THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: ***Healthy Eating and Active Living to reverse Diabetes (HEAL Diabetes) Pilot Study***

PRINCIPAL INVESTIGATOR: *James E. Bailey*
University of Tennessee Health Science Center
956 Court Avenue, Coleman D228 A
Memphis, TN 38163

CO-INVESTIGATOR(S): *Frankie Stentz, Burton L. Hayes, Satya Surbhi, Asos Mahmood, Rick Bloomer, Tracy Bruen, Umar Kabir, Susan Butterworth, Alexandria Boykins*

1. KEY INFORMATION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family before you decide to take part in this research study. Please tell the study staff if you are taking part in another research study.

The purpose of this study is to provide initial evidence of the practicality and value of a multi-part intensive weight loss and maintenance program designed for people in Memphis. HEAL Diabetes is an intensive plant-forward healthy eating program designed to reverse type 2 diabetes. This plant-forward healthy eating program encourages you to mostly eat vegetables and fruits, along with lean meats like chicken and fish, egg whites or whole eggs, nuts and seeds, and skim or low-fat milk. There are millions of people in the U.S. living with diabetes and other obesity-related health conditions. While medication therapy has been used to lower blood sugar, cholesterol, and blood press for people with diabetes, the improvements have been modest. Studies have shown that intensive weight loss and weight loss maintenance led to long-term remission of diabetes for as many as half of all patients. Although weight management is an essential therapy for diabetes and other obesity-related conditions, there has been a lack of sensible approaches for implementing successful weight loss and diabetes remission programs. Also, multi-part weight loss interventions like HEAL Diabetes are generally unavailable for Memphians. Before this holistic diabetes treatment alternative can become a model in the future, it is critical to know how this approach works.

Main Consent Form

Procedures:

This is a pilot study. A pilot study is a small study, which is conducted to understand whether a program will work. The information collected in this study will be used to provide early evidence of the feasibility of this approach to reversing diabetes. In this study, we will be collecting data from your health hub visits, as well as your medical records. We will be asking you to complete some additional questionnaires about your background, resources, and diabetes care practices. We will also be collecting weight, blood pressure, and A1c (blood specimens) measures and conducting lab tests to see how your body responds to lifestyle changes, including diet and exercise.

In this study, you will be randomly assigned (like drawing numbers from a hat) to receive the usual approach for treating diabetes or a plant-forward healthy eating and multipart weight-loss program. You have a 1 in 2 chance that you will not receive the most intensive weight loss program. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to determine which you receive. It is not known whether this multipart weight loss program is a good as, better than, or worse than the usual care.

You may be randomly assigned to the Enhanced Care Group (health coaching for plant-forward healthy eating and weight loss) or the Intensive Care Group (health coaching and additional support for plant-forward healthy eating and weight-loss). This study will include 72 study participants. Your participation in this study will last 12 months, which will include followup visits and monthly check-ins. This study has several phases, which are detailed below.

If you are in the Enhanced Care Group there are two study phases:

- Phase 1: Support for a Healthy Lifestyle (months 1-6)
- Phase : Healthy Lifestyle Maintenance (months 7-12)

If you are in the Intensive Care Group there are four study phases:

- Phase 1: Intensive Preparation for Change (month 1)
- Phase 2: Total Diet Replacement (months 2-4)
    - Includes Supervised Medication Discontinuation
- Phase 3: Food Reintroduction (months 5-6)
- Phase 4: Weight Loss Maintenance (months 7-12)

Main Consent Form

The following procedures are being performed for research purposes only:

- Enhanced Care Group (over 12 months)
  - Questionnaires (total=7 over 12 months)
    - Baseline visit/Visit 2 (3 questionnaires)
    - 6-month followup (2 questionnaires)
    - 12-month followup (2 questionnaires)
  - Health hub visits (4)
  - At least 1 initial meeting with a health coach
  - Blood draws (total=4)
    - You will have a total of less than 1 teaspoon of blood drawn for research purposes at baseline, 3-months, 6-months, and 12-months (total of less than 3 teaspoons over the length of the study).
  - Healthy food vouchers provided at your 3, 6, and 12-month assessments

