DEPARTMENT/SECTION OF INTERNAL MEDICINE/GERONTOLOGY & GERIATRIC MEDICINE
ROENA B. KULYNYCH CENTER FOR MEMORY AND COGNITION RESEARCH

STUDY OF NASAL INSULIN TO FIGHT FORGETFULNESS
SHORT-ACTING INSULIN ASPART
"SNIFF – QUICK"

Informed Consent Form to Participate in Research
Suzanne Craft, PhD Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have mild memory impairment or early Alzheimer's disease. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to find out whether insulin aspart improves memory when administered as a spray into the nasal passages of adults with mild memory impairment or early Alzheimer's disease.

Insulin is a hormone that is produced in the body. It works by lowering levels of glucose (sugar) in the blood. Insulin aspart is a faster-acting form of insulin than regular human insulin and is used to treat type 1 (insulin-dependent) diabetes in adults.

During this study, we will explore the effects of insulin aspart administered intra-nasally on memory and levels of certain hormones and proteins in the blood. Insulin is approved by the US Food and Drug Administration (FDA). However, using it in this way is experimental and we don't know if it will be effective to help improve cognition.

In this study you will receive either insulin aspart or placebo, which is a substance that is not thought to have any effect on your disease or condition. Placebos are used in research studies to see if the drug being studied really does have an effect. In this study, we will use saline for the placebo.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 30 people will take part in this study here at Wake Forest Baptist Health. In order to identify the 30 subjects needed, we may need to screen as many as 60 people because some will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups below.

- Short-acting insulin aspart (twice per day)
- Saline (placebo)

Randomization means that you are put into a group by chance. It is like flipping a coin: you will have a one in two chance of being placed in either group.

Neither you nor the investigator will know which study drug you are receiving. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

Your participation will involve coming to the Sticht Center on Aging & Rehabilitation at Wake Forest Baptist Medical Center 10 times over the next 4 months. During this time you will complete a series of measurements:

- Give blood samples (6 times)
- Have a physical exam (1 time)
- Take tests of memory/thinking and answer questions about your daily activities (3 times)
- Undergo a lumbar puncture (LP) (2 times)
- Have MRI scans of your brain (up to 2 times)

After you have been randomized into one of the study groups, you will administer the study drug twice a day for 12 weeks. The drug should be administered 30 minutes after breakfast and 30 minutes after dinner each day. The study insulin is administered using a Precision Olfactory Delivery (POD) device. This is a small, reusable device (smaller than a deck of cards). The device has a plastic delivery piece that is placed inside the openings of the nose.

You will be asked to measure your blood sugar level (finger-stick glucose) twice a day, 3 days per week for weeks 1-4 and once a week during weeks 5-12. The first measure taken prior to the first meal and then one hour after morning dosing using a device called a glucometer. To check your blood sugar, you will prick your finger with a lancet and then squeeze a drop of blood onto the test strip which has been inserted into the glucometer. The glucometer will then calculate the blood sugar and give a reading in about 30 seconds. You will record your blood sugar level in a log that we will give you. The study nurse will review your log, general health and medications by telephone during weeks 1, 8 and 12. These will also be reviewed during your study visits.

It is necessary for you to identify a "study partner" for this study. Your study partner will be asked to attend at least four study visits and to answer a questionnaire about your memory while you have been in the study. The study partner may also be asked to help you with administration of the nasal spray and checking blood sugar levels. You will not be considered eligible for the study until you and your study partner have signed this consent form.

DESCRIPTION OF STUDY VISITS

If you have participated in the Alzheimer's Disease Prevention Participant Repository (ADPPR) study or another study with the Kulynych Center for Memory & Cognition within the last 3 months, you may not have to repeat the following procedures at your screening and pre-study drug visits: safety labs, screening cognitive testing and LP. Data used during the completion of the previous study will be used in order to avoid duplicating those procedures. Other procedures that occur during and upon completion of the SNIFF-Quick study will be completed as described.

You will be asked to fast (no food or drinks except water) for 12 hours prior to at least 8 visits during your participation in this study. The study staff will notify you which visits you will need to fast for.

During your participation, we may need to request medical records from your primary care doctor. We will ask you to sign a medical records release form giving us permission to request these records if needed.

SCREENING VISIT – You will be asked to fast for 12 hours leading up to this visit. We will do a brief memory screening. About 2 tablespoons of blood will be drawn from you to make sure it is medically safe for you to participate in this study. Heart rate, weight and height measurements will be taken. You will have a physical exam, a review of your medical history and an ECG. Once all of the above has been completed, the study physician will review your screening test results and determine your eligibility for the study. If there is no further information needed to determine eligibility, you will be randomly assigned to a treatment group and baseline visits will be scheduled.

