Ketogenic Intervention in Depression(KIND)

The Ohio State University

IRB Approval December 01, 2022

IRB# 2022H0271

Informed Consent

The Ohio State University Consent to Participate in Research

Study Title:	**Ketogenic Intervention in Depression (KIND)**
Principal Investigators:	**Jeff Volek, PhD, RD; Scott Hayes, PhD; Jennifer Cheavens, PhD; Ryan Patel, DO**
Sponsor Name:	**The Baszucki Brain Research Fund**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your treatment through Counseling and Consultation Services (CCS) or your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit from participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form. This study involves a 12-week ketogenic diet intervention in people with depression currently engaged in counseling treatment provided through the Ohio State University Office of Student Life's Counseling and Consultation Services (CCS). A ketogenic diet is an eating pattern that is low in carbohydrate, moderate in protein, and high in fat. To facilitate transition to the ketogenic diet, we will provide you with detailed food information, ongoing coaching support, as well as some ketogenic-appropriate food items. To determine your response to the ketogenic diet, we will perform a series of different assessments at baseline and various time points over the 12-weeks as detailed in section #3. These tests will focus on how the diet affects your mental health, cognition, body composition, and blood markers of metabolic health. We will draw about 120mL (which is equal to roughly 8 tablespoons) of your blood for the entire study. In a subset of people, we will also take pictures of your brain using Magnetic Resonance Imaging (MRI). Throughout the duration of this study, you will continue to adhere to your normal scheduled appointments with your clinical team at CCS.

1. Why is this study being done?

The goal of this study is to examine whether a well-formulated ketogenic diet (KD) can be implemented into a university counseling treatment program for major depression and to test whether such a program has any benefit on mental and metabolic health.

2. How many people will take part in this study?

Up to 60 eligible individuals will be recruited through CCS.

3. What will happen if I take part in this study?

This study is about 13 weeks long (1-week baseline period plus a 12-week diet intervention period). It includes 5 in-person study appointments and two optional brain imaging appointments if you are eligible for a brain MRI.

Of the 5 appointments, you will complete the first 3 appointments at baseline (BL), one at Week-6 and one at week-12. This will be in addition to your regularly scheduled CCS appointments that occur every 3 weeks. You will also be asked to complete online questionnaires via RedCap or Qualtrics every 2 weeks. **Table 1** describes the assessments at each study appointment. Additional details of the assessments for each appointment are described starting on Page 3. Baseline appointments can be shortened, if necessary, to fit your schedule. For example, appointment 3 may be broken up into two separate sessions if it fits your schedule better.

Table 1: Scheduled study visits.

Week	Appointment #	Description	Expected Time Frame
Baseline	1	Determine potential participant interest in the study and go over pre-study eligibility form with CCS team member. A pamphlet describing the dietary protocol will be handed out at this time.	1 hr
Baseline	2a	Informed Consent Form & Structured Clinical Interview	90 min
If participant is ineligible or no longer interested, they are compensated, and study participation is terminated. If eligible and interested, participant continues in study as below:			
Baseline	2b	Mental Health Battery and Continuous Glucose Monitor / Continuous Ketone Monitor application	90 min
Baseline	3a	Weight, Hydration Status, Body Composition Testing, Survey/Side Effects, Venous Blood Draw, Body Composition, and Blood Pressure.	1 hr
Baseline	3b	Cognitive testing	1 hr
Baseline	3c	Dietary consult	45 min
Baseline	3d*	MR Testing	1 hr
5	4	Continuous Glucose Monitor / Continuous Ketone Monitor application	5 min

6	5	Weight, Hydration Status, Body Composition Testing, Survey/Side Effects, Venous Blood Draw, and Blood Pressure.	1hr
11	6	Continuous Glucose Monitor / Continuous Ketone Monitor application	5 min
12	7a	Cognitive Tests	1 hr
12	7b	Weight, Hydration Status, Body Composition Testing, Survey/Side Effects, Venous Blood Draw, and Blood Pressure.	1 hr
12	7c*	MR Testing	1 hr

It may be possible to combine or schedule additional appointments depending on your schedule. More appointments may be necessary if additional time is needed to complete any of the study tasks.
*Optional