- Intensive Care Group (over 12 months)
  - Questionnaires (total=7 over 12 months)
    - Baseline visit/Visit 2 (3 questionnaires)
    - 6-month followup (2 questionnaires)
    - 12-month followup (2 questionnaires)
  - Blood draws (total=4)
    - You will have a total of less than 1 teaspoon of blood drawn for research purposes at baseline, 3-months, 6-months, and 12-months (total of less than 3 teaspoons over the length of the study).
  - Health hub visits (14)
  - Total diet replacement for 3 months during phase 2 of study in the form of healthy food boxes delivered to your residence once a week
  - Some or all diabetes and blood pressure medications will be discontinued or decreased at the start of Phase 2

If results of the studies conducted with your blood specimen may be relevant to your health, the study doctor or the study staff may offer to share this information with you at the UTHSC Health Hub. The study staff and/or study doctor will explain the test results and what they may mean for your health.

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

- If you do not show up for visits
- If you do not follow the study doctor's instructions
- You become pregnant or have a serious illness

Main Consent Form

If you decide to stop being part of the study, you should tell the study doctor, and any information that you have already provided will be kept in a confidential manner. You may ask that your identifiable samples be destroyed.

For a detailed explanation of the study procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Risks:

Possible risks for being in this study include hypoglycemia, temporary discomfort or mental anguish adapting to the changes (i.e., new diet, increased movement and activity), and possibly breach of confidentiality and privacy by other participants during nutrition education classes. We will have procedures in place to minimize the potential for risks and side effects for you. A possible side effect, Hypoglycemia, is a condition in which an individual's blood sugar (glucose) level is lower than the standard range. You will be carefully monitored by study doctors and qualified personnel and counseled on ways to decrease the risk of hypoglycemia. Staff and patients will be trained to recognize the signs and symptoms of hypoglycemia, in addition, a physician will be available to provide support and you will be encouraged to work with your doctor to decrease or stop diabetes medications as you lose weight. Regarding discomfort and mental anguish, you will be advised of the risks and benefits of participation and informed of your right to withdraw from the study at any time if you should choose to discontinue. Finally, you will be advised on informed consent and your role in protecting the confidentiality and privacy of other participants and your own.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:

You may lose weight and diabetes may be reversed while you are in this study; however, this cannot be promised. The results of this study may help people with type 2 diabetes in the future by showing the benefits of a holistic, intensive nutrition-focused program as a treatment option.

Alternatives:

If you decide not to enter this study, there are other choices available. These include standard care for diabetes with your healthcare provider and/or service at the UTHSC Health Hub where you can have access to a health coach and system of support to help meet your health goals. Ask the study personnel to discuss these alternatives with you. You do not need to be in this study to receive help for your condition.

Voluntary Participation:

Your participation in this research study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to

which you are entitled. Deciding to not take part in this research study will not change your regular medical care in any way. If you decide to stop taking part in this research study, any information that you have already provided will be kept confidential. Your participation in this research study will be stopped by the study staff without your consent for the following reason: if you have a major illness, including metastatic cancer or malnutrition or you become pregnant during the study. Your participation in the study will be suspended until you are healthy enough to continue. The study physician will determine whether or not it is medically safe for you to continue the study. If you have an issue (e.g., broken bone, etc.) that does not interfere with the your assigned intervention, the study physician will determine whether it is safe for the you to continue participation in the study.

Adverse Events

A co-investigator will monitor you for serious adverse events. If the serious adverse event is thought to be related to study participation by either your primary care provider and the physician investigators (Dr. Bailey and/or Dr. Hayes), the investigator may request you undergo a physical examination, psychiatric evaluation, and/or laboratory testing whenever appropriate to your condition.

Voluntary or Involuntary Withdrawal:

If you are removed from the study or choose to withdraw, we will keep and analyze the data we have already collected from you, unless you want us to destroy it and discontinue further use. We will review your willingness to consent prior to each of the subsequent visits for data collection purposes (i.e., surveys, blood draws). If you do not want us to keep your data, there is no penalty or issue, it will be destroyed at your request. Withdrawing your consent to use your data will not prevent you from using health hub services or programs in the future.

