The UNIVERSITY OF CHICAGO

The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB24-2170

Name of Subject:_____

Medical History Number:_____

STUDY TITLE: *Obstructive sleep apnea and glycemic dysregulation in adults with type 1 diabetes*

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KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have type 1 diabetes. As part of this study, you will also be tested for sleep apnea. Sleep apnea is a condition where you have brief episodes during sleep when your breathing stops temporarily. It is a highly common sleep disorder in people with type 1 diabetes. To participate in this study, you must have both type 1 diabetes and sleep apnea to participate.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind. Leaving the study will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.

Why Is This Study Being Done?

We are asking you to choose whether or not to volunteer for a research study that may help us learn more about the biological and behavioral factors that may contribute to poorer blood sugar control in adults with type 1 diabetes and sleep apnea. Adults with both type 1 diabetes and sleep apnea have poorer blood sugar control, but the reasons are not clear. The purpose of this study is to better understand the factors that may contribute to poorer blood sugar control in adults with type 1 diabetes and sleep apnea. The findings from this study may lead to new ways to improve sleep and diabetes management in people with type 1 diabetes.

How long will the research last and what will I need to do?

People who agree to join the study will be asked to attend 14 visits over about 3 months. These visits will require overnight and/or daytime stays in the research unit. Additional details about the length of each study visit can be found below under Detailed Consent.

Participants in this study will be randomly assigned (like flipping a coin) to two study different study periods: the Untreated Study Period and the CPAP Treated Study Period. Participants will participate in both study periods, but they could happen in any order.

During the CPAP Treated Study Period, participants will be provided with a Continuous Positive Air Pressure device called CPAP, which is a standard treatment for people with sleep apnea and is approved by the Food and Drug Administration (FDA) for this purpose. CPAP is worn during sleep and provides a controllable pressure to keep your upper airway open during sleep so that you can breathe normally. Controlled air pressure is given by the CPAP device using one of several different types of masks: nasal masks, full face masks and nasal pillow masks.

During the Untreated Study Period, participants will not receive study treatment for sleep apnea for the duration of the study period (2 weeks).

Each study period lasts 14 days. You will spend the first three overnights (days 1-3) and the last two overnights (days 13 and 14) in the research unit.

For a complete description of study procedures, see Detailed Consent Section below.

What are my other options?

Your participation in this study is voluntary. You may choose not to participate in this study. Instead of being in this study, you may undergo sleep apnea treatment (including using a CPAP machine) as part of your routine care.

Is there any way being in this study could be bad for me?

We will ask you to complete 24-hour blood sampling during the last day of each study period. This may cause discomfort, pain or bruising. You will also be asked to use a CPAP machine with a mask, which may be uncomfortable or cause some skin irritation.

More detailed information can be found in the Detailed Risks section later in the consent form.

Will being in this study help me in any way?

There is little benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. By participating in this research, you may help us learn how sleep apnea may contribute to the development of diabetes. An overnight sleep test will also be conducted to determine the presence of Sleep Apnea. If diagnosed, the study team will provide information on how to follow-up with your routine care physician.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

What is the purpose of this research?

The purpose of this study is to better understand the factors that may contribute to poorer blood sugar control in adults with type 1 diabetes and sleep apnea.

About 40 people will take part in this study at the University of Chicago.

This study will take place in the UChicago Sleep Center, except for some cases where the 24-hour sampling may take place in Clinical Research Center (CRC), depending on nursing availability.

How long will I take part in this research?

Participants will be asked to attend 14 visits over 3 months. These will involve 11 overnight stays in the research unit, and some daytime visits (approx. 5).

What can I expect if I take part in this research?

Visit 1: Screening (one morning, 3 hours in research unit):

You will report to the research unit after a 10-12 hour overnight fast (nothing to eat or drink except water).