Eligibility Screening: Your treatment provider at CCS will have already gone through a prescreening check list with you prior to this eligibility appointment. After I have read through this form with you and you decide to consent to this study, you will be interviewed about your mental health history and current symptoms. You will also complete self-report questionnaires about your current dietary habits, mood, mental health, and typical behaviors. These measures will be used to determine your eligibility for the study. If any of these measures indicate that you are ineligible or it is unsafe for you to participate, then you will not be able to be in the study. If you meet the eligibility , you will be asked to participate in the following study components:

Ketogenic Diet Intervention

After all baseline testing, we will select a day for you to start consuming a ketogenic diet for 12-weeks. Ketogenic diets are low in carbohydrate, high in fat, and moderate in protein. Foods permitted include non-starchy vegetables, eggs, cheese, cream, butter, sour cream, nuts/seeds, oils (olive, canola, coconut), certain fruits (tomatoes, berries, olives, avocado), meats (beef, chicken, fish, pork) and other naturally low-carbohydrate foods. We will ask you to limit foods with a high sugar or starch content such as cereal, pasta, sweets, some vegetables (peas, corn), fruit juices, and regular soda. You will be provided individualized counseling by trained dietitians who will educate and support you in following the ketogenic diet. The dietitians will provide educational materials, meal plans, food lists, and ongoing support throughout the 12-week intervention. This will include provision of some staple ketogenic-appropriate foods to help you adhere to the diet. You will have the opportunity to ask questions via phone or text as often as you need.

Assessments

Clinical Interview/Behavioral Assessment (baseline, week 6 and week 12): At these appointments (estimated duration of 2 - 3 hours, with scheduled breaks), you will be asked a variety of questions about your mental and physical health, sleep, and fitness habits. You will also be asked to fill out an online survey to assess depressive symptoms via an internet-based

survey and questionnaire administration program (REDCap / Qualtrics) every two weeks. Additionally, you may also be asked to fill out demographic, mood, health, or behavioral questionnaires.

Body Composition Assessment (baseline, week-6, and week-12): You will also be asked to complete a dual-energy x-ray absorptiometry (DXA) scan. You will lie still on a table while the DXA machine takes pictures of your body (approximately 4-5 min) and gives us results of body fat and muscle mass. Female participants must complete a pregnancy test (urine HCG) prior to the DXA scan. This research study involves exposure to radiation from a DEXA EXPERT spine, femur or whole-body scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is about 0.78 mSv or 78 mrem and is approximately equivalent to a uniform whole-body exposure of 95 days of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

Cognitive Tests (baseline, week-6, and week-12): Cognitive assessments will be done using computer-based tests that will measure various aspects of cognition such as attention, concentration, reaction time, memory, processing speed, decision-making, and executive function. Theses assessments may ask you to perform a variety of tasks, designed to measure various aspects of cognition and memory. You may read or listen to words or sentences, look at images, listen to sounds, draw objects, or imagine events. You may be working on the computer or doing paper and pencil tasks. The experimenter will explain each task and you may need to respond verbally, with written responses, or by pressing buttons.

Blood Draw (baseline, week-6, and week-12): A blood draw will be performed by a trained individual. During this procedure, the skin overlying the large veins of the forearm will be carefully cleaned with alcohol. A needle will then be inserted into the vein and approximately 40 ml (2.7 Tablespoons) of blood drawn into multiple tubes. The study team will process the blood for determination of various health markers.

Continuous Glucose/Ketone Monitor (baseline/week-1, weeks 5-6, weeks 11-12): Adhesive patches with a tiny needle will be placed on the back of your arm that will automatically measure your glucose and ketone levels every minute. Each patch is worn for 2-weeks.

Finger Sticks (daily): Throughout the duration of the dietary intervention, you will be asked to perform finger-stick testing each morning to measure your blood glucose and ketone levels via a drop of blood. This drop of blood will provide us with the information we need to adjust your diet so that you maintain a specific level of ketones in your blood. You will be provided with the glucose/ketone meter, and we will teach you how to use it.

Sleep/Activity Monitor (daily)*:* A tracker (Oura ring) will be worn on your index finger to monitor your sleep and activity throughout the study.