2. DETAILED PROCEDURES TO BE FOLLOWED:

Approximately 72 subjects will be participating in this study. Your participation in this study will last for 12 months. In this 12-month period, you will have at least a monthly meeting with your health coach.

All study visits will be scheduled during primary site (UTHSC Health Hub at 534 North Second Street, Memphis, TN 38105) hours (8:30am-4:30pm), at a time that is best for you.

Visit 1/Screening – 1.5 hour:

- Collect a small blood sample by fingerstick to measure A1c
- If you are female and childbearing age, we will collect a urine sample
- Check height and weight

- You will provide a list of your current medications
- You will have your blood pressure taken (2-3 readings in one sitting)
- You will get text messages and phone calls on your cell phone right after Visit 1
- You will need to respond to these text messages and phone calls using your cell phone. If you do not respond to these text messages and phone calls, you will not be able to be in the study.
- You will be notified of your eligibility for study by the end of these two weeks

Visit 2/ Baseline & Randomization (within two weeks of Run-in Period) – 1.5 hour:

- You will answer questions on the computer asking about things like your health, age, race, gender, medications, and contact information and physician contact group
- You will be told your group assignment:
    - You will be randomly assigned (like drawing numbers from a hat) to be in the Intensive Care group or Enhanced Care group. You have a 1 in 2 chance of being in the Intensive Care group or the Enhanced Care group.
    - The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known which group is the best treatment.
- You will be given your "HEAL Diabetes Toolkit"
- You will meet your health coach

Visit 3/Follow-up (3 months after Visit 2) – 1 hour

- Collect a small blood sample by fingerstick to measure A1c
- Check weight

Visit 4/Follow-up (6 months after Visit 2) – 1 hour

- Collect a small blood sample by fingerstick to measure A1c
- Check weight

Visit 5/Follow-up (12 months after Visit 2) – 1 hour

- Collect a small blood sample by fingerstick to measure A1c
- Check weight

Enhanced Care Group:

If you are in the Enhanced Care group, you will be encouraged to participate in regular health coaching sessions and you will get the "HEAL Diabetes Toolkit," and 10-minute introduction to UTHSC Health Hub services and the toolkit during Visit 2. The toolkit will include diabetes

educational materials, information about diabetes support services, and things to help with healthy behaviors. The educational materials will be about diet/weight loss, physical activity, medications, and goal setting. Health coaching sessions will involve you and your health coach discussing your health goals and codeveloping strategies and solutions to reach them. You will also receive three healthy food vouchers following your 3-, 6-, and 12-months assessments. We will provide additional information about the vouchers at a later date. If you are in this group, you do not need to do anything else except show up for the study visits described above and work with your health coach. You do have the option to keep using general health hub services and the standard services offered for diabetes patients.

In-Person Visits for Enhanced Care group:

- Individual health coaching over 6 months (1 mandatory session) (1 hour)
    - Other health coaching sessions are recommended but are optional.
- Group support sessions (1.5 hours)
    - Recommended but are optional.
- Cooking Classes (2 hours)
    - Recommended but are optional.

Intensive Care Group:

If you are in the Intensive Care group, you will get the modified "HEAL Diabetes Toolkit," and 10-minute introduction to UTHSC Health Hub services and the toolkit during Visit 2. The toolkit will include diabetes educational materials, information about diabetes support services, and things to help with healthy behaviors. The educational materials will be about diet/weight loss, physical activity, medications, and goal setting. People in this group will participate in individual health coaching, group support sessions, and cooking classes. Health coaching sessions will involve you and your health coach discussing your health goals and codeveloping strategies and solutions to reach them. Group support sessions will include you receiving health related information and being able to interact with others in the Intensive Care Group to provide and receive social and emotional support during the study.