This visit will last between 3 and 4 hours.

PRE-STUDY DRUG / POST STUDY DRUG

There are two pre-study drug and two post-study drug visits that will allow us to compare "before" and "after" study drug measurements. The pre-visits will take place the week before you start the study drug, and the post-visits will take place after 12 weeks of study drug. Each visit is described below:

MRI BRAIN SCAN (PRE-STUDY DRUG / POST STUDY DRUG)

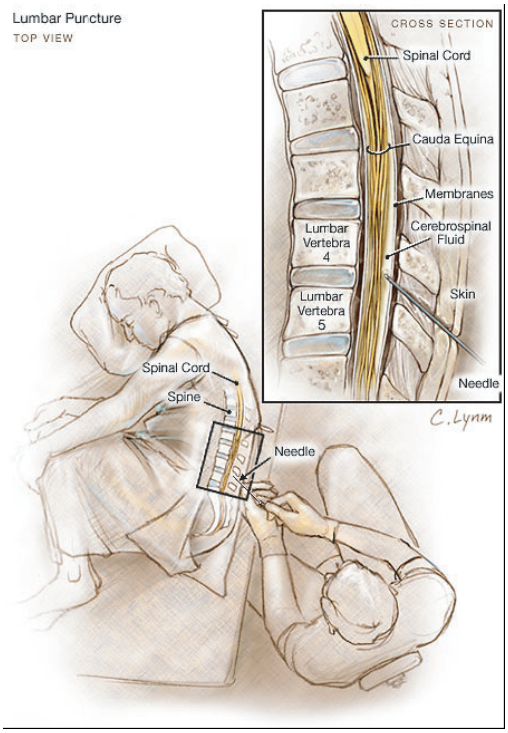
A magnetic resonance imaging (MRI) scan will be done at the beginning and end of the study. An MRI uses a large magnet and computer equipment to produce electronic pictures of your brain.

You will lie on your back and enter the MR machine for the scan, during which time you will hear loud knocking noises. You will be asked to keep as still as possible while pictures of your brain are recorded. People with pacemakers, aneurysm clips, cochlear implants, or metal/foreign objects in their eyes are not permitted to undergo MR studies. Prior to having the MRI scan, you will be asked questions about your medical history, blood pressure, heart rate, respiration measurements will be collected. A finger stick will be done to measure the amount of sugar in your blood as well. The MRI takes about 45 minutes to complete.

This visit will take about 1 ½ hours to complete.

LUMBAR PUNCTURE (PRE-STUDY DRUG / POST STUDY DRUG)

An LP is a procedure in which a small amount of the fluid that surrounds the brain and spinal cord is removed from the lower back. You will be asked not to eat or drink anything (you may have water) for at least 12 hours before the lumbar puncture visit. However, because you will need to be well hydrated, please drink plenty of water. You will be positioned sitting up and bent forward or lying on your side and your lower back will be cleaned with antiseptic. Local anesthetic (lidocaine, 1%) will be injected into the skin of your lower back. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends, and about 25 milliliters (less than 2 tablespoons) of fluid will be removed. Your body replaces this spinal fluid within 1-2 hours. After the LP is complete, you will remain in the clinic while resting quietly for about half an hour. You will be given something to eat and drink and detailed instructions on self-care after the LP will be provided. Specifically, you will be asked to avoid any strenuous physical activity for 24 hours.



COGNITIVE VISITS (PRE-STUDY DRUG / POST STUDY DRUG)

At the beginning of the visit, we will draw your blood (about 3 ½ tablespoons) to measure several of your body's chemicals (hormones and proteins). We will then give you a small snack, and 30 minutes later, the cognitive testing will begin. You will be asked to do several tasks, such as remembering stories, lists of words, and designs. Some of the tasks involve pressing a yes or no button using a computer. These are not intelligence tests and we will not be determining your "IQ" from them.

You may choose not to answer any questions or items in any test. After testing is complete, you will undergo a second blood draw (about 1 tablespoon) to get measurements of certain proteins after your meal.

Previous studies have shown that a gene called apolipoprotein E (ApoE) may be linked to how well some people do on memory tests after they have taken glucose. This information suggests that memory is related to both blood sugar control and genes. If you have not had this test previously while taking part in another research study with us, we will collect an additional 1 1/3 tablespoons of blood during your visit to see what form of the ApoE gene you have. The ApoE test can also identify subjects who may have an increased risk of developing AD. However, the test alone does not predict who will or will not develop AD and is used for research purposes only; you will not receive the results. The blood draw for ApoE will only occur once during the study.