- Your vitals (blood pressure, heart rate) height and weight will be measured.
- You will undergo a fasted single blood draw (about 2 tablespoons) for lab testing.
- We will review your demographics, medical history and any family history of diabetes.
- You will undergo 20-min indirect calorimetry. A clear plastic hood will be placed over your head and shoulders for 20 minutes to measure the rate at which your body burns calories. During this time, you will remain at rest in a bed.
- You will also be asked to complete a questionnaire about your sleep, which will take about 15 minutes.
- You will be fitted for a CPAP mask for use during Visit 2 below.
- For women of childbearing potential, we will perform a urine pregnancy test
- If you are eligible at this point, you will be sent home with a WatchPAT One device to wear at home for one night to test for sleep apnea. The WatchPAT includes a snore/body position sensor worn as a sticker on the chest, small monitoring device worn on the wrist, and a finger probe worn on a

finger. After use you can dispose of the device.
- If you are not eligible after completing the in-clinic activities, you will withdrawn from study and will not be sent home with the WatchPAT device.

If the at home sleep test shows that you have sleep apnea, you will be eligible to participate in the study, and will be asked to come in for Visit 2 as your next study visit. If sleep apnea is not detected, you will be withdrawn from the study.

Study Randomization:
Before the next study visit (Visit 2), participants will be randomly assigned, like a flip of the coin, to either the Untreated Study Period or CPAP Treated Study Period as their initial study assignment. All participants will complete both study periods, but they could happen in any order. After completing the first assigned study period, there will be a 3-week Washout Period where no study activities take place. After the Washout Period, participants will begin their second study period (either the Untreated or the CPAP Treated Study Period, whichever was not completed as the first study period). Your study participation will be complete once you finish your second study period. Both study periods are described in detail below (after Visit 2).

Visit 2 CPAP Titration (overnight in research unit):
For this visit, you will sleep in the research unit for 1 night with bedtimes 11PM-7AM. During the CPAP Titration, you will wear the CPAP mask that was fitted for you at Visit 1 during your night of sleep. The purpose for this visit is to find the optimal pressure to treat your sleep apnea. During this study sensors will be pasted on your head to measure your brain waves and on your legs to measure your leg movements, and a small sensor will be taped on your finger to measure your blood oxygen level (without collecting any blood). You will also be wearing sensors that will be put in front of your nose, around your chest and belly to measure your breathing.

After Visit 2, you will begin your first assigned study period, either the Untreated or CPAP Treated Study Period.

Visit 2 will occur 1 week after visit 1 (+ 3 weeks).

UNTREATED STUDY PERIOD

Untreated Day 0 (3 hours in the research unit):
- Meet with our certified diabetes care and education specialist for standard diabetes education.
- Review and optimize your insulin pump/CGM (continuous glucose monitor) use, and to ensure that your device and alarm settings are set-up properly and optimally. You will continue to use your own CGM device and insulin pump as a part of your routine care.
- You will be asked to download the 'Lose it' app on your phone and will be taught how to use the app to track the food you eat.
- You will receive the wrist activity monitor (Actigraph LEAP, like a watch that monitors your activity levels).

Untreated Days 1-3 (overnight in research unit):

- You will report to the research unit at 9PM on each night for Days 1-3. You will sleep overnight in research unit with bedtimes 11PM-7AM.
- A diabetic breakfast will be provided every morning after overnight stays. You can leave the research unit each morning after breakfast to engage in your daily routine activities.
- Body composition measured on lab scale (step on a scale barefoot and hold still for a couple of minutes).
- You will be asked to complete a questionnaire on your diabetes management and care on Day 1 (about 15 minutes).
- Each morning, upon wake, you will complete a questionnaire online about your last night's sleep (about 15 minutes).
- You will be asked to do the following regardless of whether you are at the research center or at home:
    - Track food intake on 'Lose It' app.
    - Wear activity monitor.
    - Weigh yourself daily on your at-home digital scale.

Untreated Days 4-12 (at-home):

- Track food intake on 'Lose It' app.
- Wear activity monitor.
- Weigh yourself daily on your at-home digital scale.
- Each morning, upon wake, complete a questionnaire online about your last night's sleep.