Cooking and nutrition classes will include nutrition education, like reading food labels, learning about healthier options, and learning healthier and affordable ways to shop and prepare the foods you enjoy. During cooking classes, you and group members will learn and prepare different healthy recipes. Please note that if you agree, photos may be taken during these cooking demonstrations. You will also get healthy food boxes for 3 months delivered to your residence once a week at your convenience. Healthy food will be provided to the household to help aid and support you in your efforts, but your family members are not in the study and will not participate

in study procedures like very low calorie eating (unless recommended by their healthcare provider) or surveys. Additionally, if you are in this group, you get motivational text messages, transportation assistance, grocery store tours, and physician-supervised and assisted discontinuation of diabetes medications. If you are in this group, you are required to attend all program events and study visits described above.

If you are in the Intensive Care Group, you will likely need to stop or decrease antihypertensive, diuretic, and diabetes medications on the day you begin the total diet replacement and intensive weight loss phase. This is a safety measure, because your blood pressure and blood glucose are expected to decrease as you lose weight. Your primary care doctor will be informed of any changes in your medications. This medication discontinuation will be supervised by the UTHSC Health Hub's medical director (Dr. Burton Hayes). If the medical director in consultation with your primary care physician decides that you need to continue any of your diabetes and/or antihypertensive medications, you will not be withdrawn from the study. The initial meeting with the medical director will take place during Week 4 of Phase 1 of the program. The medication discontinuation will start during phase 2 of the program.

You will be encouraged to continue any glucose monitoring or blood pressure monitoring recommended by your primary care physician and/or diabetes doctor. You will be provided instructions in your HEAL Diabetes toolkit, as well as verbal counseling on ways to monitor for blood glucose and blood pressure related concerns, as well as ways to minimize the occurrence of glucose and blood pressure related issues, and instructions on when to contact emergency services and the study physician.

In-Person Visits for Intensive Care group:

- Phase 1 (month 1)
  - Individual health coaching (three times a month for 1 hour)
  - Group support sessions (twice a month for 1.5 hours)
  - Cooking/Nutrition classes (twice a month for 2 hours)
- Phase 2 (months 2-4)
  - Individual health coaching (twice a month for 1 hour)
  - Group support sessions (once a month for 1.5 hours)
  - Cooking/Nutrition classes (once a month for 2 hours)
- Phase 3 (months 5-6)
  - Individual health coaching (once a month for 1 hour)
  - Group support sessions (once a month for 1.5 hours)
  - Cooking/Nutrition classes (once a month for 2 hours)
- Phase 4 (months 7-12)
  - Individual health coaching (once a month for 1 hour)
  - Group support sessions (once a month for 1.5 hours)

- Cooking/Nutrition classes (once a month for 2 hours)

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as a researcher's computer is stolen, or an electronic database is hacked). However, we will use careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

This research may involve risks to you or to the embryo or fetus (if you have an unexpected pregnancy), which are currently unforeseeable. For your protection, if you should become pregnant you will be removed from the study. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs. You also have the right to withdraw your consent and be removed from the study (at any point), if you choose. The possible risks and discomforts associated with participation, include:

Pregnancy Risks for Females: Females who are pregnant or nursing a child may not take part in this study. If you are a female and able to become pregnant, you will have a urine test to make sure that you are not pregnant before you receive treatment in this this study. If you should become pregnant at any point during the study, you will be withdrawn from the study.

Hypertension (Less than 5%): Potential risks of medication discontinuation include uncontrolled hypertension. But since blood pressure usually drops rapidly with intensive weight loss, it is safer to reduce hypertension medications during the program. We will monitor your blood pressure during health hub visits, as well as through consultation with your regular care provider to make sure your blood pressure is controlled.

Hyperglycemia (Less than 5%): Potential risks of medication discontinuation include hyperglycemia. But since blood glucose usually drops rapidly with intensive weight loss, it is safer to reduce most diabetes medications during the program. We will monitor your blood sugar during health hub visits, as well as through consultation with your regular care provider and your home measurements to make sure your blood glucose is within an acceptable range.