During the pre-study drug cognitive testing visit, you and your study partner will be trained in the use of the POD nasal insulin device and glucometer for checking blood sugar levels. You will be given precise written instructions on how to administer the study drug using the nasal device and how to perform the finger-stick glucose check. You will demonstrate the techniques to the study nurse.

Each cognitive visit will last approximately 3 hours.

ADDITIONAL COGNITIVE VISIT

In addition to the pre- and post-treatment cognitive visits, you will attend one additional visit that will be identical to the other cognitive visits. It will occur when you are halfway done with the study (after 6 weeks of taking the study drug). Approximately 1 tablespoon of blood will be drawn at this visit to monitor your continued medical safety.

As part of this research study, you will be audio recorded using a digital device while performing some of the cognitive tests. This is to assure accuracy as we record your answers. You will not be able to inspect, review, or approve the content of the audio recordings. You may request the recording be stopped at any time, and you can withdraw your consent to use the recording before any information is transcribed. All recordings will be erased once the data is reviewed for accuracy.

CHECK-IN VISITS

At 2, 4, 6 and 10 weeks after you begin study drug, you will have check-in visits. At these visits, we will inspect your nasal cavity and study drug device. Your usage of the study drug will be reviewed as well as your blood sugar monitoring log. We will ask questions about any adverse events you may have had. We will also collect about 1 tablespoon of blood at the week 6 visit for continued monitoring of your medical safety and/or study outcomes. Each check-in visit will last approximately 30 minutes.

DAILY DOSING WITH THE STUDY DRUG

The study drug will be either insulin aspart or placebo (saline). It will be administered twice a day, 30 minutes after eating breakfast and 30 minutes after eating dinner. You will be asked to blow your nose into a tissue before taking the study drug. Place the tip of the POD device into one nostril with the flat side of the tip resting against the center wall of your nose. The guard should be against the center of your nose and upper lip. Once the device is in place, press down firmly on the canister to deliver the dose. Try to avoid exhaling while the dose is being delivered, this only lasts for a few seconds. Repeat in your other nostril. Do not lie down or blow your nose for 15 minutes after administration. Your study partner may help you during this process.

During study weeks 1 – 4, you will choose 3 days per week to monitor and record your blood sugar, once prior to your first meal of the day and again 1-2 hours after dosing with the study drug. You will be asked to record your blood sugar results in a log that we will provide you. During weeks 5 – 12, you will be asked to record your blood sugar one day per week.

PRECISION OLFACTORY DELIVERY (POD) DEVICE

The Precision Olfactory Delivery Device or POD provided to you as part of this study should only be used as previously described to you. You should not give the POD to any individuals not directly related to the administration of the study insulin or placebo. Do not make changes, modifications, or improvements to the POD device. If you have any questions about the device, contact the study staff. Any POD devices provided to you will be returned upon completing your participation, study termination or at the request of the study PI or staff. The POD device is manufactured by Impel NeuroPharma, Inc. By participating in this research study, you will not have ownership rights to the POD device.

TELEPHONE MONITORING

A study team member will call you during the first week of taking the study drug, week 8 and week 12 to review your blood sugar monitoring log and to make sure that you are not having any problems.

A study team member will complete a telephone questionnaire with you after each LP procedure.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 4 months. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. There are no known risks associated with receiving the study placebo. There are also no known consequences of not receiving active therapy. Risks and side effects related to your participation in this study are outlined below:

NASAL INSULIN ADMINISTRATION

No serious adverse reactions to insulin given through the nasal passages have been observed in similar studies. Insulin given in this manner has not been associated with low blood sugar in our previous studies. Nevertheless, the study nurse will train you to recognize signs of low blood sugar such as shaking, fast heartbeat, sweating, dizziness, anxiousness, hunger, impaired vision, weakness, headache, and irritability. If you develop these symptoms, check your blood sugar level, eat a snack, and call the study nurse, Deborah Dahl at [redacted].

A few subjects in previous studies complained of "drippy nose" after being given the study drug, but these symptoms did not persist beyond the initial use of the study drug. As with any drug, there may be unexpected side effects to insulin aspart.

RISKS ASSOCIATED WITH USE OF THE NASAL DEVICE

There are risks that may occur from use of the nasal device, although these are not expected to be serious. It is important that you carefully follow the instructions you are given about how to administer the study drug. If you don't carefully follow the instructions, it is possible that you may not receive the correct dose. You could also experience some discomfort to your eyes or face if you do not hold the device to your nose as directed. You and your study partner will be instructed on how to properly operate and care for the device.