MRI Session (**optional;** baseline and week-12): If you are asked and decide to participate in this supplemental testing (estimated duration of 1 hour), you will complete an MRI scan, which takes pictures of your brain so we can look at brain structure and function. You will be asked

to remove all metal objects from your person – including but not limited to – cell phones, watches, jewelry, change, wallet (with credit cards), and shoes. Before you enter the scanner, you will also need to remove your glasses, hearing aids, and dentures (if removable). We may ask you to change into comfortable clothing, such as a gown, that is safe to wear in the MRI room for the imaging session and prepare for the session by using the restroom if necessary.

During the MRI session, you will lie on your back on the bed of the scanner. The MRI technician will provide padding for your head and knees to make you more comfortable while lying down. We will give you earplugs to reduce the noise experienced while in the scanner. If available, we may ask you to wear things such as a belt or mask or device on your finger that allows us to measure your breathing, heart rate, and gas you breathe out such as carbon dioxide. We will ask you to remain as still as possible during the imaging session because motion during the scanning reduces image quality.

Once you are comfortably situated in the MRI scanner, the investigators will leave the scanning room, but will observe the session through the glass window. The investigators will talk to you on the intercom system and will confirm that you are comfortable. You will be able to communicate with the investigators through the intercom system. For some scans, you may see pictures, symbols, or words, and will be asked to answer a question about the item. For some scans, we may ask you to hold your breath for brief periods of time. For other scans, you can lie still and rest. You will be in the scanner for up to 2 hours. We will announce the beginning of each scan and ask you to confirm that you are prepared. During the scan session, you will hear loud noises. If for any reason you are unable to continue with the MRI session, you can signal the MR technician who will immediately discontinue the scan.

Analysis

All the blood we collect from you will be kept in a cold storage freezer in our biochemistry lab. Your samples will be labeled with your subject identifier and not your name to maintain confidentiality. We will be measuring several markers in your blood related to metabolism and cardiometabolic response. However, since we will be storing your blood for up to five years, we may think of other markers to measure that we did not think of prior to the start of this study. Any future analysis that we may conduct will be related to this current study only and will not be used for any other research study. You have the right to decline the use of your samples for any potential future analysis. Below are two check boxes indicating that you either will allow us or will not allow us to use your blood to measure future markers. If you select not to allow us to use your blood for future tests, then any leftover samples will be destroyed. Please select an option below and sign your name with today's date. The extra signature indicates that you have thought about, read and understand this option. Please keep in mind that the selection of either option will have no impact or penalty during your participation in the study, and you will not lose any benefits to which you are otherwise entitled.

____ **Yes**, I give permission to use my blood samples for any future analysis.

____ **No**, I do not give permission to use my blood samples for any future analysis.

Participant Signature: _____

Date: _____

4. How long will I be in the study?

Your participation in this study will last for a total of 13 weeks, split into one week of baseline testing and 12 weeks of the dietary intervention. The Baseline (BL) visit will consist of 3-4 appointments, depending on your participation in fMRI testing. Week-6, and week-12 of the dietary intervention consist of 1-2 appointments each. We anticipate it will take approximately 21.5 - 24 hours to complete all appointments for this study. You can voluntarily withdraw from this study at any point. Please be aware that the study personnel may terminate your participation depending on your ability to take part in the study activities, such as an inability to complete portions of the assessment or if staff consider it to be unsafe for you to participate.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your services through CCS or future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Travel: Travel to The Ohio State University for the assessment appointments may be inconvenient.

Clinical Interview and Behavioral Component: The behavioral health counseling will take place outside of the study, through CCS. However, we will collect relevant information for the study. There is minimal risk associated with completing questionnaires and interviews and you are not expected to experience negative reactions above those experienced in everyday life.

Surveys: Surveys administered in this study are designed to evaluate psychological aspects of mood, satiety/hunger, which may make you uncomfortable. The surveys have potential to cause you to feel anxiety, stress, depressive feelings, etc. You can skip any question(s) that make you uncomfortable. Research key personnel will help to provide contact information for resources such as the student health center, medical center, or emergency department if necessary to aid with intense psychological distress induced by surveys.

Body Composition-DXA: You will be exposed to a very small amount of radiation by the scanner used to measure your body composition. Exposure to any amount of X-ray radiation, no matter how low, may cause abnormal changes in cells. However, the body continuously repairs these changes, and the amount of radiation is very low in this study. DXA includes exposure to radiation similar to a flight from New York to Los Angeles or 125 times less than the radiation associated with a standard chest x-ray; any exposure to radiation may elevate cancer risk. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from

this research may range from about one in 500,000 to about one in 200,000. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all. You will only be asked to complete the DXA assessment three times, which will minimize risks.

