, research staff members will provide you with a letter describing the study and a form (PARmed-X) that your healthcare provider will need to complete, sign and provide to the research team before you can continue participating in the study.

Should you meet all inclusion criteria, you will be given two physical activity monitors. One, a Fitbit Charge 2, will be temporarily blinded so that you cannot see the numbers. The other is an Actigraph GT3X-BT. You will be taught how to use these monitors and given handouts on Actigraph Instructions and Fitbit Screening Use Instructions. You will be given an Actigraph Log form to complete during the next week. You will also be asked to sign a Physical Activity Monitors Loan Agreement. You will be given instructions on how to wear these physical activity monitors and be asked to wear them both for one week. Arrangements will be made with the research team so that, at the end of the one week trial period, you can come to the Physical Activity and Cardiovascular Health Research Lab housed in the Armour Academic Center. At that time the research team will need to assure that your most recent steps from the Fitbit are synced to your phone. They will also download your physical activity data from your Actigraph. The research team will then verify how many steps you are walking on average every day and share those results with you.

If you have not worn your monitors as instructed, you will be given an extra week to wear them. Arrangements will be made again so that you can return the devices after the one week of wear time.

If you have worn your monitors as instructed, and the study staff determines that you are meeting goals for physical active (over 7,500 steps on average per day) then you will be contacted, told you are ineligible for further participation, provided an electronic copy of *Step it Up!*, an informational booklet on physical activity from the Surgeon General's Office, and thanked for your time.

If you have worn your monitors as instructed, and the study staff determines that you are within the threshold of less than or equal to 7,500 average steps per day for participation in the study, you will be contacted by the research team and scheduled for your baseline data collection appointment.

Baseline Interview and Randomization (D1)

The following questionnaire and measurements will then be completed:

1) Demographic Questionnaire assessing: age, ethnicity, marital status, children status, caregiver status, education, income/hardship, job, and shift)
2) Neighborhood Environment Walkability Scale (NEWS): 28 item survey observing your perception of the characteristics in your neighborhood that are conducive to walking
3) Exercise Benefits/Barriers Scale: 43 item survey observing your reactions to statements that relate to positive/negative ideas about physical activity
4) McAuley's Self-Efficacy for Overcoming Barriers to physical activity: 17 item survey reflecting the benefits in your ability to continue to be physically active in the face of barriers
5) Social Support and Exercise Survey: 13 item scale of family and friend support
6) Outcome Expectations: 11 item scale measuring expected changes due to becoming more physically active
7) International Physical Activity Questionnaire (IPAQ): 27 items that ask about the time you spent being physically active in the last seven days
8) Sedentary Behavior: time spent engaging in 9 sitting behaviors in past 7 days
9) Emotional Distress Depression Short Form: 8 item survey measuring depressive symptoms in the past 7 days
10) General Health via PROMIS Scale v 1.2: 10 items assessing general health, physical activity, emotional problems and fatigue
11) Sleep via PROMIS Sleep Impact Short Form: 10 items assessing various aspects of the past 7 days of your sleep
12) Aerobic fitness via a test involving stepping in place to a predesignated height for two minutes

You will be asked to sign an Oath of Confidentiality agreement that notes that you will not discuss your experience with the physical activity program with anyone else in your workplace until after the participation in the study ends. After you complete your baseline measures, you will be given an appointment to return for a 30-minute program orientation. You will be randomly assigned to one of the first two initial treatments: physical activity monitor or physical activity monitor + text messages.

Program Orientation Appointment

You will be given back your un-blinded Fitbit, and provided general guidance on device usage, and given a handout on Fitbit Intervention Use Instructions. The orientation leader will open up your display on the Fitbit monitor so that you can see the information on it. You will receive information about tracking daily steps, physical activity intensity and heart rate. The device will be used to set goals and self-monitor your physical activity throughout the study. It is important to remember that the device cannot be worn during bathing or swimming. You will be instructed to wear your Fitbit when you are awake, preferably all of the time. A research team member will

then show you a video about becoming more physically active and that includes information about your participation in this study.

Research staff will work with you to set an initial physical activity goal to gradually increase walking frequency, duration and intensity. You may elect to only increase frequency without moving to increased duration and intensity. Research staff will first emphasize frequency (walking more times throughout the day), then duration (adding 10- to 30-minute bouts of physical activity), and finally intensity.

The initial step count goal that you determine with the help of the research staff will be entered electronically into the Fitbit. You will be able to check your progress on a mobile device or personal computer using the Fitbit.com website. The research team will have access to this data as well, and will use this data in order to send you text message reminders when you have not been wearing your device or when you have not synced the device for four days. If no data are recorded for one week, a research staff member will contact you directly over the phone.

