Official title: Effects of CPAP on Diet, Physical Activity, and Cardiovascular Risk

NCT #: NCT01944020

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Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAO2006
Principal Investigator: Ari Shechter (as4874)
IRB Protocol Title: Effect of CPAP on diet, physical activity, and cardiovascular risk

General Information

Consent Number: CF-AABC0350
Participation Duration: 9 weeks
Anticipated Number of Subjects: 25

Research Purpose: The purpose of this study is to see if treatment of obstructive sleep apnea with continuous positive airway pressure (CPAP), affects your appetite level, physical activity levels, and body weight.

Information on Research

INTRODUCTION - CPAP participants

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:
- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit; and
- options, other than taking part in this study, that you have.

The Principal Investigator of this project (Dr. Ari Shechter) will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research is described below. This consent form is written to address a research subject.

PURPOSE

You are being asked to join this research study which will examine the effect of treating sleep apnea on your body weight and health. Specifically, you will be using a continuous positive airway pressure (CPAP) machine. The CPAP is a way of treating sleep apnea that works by blowing air through a nose mask connected to a pump. You wear the mask during the entire night. Wearing this mask during the night allows air to be pushed into your throat and airways to help improve your breathing during sleep. We will look at how different pressure settings of this CPAP machine affect

the amount of food you eat, your hormone levels, your physical activity levels, and the amount of calories your body burns. You are being asked to take part in this study because you are overweight, were recently diagnosed with obstructive sleep apnea, and were prescribed CPAP but did not yet start treatment with CPAP. You will be one of approximately 25 men and women to enroll in this study at the New York Obesity Nutrition Research Center at Columbia University Medical Center.

PROCEDURES

In order to qualify for the study, you must be between 18 and 65 years of age. Your body mass index (BMI, dened as weight in kilograms divided by your height in meters squared) must be 25 or above. You may have the metabolic syndrome (i.e., a combination of medical disorders occurring together including high blood pressure, obesity, raised levels of glucose in the blood, and abnormal amounts of fat and cholesterol in the blood), although you may not participate if you have type 2 diabetes. You also may not participate if you have a history of coronary artery disease, transient ischemic attack (mini stroke), or stroke. You must not currently be taking any anti-psychotic medications, or hypnotics and/or other drugs to treat insomnia. You must be able to refrain from driving during the 7-day baseline monitoring phase. You cannot be a commercial driver, or have had any recent near-miss or prior car crashes due to excessive daytime sleepiness. Therefore, we will only include participants who do not habitually drive, and will ask you to not drive a car during the baseline 1 week period and not to drive yourself home after the first laboratory visit where you do not use CPAP. You cannot participate in the study if you have uncontrolled severe hypertension (high blood pressure that is not being treated).

The study will be conducted at the New York Obesity Nutrition Research Center at Columbia University Medical Center. You are being approached for participation in the study because you have recently been diagnosed with obstructive sleep apnea and were prescribed CPAP to treat this disorder.

Once you are accepted and enrolled in the study, you will be asked to wear an Actigraph to monitor your physical activity and sleep patterns for a baseline pre-experimental period of 1 week. The Actigraph is a small device that you wear attached to your waist during the day and on your wrist during sleep, and is about the size of a watch. You will also keep a sleep diary to record your bedtimes and wakeup times and a 3-day food diary to record all foods that you eat over a 3-day period.
You will then be asked to enter the Clinical Research Resource (CRR) at Columbia University Medical Center at around 9:00 am and remain on site for 1 full day (24 hours). At the New York Obesity Nutrition Research Center, measures will be taken of your height, weight, neck circumference, waist circumference, and body composition. Neck and waist circumference will be measured with a measuring tape. Body composition will be measured with air displacement plethysmography. We will measure your total body fat and lean tissue mass while you are sitting inside the scanner. You will be asked to change into a bathing suit and shower cap, and sit still while inside a small chamber. You must sit relatively still for about 5 minutes while you are being scanned. This test will give us information about your body fat. If you are a woman, you will be asked to provide a urine sample for a urine pregnancy test before the scan. At this time we will also obtain a blood sample. During this sample, we will collect 12 ml, or about 2 and a half teaspoons, of blood. You will also be asked to ll out short questionnaires on your level of hunger and alertness each hour you spend awake. While not lling out questionnaires, you will have free time to watch television, read, use the computer, talk on the telephone, etc. You will be permitted to use your cell phone.