Untreated Day 13 (overnight in research unit):

- You will be asked to arrive to the research unit at 8PM and will be provided dinner upon arrival.
- You will have an overnight sleep study. During the overnight sleep study sensors will be pasted on your head to measure your brain waves and on your legs to measure your leg movements, and a small sensor will be taped on your finger to measure your blood oxygen level (without collecting any blood).You will also be wearing sensors that will be put in front of your nose, around your chest and belly to measure your breathing.
- You will remain in the research unit through Day 14 as described below.

Untreated Day 14 (continued and overnight research unit):

- You will be asked to stay all day and night in the research unit.
- Upon wake, an IV catheter (needle attached to a small plastic tube) will be placed into a vein of your arm for blood draws. Over the next 24-hour period, blood will be collected to measure your sugar levels and various hormones (approx. 1.5 cups). You will be monitored for any signs and symptoms of hypo/hyperglycemia (high or low blood sugar) by the research staff.
- The nurse will place a heart monitor for the duration of the blood sampling.
- You will be asked to stay in bed for the entirety of the day.
- You will be asked to complete questionnaire on your diabetes management and care.
- You will be provided with standardized meals at 8AM, 1PM and 6PM. Additional snacks or juice will be available if needed.
- You will sleep in the research unit with regular bedtimes 11PM-7AM

- Upon wake, your blood pressure will be measured three times in a row.
- You will undergo 20-min indirect calorimetry.
- We will ask you to share your CGM and insulin pump data for the past 14 days.

CPAP TREATED STUDY PERIOD

During this study period, we will treat your sleep apnea using a device called CPAP. CPAP provides a controllable pressure to keep your upper airway open during sleep so that you can breathe normally. The pressure acts much in the same way as a splint, holding the airway open. Controlled pressure is given by the CPAP device using one of several different types of masks: nasal masks, full face masks and nasal pillow masks. The mask will be individually fitted to your needs and comfort. The research staff will help to choose the most comfortable mask and educate you regarding the CPAP machine. You will be asked to sleep with CPAP machine to treat sleep apnea for all 14 nights of this study period.

The activities in the CPAP Treated Study Period are the same as those in the Untreated Study Period, except you will be asked to sleep with the CPAP machine for the duration of this study period.

Treated Day 0
This visit will include 3 hours in the research unit and involve all the procedures described in Untreated Day 0 above. Additionally, you will be fitted with a CPAP mask and receive CPAP treatment education. This CPAP mask fitting will be more customized than that done during Visit 1.

Treated Days 1-3 (overnight in research unit):
You will complete all the same procedures as Untreated Days 1-3. In addition, you will be asked to sleep with a CPAP machine. The first 3 nights are in the research unit to achieve complete treatment of OSA. While you are sleeping in the research unit, the overnight technician can help you adjust the mask and gain familiarity with the CPAP machine.

Treated Days 4-12 (at-home):
Days 4-12 you will sleep at-home with the CPAP machine and monitored remotely. You will be asked to keep regular bedtimes 11PM-7AM. Additionally, you will be asked to complete all of the same activities involved in Untreated Days 14-12.

Treated Days 13 and 14 (overnight in research unit):
These will include the same activities as Untreated Days 13 and 14. You will be asked to arrive at the research unit at 8PM on Day 13 and will stay through Day 14 and overnight. You will be asked to use the CPAP machine during these overnights.

STUDY COMPLETION AND OSA TREATMENT
Upon completion of this study, you will work with your routine care physician to continue treatment for your OSA. If you request, the study team can provide your physician with CPAP specifications used during this study.

You will not be able to keep the CPAP machine, activity monitor, digital scale, or any other study

provided devices after the study period ends.