The Fitbit mobile app will be programmed by the research staff to initiate automatic notifications for you, when you have achieved 75%, 100% or 125% of your daily step goal.

If you have been assigned to the text message component of the study, research staff members will work with you on selecting physical activity text messages that will be important to you. You will receive those text messages three times a week, on days of the week and times that you choose, for the first 8 months of the study. Research staff will contact you once a week to inform you of your step classification and discuss any changes to your text messages for the upcoming week.

Monitoring of physical activity will start immediately after you complete the program orientation. Evaluation of your response or non-response to the initial treatment randomization will take place 8 weeks after the orientation date.

Lastly, you will be scheduled for your Data Collection Weeks 9-10 Appointment.

Decision Point 1: Week 8

Research staff will determine if you are a responder or a non-responder to the treatment, based on your daily step count, and will call you with this update. They will inform you of the results of the next level of randomization at your Data Collection Weeks 9-10 Appointment.

Data Collection Weeks 9-10 and Augmented Treatment Appointment (D2)

If you have been deemed a responder, you will be instructed to continue using the initial treatment you received in the first 8 weeks of the study.

If you have been deemed a non-responder, you will continue your initial treatment and be randomly assigned to the additional treatment of either personal phone calls or five group

meetings. If you are assigned to the personal calls component of the study, the research team will explain the motivational interviewing telephone calls made by a specialist in such interviews. The research team will arrange your schedule for receiving these personal calls every two to three weeks over the upcoming 24 weeks. If you are assigned to the group meeting component of the study, the research team will explain to you information regarding the five, 45-minute group meetings that will be held every 4-6 weeks over the next six months. You will be asked about your preferences for start time and availability and the group leader, a trained interventionist, will work to develop a schedule based on the collected feedback from the whole group. You will receive a schedule by week 11 of the study to better ensure that all group members are available.

In addition, you will complete another set of questionnaires and measurements:

1) Exercise Benefits/Barriers Scale
2) McAuley's Self-Efficacy for Overcoming Barriers to physical activity
3) Social Support and Exercise Survey
4) International Physical Activity Questionnaire (IPAQ)
5) Sedentary Behavior
6) Emotional Distress-Depression Short Form 8b
7) PROMIS Scale v 1.2
8) PROMIS Sleep Impact Short Form
9) Outcome Realizations survey: 11 items measuring realized change due to becoming more physically active
10) Research staff will measure your blood pressure readings, your weight, waist circumference, and aerobic fitness via a test involving stepping in place to a predesignated height for two minutes (at each assessment point, when these physical measures are collected, you will be given a Physical Measures form with the results)

You will also receive a new step goal based on your average daily step count. For the second time in the study, you will be given an Actigraph to wear for one week along with instructions for use. During this time, you will be wearing both your Actigraph and your Fitbit simultaneously. As before, arrangements will be made by the research team staff to either pick up your Actigraph one week later, or have you return your device to the Physical Activity and Cardiovascular Health Research Lab housed in the Armour Academic Center using the secured metal drop-box on the outside of the main office door. After one week, you will return to wearing only your Fitbit.

Finally, you will be scheduled for the Data Collection Week 35-36 Appointment.

<u>Data Collection Weeks 35-36 Appointment (D3)</u>

You will complete another set of questionnaires and measurements:

1. Exercise Benefits/Barriers Scale (Revised for PA)
2. McAuley's Self-Efficacy for Overcoming Barriers to PA
3. Social Support and Exercise (Revised for PA)

4. Outcome Realizations
5. International Physical Activity Questionnaire (IPAQ) long-form
6. Sedentary Behavior
7. Emotional Distress-Depression Short Form 8b
8. PROMIS Scale v 1.2
9. PROMIS Sleep Impact Short Form
10. For those in the Group Meetings Condition only:
    a. Social Provisions Scale
        i. 24 items, 6 sub-scales each comprised of 4 questions scaled from 1 strongly disagree to 4 strongly agree reflecting:
            1. Social provisions of attachment
            2. Social integration
            3. Reassurance of worth
            4. Reliable alliance
            5. Guidance
            6. Opportunity for nurturance
11. Research staff will measure your blood pressure readings, your weight, waist circumference, and aerobic fitness via a test involving stepping in place to a predesignated height for two minutes

The research team will give you a new step goal, based on your average daily step count. For the third time in the study, you will be given an Actigraph to wear for one week along with instructions for use. During this time, you will be wearing both your Actigraph and your Fitbit simultaneously. As before, arrangements will be made by the research team staff to either pick up your Actigraph one week later, or have you return your device to the Physical Activity and Cardiovascular Health Research Lab housed in the Armour Academic Center using the secured metal drop-box on the outside of the main office door.