During the laboratory day, you will have the opportunity to self-select your food intake. You will have access to a specified food budget for the day (up to $55.50) to purchase foods and beverages of your choice. You will be escorted by study personnel to local markets where you will be able to purchase foods you want to eat during the day. You will also have the opportunity to purchase food from take-out restaurants throughout the day. The only restrictions that will

be imposed are that nutrient information must be available for the items purchased and that beverages must be nonalcoholic. You will not be able to keep any food not consumed during the experimental day. You will not be allowed to take any purchased foods home.

Bed times and wake times will be constant in the lab and your sleep schedule will be from 11:00 pm to 7:00 am. Specically, after the day spent in the lab, you will go to bed at 11:00 pm and be woken up at 7:00 am in the morning. You will then be allowed to go home. During the night spent in the lab, your sleep will be recorded by placing electrodes on your head and face that will be held in place with an adhesive paste, and you will be asked to use the CPAP machine at the specic setting during the night. The portable polysomnographic (PSG) sleep recording device will also then be arranged by a member of the technical staff. The PSG recording will involve attaching metal electrodes to various locations on your scalp, and also on the skin near your eyes and chin. These electrodes are attached with the use of an adhesive paste and in some cases a tape. You will be discharged after awakening from the sleep episode.
We will obtain these pre-treatment measurements again at after you use the CPAP for 2 months during the treatment phase, described below.

During the treatment phase, you will be asked to use the CPAP machine at home at the given setting each night while you sleep for 8 weeks. After the 8 week period, you will be asked to return to the Clinical Research Resource (CRR) at Columbia University Medical Center, and remain on site for 1 full day (24 hours). You will then repeat all of the procedures done during the pre-treatment phase, as described above.

During the 8 week treatment phase, your nightly use of the machine will be checked and only compliant participants will be able to continue in the study. The compliance of machine use will be checked with a built-in memory chip that records how long you wear the mask each night. We will also ask you to ll out a daily CPAP compliance log in which you document how many hours you used the CPAP during the previous night. We will also periodically call you at random times to conrm CPAP use. During the nal week of the treatment phase, measures of physical activity (wrist-actigraphy), food intake (3-day food log), and subjective (sleep-wake log) and objective (wrist-actigraphy) sleep will be taken, as described above.

The total duration of the study is 9 weeks. This includes the 1-week baseline pre-experimental monitoring of physical activity and sleep with the actiwatch, the 1-day pre-treatment laboratory visit, the 8-week treatment phase, and the second 1-day post-treatment laboratory day. At the end of the second 1-day laboratory visit, you will have completed the entire experiment.

Use of Data/Specimens

Your blood samples will be analyzed for hormone measurements related to appetite, cardiovascular health, and energy balance. The Principal Investigator will keep any leftover blood samples for future assays of other hormones related to appetite that are not initially done. Blood samples will be retained for a maximum of 10 years after the publication of the main results. Blood samples will be stored at the New York Obesity Research Center and will be anonymously coded. Your name, date of birth, or any other personal identifying information will not be on these samples. You cannot participate in this study if you do not agree to have your samples stored for future testing. You will not receive the results of future tests.

Permission for future contact

The researchers may want to contact you in the future to let you know about other research studies that we think you

may be interested in and qualify for and provide information on the results of this study.

Please initial below to show whether or not you give permission for future contact.

YES _____ I do give permission to be contacted in the future for research purposes.

NO _____ I do not give permission to be contacted in the future for information relating to this study.

Risks

RISKS

There may be risks or discomforts if you take part in this study.

Sleep Recording

There are minimal risks associated with the in-lab PSG recording. Affixing or removing electrodes to the scalp and face for the PSG recording may cause mild irritation to some patients. Hypoallergenic materials will be used to minimize irritation associated with the PSG recordings.

Blood Sampling

There are minimal risks associated with the blood sampling, which may produce some minor bruising at the insertion site for the needle. Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn. Blood sampling will be carried out by a trained nurse following standard procedures. A physician will be on call during the entire procedure. You may also experience dizziness or fainting after the blood samples.

Daytime Sleepiness

You will be asked not to drive when you are ready to go home after the first 1-day laboratory stay where you did not use your CPAP. This is because you may experience some daytime sleepiness when you do not use the CPAP.

You will not be exposed to harmful materials and will not be at an increased risk of harm compared to before starting the active CPAP treatment.