Ketogenic Diets: The diet intervention may be challenging because it will require you to limit foods you are accustomed to eating. We will make sure you are aware of the general dietary requirements including lists of foods you will need to restrict (as well as foods that will be permitted) during the informational session, so you can make an educated decision to participate.

Continuous Ketone/Glucose Monitor: The patch application may cause a slight immediate discomfort at the specific stick site. Under normal conditions, there are minimal risks to you when performing application that include: bruising; light-headedness or dizziness due to fear of needles; and infection.

Finger-stick Testing: The finger stick may cause a slight immediate discomfort at the specific stick site. Under normal conditions, there are minimal risks to you when performing finger-sticks that include: bruising; light-headedness or dizziness due to fear of needles; and infection.

Blood Draws: Blood draws may cause discomfort at the skin puncture site and a small bruise may develop that may persist for several weeks. There is also a small possibility of an infection. Every precaution to avoid infection will be taken including the use of sterile disposable needles and gauze and the practice of aseptic (sterile) techniques during the blood draw.

Optional MRI Session: During the MRI procedure, you will hear many different sounds produced by the scanner. These sounds are sharp and repetitive and can cause anxiety in some people. We will minimize this with earplugs and/or headphones, and these sounds are not harmful to your hearing. If you are asked to hold your breath or exercise during the scan, you may experience increased breathing and heart rate, sweating, or muscle fatigue. Extended periods of time in the MRI scanner can become uncomfortable. We will use all means to promote comfort including the use of pillows and padding.

Some people experience a “closed-in” feeling due to the small space within the MRI machine. If you experience such feelings, you can signal the researchers. You can do this at any time to stop the scan. On rare occasions, some people may experience one or more of the following: momentary dizziness, metallic taste, tingling sensations, or muscle twitches. Please tell the study staff over the intercom if any of these sensations occur. Some people may experience feeling “light-headed” or muscle fatigue. If you experience any feeling that makes you particularly uncomfortable, you can signal the researchers. You can do this at any time to stop the scan.

During the MRI, metal becomes magnetized and can heat up or move. You should not have the MRI procedure if you have shrapnel, surgical metal clips, or implants, including a pacemaker, in your body, as this could result in physical harm. Dental fillings are not a problem. If there is any question about whether there is metal in your body that would make it unsafe to undergo

MRI, you will not be able to take part in the study. You will need to remove all jewelry and clothing that contain metal when having the MRI such as (but not limited to) rings, bracelets, watches, hair clips, hair bands with metal clips, and underwire bras.

Currently there are no known risks of harm to an unborn child from MRI. However, MRI might involve risks to the embryo or fetus, which are currently unforeseeable. Therefore, if you are pregnant or trying to become pregnant, you should not have the MRI procedure.

The scans performed in this study are for specific research purposes and are not optimized to detect medical abnormalities (you are not given any MRI contrast agent). The standard OSU and FDA screening and safety guidelines for MRI will be followed. The MRI scans you receive in this study are not intended to be diagnostic and do not replace a clinical MRI scan reviewed by a qualified radiologist. You will be required to provide a primary care physician (PCP) to complete the MRI scan and your MR images will be reviewed by a radiologist within 30 days. Any incidental findings will be shared with your PCP as recommended by the radiologist; however, a lack of notification of incidental findings by our lab does not indicate that your scans are within normal limits. You will be provided with either a CD or printed paper containing a link that will allow you to view your structural scans, if you desire. All incidental findings for MRI, and cognitive assessments will be communicated to you and your PCP within 30 days.

In addition to the risks listed above, you may experience a previously unknown risk or side effect. Please sign below regarding your consent to MRI imagine for this study.

Yes, I consent to performing the MRI imaging for this study. ☐

No, I do **NOT** consent to performing the MRI imaging for this study. ☐

Participant Signature: _____

Date: _____

Please indicate which primary care physician you wish for us to send any incidental findings.