After one week, you will return to wearing only your Fitbit. If you were assigned to receive text messages, phone calls, or group visits, you will be told at this visit that those components of the study are complete.

Finally, you will be scheduled for the last visit, the Data Collection Weeks 51-52 Appointment.

<u>Final Data Collection Weeks 51-52 Appointment (D4)</u>

You will complete another set of questionnaires and measurements:

1. Exercise Benefits/Barriers Scale (Revised for PA)
2. McAuley's Self-Efficacy for Overcoming Barriers to PA
3. Social Support and Exercise (Revised for PA)
4. Outcome Realizations
5. International Physical Activity Questionnaire (IPAQ) long-form
6. Sedentary Behavior
7. Emotional Distress-Depression Short Form 8b

8. PROMIS Scale v 1.2
9. PROMIS Sleep Impact Short Form
10. For those in the Group Meetings Condition only:
    a. Social Provisions Scale
11. Research staff will measure your blood pressure readings, your weight, waist circumference, and aerobic fitness via a test involving stepping in place to a predesignated height for two minutes

For the fourth and final time in the study, you will be given an Actigraph to wear for one week along with instructions for use. During this time, you will be wearing both your Actigraph and your Fitbit simultaneously. As before, arrangements will be made by the research team staff to either pick up your Actigraph one week later, or have you return your device to the Physical Activity and Cardiovascular Health Research Lab housed in the Armour Academic Center using the secured metal drop-box on the outside of the main office door.

After one week, you will return to wearing only your Fitbit. Once you return your final Actigraph, you will be allowed to keep your Fitbit and the Fitbit property (formerly owned by Rush University) will be signed over to you. Instructions will be provided to you on how to use your Fitbit on your own, since you have completed the study.

Each of the four study visits you complete will earn you $40 in gift cards for a total possible compensation of $160 throughout the duration of your participation in the study. However, after you complete the Final Data Collection Weeks 51-52 Appointment, you will receive only a $20 gift card. You will receive the final $20 gift card once your final Actigraph is returned following the one week assessment period.

Confidentiality

During this study, Dr. Buchholz and her study team will collect information about you for the purposes of this study.

- Demographic data including medical history, race/ethnicity, age, etc. will be collected during screening in order to assess initial eligibility as well as differences in the effectiveness of the intervention.
- Neighborhood walkability metrics will be collected at screening for the purposes of identifying eligible participants to enroll into the study that do not have substantial barriers to physical activity that are necessary for participation in the study.
- We will obtain a finger stick for blood in order to assess you A1C to determine if it is safe for you to participate in a study that seeks to increase your physical activity. This data will only be used during the screening process to determine your eligibility.
- At each study visit, including screening, researchers will collect questionnaire data on emotional distress and depression, your expectations to physical activity progress, exercise benefits and barriers, self-efficacy for overcoming barriers to physical activity, social support and exercise, occupational activities, general health, sleep, sedentary behaviors, and, for those in the group meetings component, social provisions, in order to

determine the effectiveness of the intervention.
- At each study visit, including screening, researchers will collect physical measurements of your weight and waist circumference, and aerobic fitness to ensure that you are not responding adversely to the intervention and also to measure the intervention's effectiveness. Your height will only be collected once at baseline.
- ActiGraphs and Fitbits will collect data on your daily physical activity in order to track the effectiveness of the intervention.

The research team will create a confidential unique email account through Rush University, to be used only for this study. Your name will not be used in the email account; instead a study identification number will be used. This email account will be used to set up your Fitbit online account that will be paired with your Fitbit wearable activity monitor and Fitbit mobile app allowing our research team to remotely collect your physical activity data for the purpose of this research study. Also, we will ask for your phone number, which we may use to call you during the study, or send you text messages.

All of your questionnaires and physical information will be maintained using an identification number and will be kept separate from your name at all times. Your blood results will be stored only with an identification number.

After all information collected from you has been analyzed (within 2 years after the end of the study), the identification number will be removed from the data, which will remain completely anonymous thereafter. The hard copies of the data will be kept for 3 years, and then destroyed.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected. Whenever we use the information you give us, only a code number will identify you. Only you and the people working on the study here will know your code number. Your name will never be used. You will not be named in any publication or presentation from this study.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study nurse practitioner and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.
In order to conduct the study, the study nurse practitioner, Dr. Susan Buchholz, may use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What type of audio recording and observing will be done in this study?
Some of your visits with the research staff may be tape recorded to see how well the Working Women Walking Program staff is doing. The project staff will use the tape to type out what was said during the visit and evaluate the information given. Then the tape will be erased. If you are selected for tape recording, you will be told before taping starts. You may have the tape recorder turned off at any time. Your name will never be used with the recording or on any paper reports. There may also be times when a research team member may observe the interactions between you and staff members. You will be asked in advance if you mind having the observer there. You may refuse. If you do agree to have the observer in the room they will be out of the way, and you will be asked to interact as usual. This is the research teams' method of evaluating how well your visits are going.