Deception

As part of this experiment you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.

Benefits

BENEFITS

There is no anticipated direct benefit to you individually from your participation in this study. You will be given the results of your individual tests as well as the average of all participants for each phase when the study is completed, if you request. Your participation in this study will allow the scientific community to have a better understanding of the impact of sleep and CPAP treatment on body weight control.

Alternative Procedures

ALTERNATIVES

Alternatives You may choose not to take part in this research study.

You do not have to take part in this study to get treatment for your condition. You may continue your CPAP treatment even if you choose to stop participation in the study, or if you choose to not enroll in the study.

Confidentiality

CONFIDENTIALITY

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your specimens and questionnaire responses will be assigned a code number, and separated from your name or any other information that could identify you. The following individuals and/or agencies will be able to look at and copy your research records:

- The investigator, study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB')

Compensation

COMPENSATION

You will be compensated for your participation in this study.

You will receive $500 for participation. You will receive $200 for completing the rst experimental phase (including

ambulatory and laboratory measures) and $300 for completing the second experimental phase (including ambulatory and laboratory measures). Therefore, if you complete both study periods, you will receive $500.00 to compensate for your time commitment in this study.

Should you decide to withdraw from the study at any time before its completion, you will be compensated in a pro-rated amount as follows: $50 for the ambulatory portion of experimental phase 1, $150 for laboratory day of phase 1, $100 for the ambulatory portion of experimental phase 2, $200 for laboratory day of phase 2. If you complete all of Phase I but not Phase II, you will be $200 for Phase I and any portion of Phase II completed as detailed above. There is no compensation provided for screening for this study.

It is possible that there will be a loss of confidentiality due to interactions with the Office of the Treasurer when processing your payment for participation in the study. We will take all efforts to limit this. There may also be delays in the receipt of payment due to unforeseen circumstances which can slow the processing of the payment.

Additional Costs

COSTS

There are no costs to you for taking part in this study.

Voluntary Participation

VOLUNTARY PARTICIPATION

Voluntary participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center.

Termination of participation by investigator

You should know that we will not let you participate in the study any more if you experience side-effects or adverse reactions to the CPAP treatment. In addition, your participation will end if the investigator stops the study earlier than expected.

Additional Information

Consent Statement

Questions

If you have any questions or are hurt while taking part in this research study, you should contact Dr. Ari Shechter,

Ph.D, by phone at 212-851-5584 or by email at as4874@columbia.edu.

If you have any questions about your rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at irboffice@columbia.edu.

More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Study Subject

Print Name _____ Signature _____

Date _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date _____

Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAO2006
Principal Investigator: Ari Shechter (as4874)
IRB Protocol Title: Effect of CPAP on diet, physical activity, and cardiovascular risk

General Information

Consent Number: CF-AABC0400
Participation Duration: 9 weeks
Anticipated Number of Subjects: 25

Research Purpose: The purpose of this study is to see if treatment of obstructive sleep apnea with continuous positive airway pressure (CPAP), affects your appetite level, physical activity levels, and body weight.

Information on Research

INTRODUCTION - Control participants

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:
- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit; and
- options, other than taking part in this study, that you have.

The Principal Investigator of this project (Dr. Ari Shechter) will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research is described below. This consent form is written to address a research subject.

PURPOSE

You are being asked to join this research study which will examine the effect of treating sleep apnea on body weight and health. Specifically, one group of participants will be using a continuous positive airway pressure (CPAP) machine, and another will not. The CPAP is a way of treating sleep apnea that works by blowing air through a nose mask

connected to a pump. People undergoing treatment wear the mask during the entire night. Wearing this mask during the night allows air to be pushed into your throat and airways to help improve your breathing during sleep. We will look at how different pressure settings of this CPAP machine, or not using the machine, affect the amount of food people eat, your hormone levels, your physical activity levels, and the amount of calories your body burns. You are being asked to take part in this study because you are overweight, were recently diagnosed with obstructive sleep apnea, and are not planning on using the CPAP device. You will be one of approximately 25 men and women to enroll in this study at the New York Obesity Nutrition Research Center at Columbia University Medical Center.