What happens if I say yes, but I change my mind later?
You can leave the research at any time; it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)
There are some risks you might experience from being in this study. They are:

CPAP risks:
- nasal congestion or runny nose
- nasal or mouth dryness
- nose bleed (rarely)
- skin rash or irritation from mask

You will be fitted by a professional who specializes in CPAP. Every effort will be made to assure that the device is comfortable and easy to use. We will attempt to minimize any discomfort by individually fitting the mask to your face before use and by determining the right amount of humidity and air pressure to meet your individual needs.

Untreated Sleep Apnea risks:
For the duration of the study, you will be asked to not treat your sleep apnea using a CPAP machine.
- Snoring
- Unrefreshing sleep
- Daytime fatigue

You will be given results of your sleep evaluations, a brochure on sleep apnea and its consequences, and information on available sleep centers to obtain further care.

Body composition scale risks:
- Electrical pulses are given during the body composition measure

The amount of electrical pulses given during the body composition measure is very low and cannot be felt. We will ask if you have any artificial electrical implants, like a defibrillator or pacemaker will not be included in study. A safety questionnaire will be asked before every scan.

Blood draw risks:
- Temporary pain
- Slight bruising
- Possible inflammation at site of needle stick
- Feeling faint or lightheaded during the blood draw

An experienced research nurse will draw blood under sterile conditions to avoid these complications.

24-hour blood sampling risks:
- Discomfort
- Light-headedness

- Fatigue
- Slight bruising
- Possible inflammation from IV insertion

An experienced research nurse will insert the IV and draw blood under sterile conditions to avoid these complications. The nurse will ask you to move your legs periodically throughout the day. You can get up if needed, under the supervision of the research nurse. Additional snacks and drinks are available throughout the day, if needed.

Overnight sleep study:

- Skin irritation from monitoring sensors

You will be advised on how to prepare for your overnight sleep study and an experienced sleep technician will set up all sensors with care. The activity monitor can be removed.

Indirect Calorimetry:

- discomfort and feelings of claustrophobia

You will be asked to move as little as possible and remain completely relaxed while breathing comfortably under the plastic hood. You can see out of the clear plastic hood and breathe normally, if you have any feeling of claustrophobia the hood can be removed immediately.

Non-physical risks

Loss of Confidentiality: Information we collect about you may be accessible to individuals that are not part of the research team. Every care will be taken to assure that this does not happen. This is described in the Confidentiality section of this consent form.

What happens if I have an injury?

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, you may receive such emergency medical treatment at the University of Chicago Medical Center, UChicago Medicine Ingalls Memorial Hospital, UChicago Medicine Northwest Indiana, UChicago Medicine AdventHealth Bolingbrook, UChicago Medicine AdventHealth Glen Oaks, UChicago Medicine Advent Health Hinsdale, or UChicago AdventHealth LaGrange at no cost to you. You must notify Dr. Tasali as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let Dr. Tasali know right away.

In the event of an emergency, you should seek care at the nearest emergency room or call 911.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Efforts will be made to limit the use and disclosure of your Personal Information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the Office of Clinical Research, and other representatives of this organization. Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research

including the Office of Human Research Protections (OHRP).

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you agree to take part in this study, your genetic and health information and as applicable a portion of your specimens will be placed into one or more scientific databases. In particular, the National Institutes of Health maintains a database called “dbGaP.” The NIH database is a restricted database, meaning a researcher who wants to study information from dbGaP must work with the group overseeing the database to obtain the information. Security measures are in place to protect these data.

Researchers with an approved study will be able to see and use some of your information, but your name and other information that could directly identify you (such as your name or address) will not be placed into the database. There is a risk that someone could use your unique genetic information to trace data back to you or your family, but this risk is very small. There is no direct benefit to you that is expected from any secondary research that may be conducted.

If you decide to withdraw from the study as outlined in the following section, your data will be withdrawn from these databases. However, if your data have already been submitted to an NIH database and distributed to other researchers, or your data have been de-identified and can no longer be linked back to you, your data will not be able to be withdrawn.