Hypoglycemia (Less than or equal to 5% risk): Potential risks of intensive weight loss include hypoglycemia. Symptomatic hypoglycemia is expected to be rare, and it is usually not serious and is also reversible, but very rarely can result in hospitalization. However, this problem almost always can be avoided if diabetes medications that lower blood sugar are discontinued.

Symptomatic gallstones (Less than 1% risk): Potential risks of intensive weight loss include gallstones. Symptomatic gallstones are expected to be very rare. However, this discomfort usually resolves or greatly diminishes within one week as long as you stick with your healthy diet. This potential risk is not serious and is completely reversible.

Hunger (Greater than 50% risk): There is a risk of discomfort related to hunger and/or adapting to a new diet, but usually this discomfort decreases or goes away after the first 3-4 days on the new eating plan. Risks of initial discomfort related to hunger and/or adapting to a new diet is expected to be very common, but temporary.

Fasting: The potential discomforts associated with fasting are minor and include dizziness, headache, stomachache, or feeling faint. However, this discomfort usually resolves or greatly diminishes within one week if you stick with your healthy diet. These potential risks are not serious and are completely reversible.

Fingerstick Blood Draw: Risks associated with drawing blood from your finger include minimal discomfort. Lightheadedness, and/or fainting are also possible, although unlikely.

Confidentiality: As a result of your participation in this study, there is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

Questionnaires/Surveys: Completion of the study surveys may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study.

Previously Unknown Medical Conditions or Genetic Risk Susceptibilities: If screening visits indicate you have undiagnosed and untreated hypertension (high blood pressure) or obesity, and you are made aware of this result, it may cause mental stress, unfair treatment from other people, or other unanticipated problems. However, the Health Hub medical director will attempt to contact your primary care provider and share the information. The medical director and staff will also work together to assist you in making referrals and scheduling needed follow-up care for any and all conditions identified.

4. CONFIDENTIALITY:

Research records/specimens

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).
All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your fingerstick blood samples and urine samples will be labeled with a code and will be transmitted to Dr. Frankie Stentz at the UTHSC Endocrinology Lab, 956 Court Ave. Memphis, TN 38163.

A master key/list which links your name with the code on your research record and specimens will be maintained by UTHSC research personnel at 956 Court Ave. Memphis, TN 38163.

Identifiers might be removed from your private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record at the UTHSC Health Hub. As such, it may be available to your insurer. However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Limits to Confidentiality
Information obtained during the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits

- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- UTHSC Uptown Health Hub
- Shelby Cares
- Regional One Health
- Christ Community Health
- The University of Memphis

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed. You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, Regional One Health, or the agents of either from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Regional One Health do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.
No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact Dr. James Bailey at 901-359-1333, Dr. Umar Kabir at 901-262-0466, or Alexandria Boykins at 901-292-7484, if you have questions about your participation in this study. You may also call if you have general questions, concerns, or complaints about the research.

If you feel you have had a research-related issue, contact Dr. James Bailey at 901-359-1333 (24-hour/7-day telephone number/cell phone) or Dr. Umar Kabir at 901-262-0466 (cell).

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. The program is free of charge during this study. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company. Although, if you elect to receive motivational text messages, standard texting rates will apply.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about

your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- Certified mail will be sent to you requesting that you call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- The email you provided us with will be e-mailed.

Put your initials on **one** of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Sometimes we wish to keep your contact information, medical diagnosis, and other health information to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on **one** of the lines below:

_____We CAN keep your contact information and health information to ask you about participating in future studies.

_____We MAY NOT keep your contact information and health information to ask you about participating in future studies.

Put your initials on **one** of the lines below:

Sometimes we may want to take photos of group activities (e.g. nutrition classes, cooking demonstrations) to be used for policy papers, conference presentations, and/or TN Heart Health Network or other evaluation reports.

_____We MAY take photos of group meetings (the cooking classes) and use them for the purposes mentioned above.

_____We MAY NOT take photos of group meetings and use them for the purposes mentioned above.

Main Consent Form

10. CONSENT OF SUBJECT:

You have read or have had someone read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**