PROCEDURES

In order to qualify for the study, you must be between 18 and 65 years of age. Your body mass index (BMI, dened as weight in kilograms divided by your height in meters squared) must be 25 or above. You may have the metabolic syndrome (i.e., a combination of medical disorders occurring together including high blood pressure, obesity, raised levels of glucose in the blood, and abnormal amounts of fat and cholesterol in the blood), although you may not participate if you have type 2 diabetes. You also may not participate if you have a history of coronary artery disease, transient ischemic attack (mini stroke), or stroke. You must not currently be taking any anti-psychotic medications, or hypnotics and/or other drugs to treat insomnia. You must be able to refrain from driving during the 7-day baseline monitoring phase of the study. You cannot be a commercial driver, or have had any recent near-miss or prior car crashes due to excessive daytime sleepiness. Therefore, we will only include participants who do not habitually drive, and will ask you to not drive a car during the baseline 1 week period and not to drive yourself home after the first laboratory visit where you do not use CPAP. You cannot participate in the study if you have uncontrolled severe hypertension (high blood pressure that is not being treated).

The study will be conducted at the New York Obesity Nutrition Research Center at Columbia University Medical Center. You are being approached for participation in the study because you have recently been diagnosed with obstructive sleep apnea and are not using CPAP to treat this disorder.

Once you are accepted and enrolled in the study, you will be asked to wear an Actigraph to monitor your physical activity and sleep patterns for a baseline pre-experimental period of 1 week. The Actigraph is a small device that you wear attached to your waist during the day and on your wrist during sleep, and is about the size of a watch. You will also keep a sleep diary to record your bedtimes and wakeup times and a 3-day food diary to record all foods that you eat over a 3-day period.
You will then be asked to enter the Clinical Research Resource (CRR) at Columbia University Medical Center at around 9:00 am and remain on site for 1 full day (24 hours). At the New York Obesity Nutrition Research Center, measures will be taken of your height, weight, neck circumference, waist circumference, and body composition. Neck and waist circumference will be measured with a measuring tape. Body composition will be measured with air displacement plethysmography. We will measure your total body fat and lean tissue mass while you are sitting inside the scanner. You will be asked to change into a bathing suit and shower cap, and sit still while inside a small chamber. You must sit relatively still for about 5 minutes while you are being scanned. This test will give us information about your body fat. If you are a woman, you will be asked to provide a urine sample for a urine pregnancy test before the scan. At this time we will also obtain a blood sample. During this sample, we will collect 12 ml, or about 2 and a half teaspoons, of blood. You will also be asked to ll out short questionnaires on your level of hunger and alertness each hour you spend awake. While not lling out questionnaires, you will have free time to watch television, read, use the computer, talk on the telephone, etc. You will be permitted to use your cell phone.

During the laboratory day, you will have the opportunity to self-select your food intake. You will have access to a

specified food budget for the day (up to $55.50) to purchase foods and beverages of your choice. You will be escorted by study personnel to local markets where you will be able to purchase foods you want to eat during the day. You will also have the opportunity to purchase food from take-out restaurants throughout the day. The only restrictions that will be imposed are that nutrient information must be available for the items purchased and that beverages must be nonalcoholic. You will not be able to keep any food not consumed during the experimental day. You will not be allowed to take any purchased foods home.

Bed times and wake times will be constant in the lab and your sleep schedule will be from 11:00 pm to 7:00 am. Specically, after the day spent in the lab, you will go to bed at 11:00 pm and be woken up at 7:00 am in the morning. You will then be allowed to go home. During the night spent in the lab, your sleep will be recorded by placing electrodes on your head and face that will be held in place with an adhesive paste, and you will be asked to use the CPAP machine at the specic setting during the night. The portable polysomnographic (PSG) sleep recording device will also then be arranged by a member of the technical staff. The PSG recording will involve attaching metal electrodes to various locations on your scalp, and also on the skin near your eyes and chin. These electrodes are attached with the use of an adhesive paste and in some cases a tape. You will be discharged after awakening from the sleep episode.

After discharge, you will be asked to continue with your regular routine for 8 weeks. After the 8 week period, you will be asked to return to the Clinical Research Resource (CRR) at Columbia University Medical Center, and remain on site for 1 full day (24 hours). You will then repeat all of the procedures done during the pre-treatment phase, as described above.

During the nal week of the 8-wk phase, measures of physical activity (wrist-actigraphy), food intake (3-day food log), and subjective (sleep-wake log) and objective (wrist-actigraphy) sleep will be taken, as described above.