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

- Screening appointment finger stick for blood sample: you may experience some discomfort, bruising, minor bleeding, and, very rarely, infection at the site of the finger stick.
- Initial screening visit fitness/step test: you may experience some fatigue, and if you have any such feelings that could be described as unusual such as inability to keep up with the exercise test, faintness, chest pain, abnormal blood pressure, cramping or weakness of legs your participation will have to be discontinued. Experienced study staff will be there with you during this procedure, and will be trained to take care of any possible outcome.
- At each study visit: you may feel uneasy talking about yourself and your personal behaviors. You can talk about any\uneasy feelings with the study nurse practitioner or research assistant. Your ability to answer research questions honestly is based on your comfort with the information so if you alert the research staff to your uneasy feelings, they will do everything possible to make you more comfortable.

There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent again continue participating in this study.

You will be told the results of your blood pressure, weight, height, blood tests, body composition, and fitness after each measurement session (height and blood only at baseline). If any of your test results indicate a medical problem, you will be informed and offered a referral to a health care provider if you do not have one. The benefits to women are increased fitness while maintaining and in some instances losing some body fat.

What are the benefits of participating in this study?

You may have improved health as a result of being in the study. It is also possible you may not directly benefit from participation in this study.

It is hoped that knowledge gained from this study may help other sedentary women in the future.

What other choices do you have to participating in this study?

If you decide not to participate in this study, there is other care available to you, such as motivational physical activity literature. A research team member will discuss these choices with you. You do not have to be in this study to be treated for high blood pressure or high cholesterol.

What are the costs to participate in this study?

There are no costs to you for participating in this research.

Will you be paid for your participation in this study?

You will be paid $40 in gift cards for each completed study visit, except for the final visit, when you will receive $20 in gift cards after your visit, and $20 in gift cards after you return the final Actigraph one week later. At that time, we will sign off the property rights to the Fitbit device to you, which you will also receive as a result of your participation in the study. If you do not finish this study, you will be paid for the study visits you have completed. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Your participation in this study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to pay you for any of these developments.

What about confidentiality of your information?

Records of participation in this study will be maintained and kept confidential as required by law. All of your questionnaires and physical information will be maintained using an identification number and will be kept separate from your name at all times. Physical copies of all study materials with identifiable information will be kept in on site at Rush University

Medical Center in a double locked facility. After all information collected from you has been analyzed (within 2 years after the end of the study), the identification number will be removed from the data, which will remain completely anonymous thereafter. The hard copies of the data will be kept for 3 years, and then destroyed. The only people who will know that you are a research subject are members of the research team at Rush University, Dr. Spyros Kitsiou at University of Illinois at Chicago who is a cooperating investigator responsible for data management related to the iCardia program, and, possibly, the regulatory bodies at the National Institute of Health (NIH). No information about you, or provided by you during the research will be disclosed to others without your written permission except:

- If necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- If required by law.

A description of this study is available on http://www.ClinicalTrials.gov, as required by U.S. Law. The research study can be found by searching for the following Clinical Trial Registry Number (NCT#): NCT03558828. 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.

Will your information be used for research in the future?
Information or specimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about studies in the future?
If you agree, we may contact you after your participation in this study to request additional information. Please initial one of the following options:

_____ Yes, I agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

_____ No, I do NOT agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study nurse practitioner's advice about how to leave this study. If you leave this study before the final study visit, the study nurse practitioner may ask you to complete the final steps. If you decide to withdraw from the study, you can stop your participation immediately.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions
- The study is cancelled for any other administrative reason

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Susan Buchholz at (312) 563-3590 or email address Susan_Buchholz@Rush.Edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study, your care at Rush University Medical Center will not change. You may choose not to participate at any time during the study. Leaving the study will not affect your care at Rush University Medical Center.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Susan Buchholz in writing at the address on the first page. Dr. Susan Buchholz may still use your information that was collected prior to your written notice. You will be given a signed copy of this document.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

SIGNATURE BY THE PARTICIPANT:

_____	_____	_____
Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject or the subject's legally authorized representative. I further attest that all questions asked by the subject or the subject's legal representative were answered to the best of my knowledge.

_____ _____

Signature of Individual Obtaining Consent ***Date of Signature***

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR

(For use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

_____ _____

Signature of Witness/Translator ***Date of Signature***

Check here if a separate witness signature is not necessary.