HIPAA-Covered Data

Federal law provides additional protections of your medical records and related health information. During this study, Dr. Tasali and her research team will collect information about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. This information will include information within your medical record, which could include your medical history and new information collected as a result of this study. The information to be used on this study includes name, date of birth, phone number, social security number (to process study payments, for tax documentation) and address (for check writing purposes), dates of study procedures, results of research tests and procedures done as part of the study. In addition, we may collect information and results of tests, procedures, or examinations that have been done for purposes outside of this study.

As part of the study, Dr. Tasali and her research team will share information about you as well as the results of your study-related procedures and tests with representatives of the data safety monitoring board (a group of reviewers who monitor safety data during the course of the study) and the National Institutes of Health (NIH) (study funder). The study monitors may also review the entirety of your medical record (for example, in the event of an audit). If the medical record is accessed, it is possible that all of the information on this study would be viewed, including your name.

While there are no plans currently, it is possible that data and samples will be shared with research collaborators inside and outside of the University of Chicago in the future. If data and/or are shared, they may include dates of study activities, but will not include any other identifying information about you. Data and samples would be shared for the purposes of research collaboration.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Tasali is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until completion of this study.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

We are collecting your tissue and/or blood as part of this study. We may use your samples for other research studies, including genetic testing, without contacting you, including sharing your samples with others for research purposes here and outside University of Chicago. It is possible that these samples may be shared with a for profit company for research.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

HIPAA covered research

The University of Chicago/University of Chicago Medical Center will not withhold treatment or refuse treating you based on whether you sign this Authorization or revoke your authorization at a later time.

If you do not sign this form, you will not receive the research-related intervention(s).

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Tasali in writing at the address on the first page. Dr. Tasali may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Compensation -

If you agree to take part in this study, you will be paid as follows:

- $50 for completing Screening Visit 1 in-clinic activities.
- $50 for completing the Screening at-home sleep apnea test (WatchPAT device).

- $50 for completing Visit 2.
- $1,000 for completing the Untreated Study Period
- $1,000 for completing the CPAP Treated Study Period

You may be paid up to $2,150 if you complete the entire study. Payments will be made after each study visit.

As policies at the University of Chicago require that these payments be given in the form of a check, you will need to complete a tax form. We will need to ask for personal information about you including your name, address, and social security number. In addition, because the process for requesting a check often takes several weeks, we will mail your check to you when it is ready. Please note that it may take 3-4 weeks after your participation end in order for you to receive your payment.

Potential Costs to You -

Clinical services provided during a clinical research study are either research-related or considered part of the usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

All of the tests, procedures, and activities you will undergo as part of your participation in this clinical research study are considered research-related. You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study. However, this does not include visits or care received at the University of Chicago Medicine (or affiliate sites) that is not related to your participation in this clinical research study. You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. Financial responsibilities from routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

The Continuous Positive Airway Pressure (CPAP) machine and any other study-related devices, such as the activity monitor and scale, are provided for research purposes only. Participants will not be billed for the use of the CPAP machine during the study; however, these devices must be returned to the research team upon completion of participation. Participants will not retain any study-related equipment after the study has ended.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

Clinically-Relevant Results

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 773-702-2348.

If you have a research related injury, you should immediately contact Dr. Tasali at 773-702-1497 or you can page her at (773) 702-1000 and ask for pager # 9050.

This research has been reviewed and approved by the BSD/UCMC Institutional Review Board ("IRB"). You may talk to them at (773)702-6505 or bsdirb@bsd.uchicago.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

If you have any questions or concerns about the Clinical Research Center (CRC), Dr. Erin Hanlon, the Research Subject Advocate for the Clinical Research Center (CRC) is available to meet with you. You can contact Dr. Erin Hanlon at (773) 834-5849.

CONSENT

Signature for Adult Subject

Your signature documents your permission to take part in this research.

_____

Signature of Subject

_____

Printed Name of Subject

Date: _____ Time: _____ AM/PM (Circle

Person Obtaining Consent

I have explained to _____the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

Investigator:

Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)