The total duration of the study is 9 weeks. This includes the 1-week baseline pre-experimental monitoring of physical activity and sleep with the actiwatch, the 1-day baseline laboratory visit, the 8-week intervening phase, and the second 1-day follow-up laboratory day. At the end of the second 1-day laboratory visit, you will have completed the entire experiment.

Use of Data/Specimens

Your blood samples will be analyzed for hormone measurements related to appetite, cardiovascular health, and energy balance. The Principal Investigator will keep any leftover blood samples for future assays of other hormones related to appetite that are not initially done. Blood samples will be retained for a maximum of 10 years after the publication of the main results. Blood samples will be stored at the New York Obesity Research Center and will be anonymously coded. Your name, date of birth, or any other personal identifying information will not be on these samples. You cannot participate in this study if you do not agree to have your samples stored for future testing. You will not receive the results of future tests.

Permission for future contact

The researchers may want to contact you in the future to let you know about other research studies that we think you may be interested in and qualify for and provide information on the results of this study.

Please initial below to show whether or not you give permission for future contact.

YES _____ I do give permission to be contacted in the future for research purposes.

NO _____ I do not give permission to be contacted in the future for information relating to this study.

Risks

There may be risks or discomforts if you take part in this study.

Sleep Recording
There are minimal risks associated with the in-lab PSG recording. Affixing or removing electrodes to the scalp and face for the PSG recording may cause mild irritation to some patients. Hypoallergenic materials will be used to minimize irritation associated with the PSG recordings.

Blood Sampling
There are minimal risks associated with the blood sampling, which may produce some minor bruising at the insertion site for the needle. Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn. Blood sampling will be carried out by a trained nurse following standard procedures. A physician will be on call during the entire procedure. You may also experience dizziness or fainting after the blood samples.

Daytime Sleepiness
You will be asked not to drive when you are ready to go home after the 1-day laboratory stay where you did not use CPAP. This is because you may experience some daytime sleepiness when you do not use the CPAP.

You are eligible for this study because you have decided not to use CPAP. Choosing not to use CPAP to treat obstructive sleep apnea may lead to greater daytime sleepiness and risk of accidents, as well as long-term cardiovascular risks such as higher blood pressure. If you change your mind during the study about this decision, you may stop the study to pursue CPAP use at any time.

Deception
As part of this experiment you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.

Benefits

There is no anticipated direct benefit to you individually from your participation in this study. You will be given the

results of your individual tests as well as the average of all participants for each phase when the study is completed, if you request. Your participation in this study will allow the scientific community to have a better understanding of the impact of sleep and CPAP treatment on body weight control.

Alternative Procedures

Alternatives You may choose not to take part in this research study.

You do not have to take part in this study to get treatment for your condition. You may continue your CPAP treatment even if you choose to stop participation in the study, or if you choose to not enroll in the study.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your specimens and questionnaire responses will be assigned a code number, and separated from your name or any other information that could identify you. The following individuals and/or agencies will be able to look at and copy your research records:
- The investigator, study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB')

Compensation

You will be compensated for your participation in this study.

You will receive $400 for participation. You will receive $200 for completing the rst experimental phase (including ambulatory and laboratory measures) and $200 for completing the second experimental phase (including ambulatory and laboratory measures). Therefore, if you complete both study periods, you will receive $400.00 to compensate for your time commitment in this study.

Should you decide to withdraw from the study at any time before its completion, you will be compensated in a pro-rated amount as follows: $50 for the ambulatory portion of experimental phase 1, $150 for laboratory day of phase 1, $50 for the ambulatory portion of experimental phase 2, $150 for laboratory day of phase 2. If you complete all of

Phase I but not Phase II, you will be $200 for Phase I and any portion of Phase II completed as detailed above. There is no compensation provided for screening for this study.

It is possible that there will be a loss of confidentiality due to interactions with the Office of the Treasurer when processing your payment for participation in the study. We will take all efforts to limit this. There may also be delays in the receipt of payment due to unforeseen circumstances which can slow the processing of the payment.

Additional Costs

There are no costs to you for taking part in this study.

Voluntary Participation

Voluntary participation
Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center.

Termination of participation by investigator
Your participation will end if the investigator stops the study earlier than expected.

Additional Information

Questions

If you have any questions or are hurt while taking part in this research study, you should contact Dr. Ari Shechter, Ph.D, by phone at 212-851-5584 or by email at as4874@columbia.edu.

If you have any questions about your rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at irboffice@columbia.edu.

More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Study Participant

Print Name _____ Signature _____

Date _____

Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date _____