Primary Care Physician (PCP): _____

PCP Phone #: _____

PCP Email: _____

7. What benefits can I expect from being in the study?

At the end of the study, we will provide you with your data about how you responded to the ketogenic diet. This feedback is not diagnostic in any way. This experience may help inform

you about ways you could modify your own diet. Our staff and registered dietitians will also be available to answer questions you may have about the diets you will be eating to aid in your nutrition education. At the end of the study and after we have completed all the analysis, you will also receive your own results back and you will be able to see if the diet led to any improvements in your health, mood, or performance.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate with no penalty or loss of benefits to which you are otherwise entitled. Your participation in this study will not alter any treatment you are receiving at OSU or with any outside providers.

9. Will my study-related information be kept confidential?

For all the data collected over the course of the study (i.e., records, biological samples and questionnaires) a unique subject identifier (i.e., a code) will be assigned and used instead of your name. This identifier, which links your name to your data, will only be available to research personnel. Any records that contain your name and identifier together will either be stored in the Clinical Psychology file storage room in a locked file cabinet or protected on a computer via password protection on the individual digital file and password protection on the computer the file(s) are stored on. All other records that only contain the subject identifier will be kept in either a file cabinet in our locked file storage room or on a password protected computer. Your name will never be used in any presentation or publication resulting from this study. The records will be maintained until the data are published.

Raw data values from the CGM/CKM monitors, which include continuous glucose and ketone values, will be submitted to the device manufacturer (Abbott Diabetes Care) with your study identification number. This is so the company can change the numbers we get from the monitors into values that we can interpret for you.

There may be circumstances where your information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. We may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. For example, we may disclose medical information (confidentiality will be broken) in cases of medical necessity or take steps (including notifying authorities) to protect you or someone else from serious harm, including child or elder abuse, or if you are in immediate danger of harming yourself or others.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies.
- U.S. Food and Drug Administration.
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices.

- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance)

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Any potential incidental findings from MRI, blood biomarkers, etc. will be shared with you. Incidental findings from the MRI imaging will be reported to your primary care physician within 30 days of finding. The remaining information (ie. Blood biomarkers) is non-diagnostic and will be provided so you may choose to share with your physician. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information. Unpublished research information/findings from this research study will be kept confidential.

10. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, de-identified data may be used or shared with other researchers without your additional informed consent. It may also be used in development of new scientific methods. The only identifying information ever attached to any biological materials will be a unique subject identifier. The coded blood samples will be stored at OSU facilities. There is no limit on the length of time we will keep your blood and information. We will keep them as long as they are useful, unless you ask to have them removed from the study or we close the specimen repository.

11. What are the costs of taking part in this study?

Other than your time, there are no costs to participate in the study. You may need to pay for parking if you do not have an Ohio State University parking pass, but we have temporary passes that we may be able to provide you.

12. Will I be paid for taking part in this study?

Yes, you are eligible to receive up to **$300** if you complete the entire study including optional MRI testing. Payment will be in the form of a check or OSU PCard. If you do not complete the full study, compensation will be prorated:

- Completion of baseline testing will result in compensation of **$50**.
- Completion of baseline and week 6 testing will result in compensation of **$100.**
- Completing all study requirements excluding optional MRI will result in the compensation of **$200**.

- Completing all study requirements including optional MRI at baseline and Week-12 will result in compensation of the full **$300**.

By law, payments to subjects are considered taxable income.

If you agree to participate, your samples will be considered a gift to The Ohio State University. The university may sell or share your samples and personal information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and personal information are sold.

- Your samples and personal information may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money.
- You cannot choose how your samples and personal information will be used. If you do not want to let others decide how your samples and personal information will be used, then you should not donate your samples.

13. What happens if I am experiencing a serious medical emergency (physical or mental) because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

If you were to indicate immediate threat to your safety or the safety of others, we will notify your CCS treatment provider immediately to address the problem. Current participation in psychotherapy is an inclusion criteria for the study and, thus, you will be connected to a therapist throughout your time in the trial. Additionally, there are two licensed clinical psychologists and a licensed psychiatrist included as research staff for this study. They will be contacted should a mental health emergency arise.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the research that may affect your decision whether to continue participation in the study.

An Institutional Review Board responsible for human subject research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed due to study participation, you may contact **Dr. Jeff Volek via email volek.1@osu.edu. 305 Anne and John Glenn Avenue, Room A041.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Wexner Medical Center, HIPAA Privacy Officer, 600 Ackerman Rd., Columbus, OH 43202, 614-292-4477.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time

Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

<u>Investigator/Research Staff</u>

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time