BLOOD COLLECTION / IV TUBE INSERTION / FINGER-STICK GLUCOSE CHECK
Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Some people may experience fainting or dizziness, and there is also a slight risk of infection at the site of the needle stick. To minimize these risks, experienced medical personnel will collect all blood and sterile conditions will be maintained. About 11 1/2 tablespoons of blood will be taken during the entire course of this study and your body will readily produce new blood to make up for the loss. There is a possibility of discomfort and bruising associated with pricking your finger for the finger-stick glucose.

COGNITIVE TESTING
Repeated evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

MRI SCAN
There are no known biological risks associated with MRI. An MRI may cause anxiety for some people due to the loud noises made by the machine and the confined space of the testing scanner. There is also a risk of injury if metal is brought into the imaging room, which might be pulled into the MRI magnet. People with pacemakers, aneurysm clips, artificial heart valves, ear implants or metal/foreign objects in their eyes are not permitted to have an MRI. You will be asked to complete an MRI screening form that would identify these objects prior to each scan to ensure your safety.

LUMBAR PUNCTURES (LP)
During and after the procedure, you may have temporary pain or discomfort at the insertion site in your back. You may feel faint. You may experience a mild headache, neck ache, or backache from the positioning required for the procedure. Rarely, a low pressure headache may develop after the procedure due to leakage of spinal fluid. If this headache persists it may require additional treatment. Uncommonly a blood patch (injection of some of your blood into the puncture site to patch the spinal fluid leak) may be required. This typically relieves the headache immediately. Because we use a very small, specialized needle in our study, the risk of a low pressure headache after a lumbar puncture is less than 1-2%.

Although very rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine l%) used for the LP. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist). Potential but very rare risks of an LP include infection of the skin or in the spinal fluid space (meningitis), bleeding, or damage to nerves in your back. The risk of these is very small. To minimize these risks, the LP procedure will be performed by experienced medical professionals who are specifically trained to carry out this procedure.

OTHER POTENTIAL RISKS
There also may be other side effects that we cannot predict. You should tell the research staff about all the drugs, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

CONFIDENTIALITY

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. We will do our best to protect your confidential information.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, the National Alzheimer's Coordinating Center has obtained a Certificate of Confidentiality from the National Institutes of Health. The Certificate of Confidentiality is needed because sensitive information will be collected during the course of this study. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the investigator from notifying state or local authorities of North Carolina if he/she obtains evidence of abuse or if you threaten violence to yourself or others.

STORAGE OF BIOLOGICAL SAMPLES

If you agree to participate in this study, we will draw about 11 1/2 tablespoons of blood over the course of the study. Less than 2 tablespoons of cerebral spinal fluid (CSF) will be collected during each LP procedure. Blood and CSF will be used for future research to learn more about other diseases. Your samples will be obtained in the Sticht Center at Wake Forest Baptist Medical Center. The samples will be stored at Wake Forest Baptist Medical Center. An Institutional Review Board (IRB) must approve any future research study using your tissue sample. Samples collected will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator and study staff will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample. Storage of blood and CSF is not optional.

The research that may be performed on your blood and CSF samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have Alzheimer's or other diseases at some point in the future. The results of the research performed with your samples will not be given to you or your doctor and it will not be put in your medical record. The research using your samples will not affect

your care. Your blood and CSF samples will be used only for research and will not be sold.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not receive benefit from participating in this study. However, your participation may help us understand how insulin affects cognition in subjects with memory impairment. The study may also help us to understand the role that insulin plays in certain conditions, such as Alzheimer's disease.

As a part of the study, we will provide you with ECG and blood test results that you may give to your physician. These tests can reveal more information about your heart, blood sugar, cholesterol levels, liver function, and kidney function. We will advise you to consult with your physician if your tests suggest that you have a medical problem.

WHAT OTHER CHOICES ARE THERE?

There are currently 5 drugs approved for the treatment of Alzheimer's disease:

- Tacrine (Cognex®)
- Donepezil (Aricept®)
- Galantamine (Razadyne®)
- Rivastigmine (Exelon®)
- Memantine (Namenda™)

Thus, alternatives to participation in this study include use of the above medications or no treatment at all. You may discuss these options with your physician.

If you currently take one of these medications, you may still be eligible for the study. However, starting a new medication at any point during the course of the study should be discussed with your study doctor.

WHAT ABOUT MY HEALTH INFORMATION?

Research records will be kept as confidential as possible within the limitations of state and federal law. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the:

- The study investigator and his/her staff, or others at Wake Forest School of Medicine who oversee research
- Other people or laboratories providing services for this research project on behalf of Wake Forest School of Medicine and Wake Forest Baptist Medical Center
- Study Sponsor (National Institute on Aging)

In order to analyze the data collected during this research study, all of the health information generated or collected about you during this study may be inspected by the study Sponsor and its authorized agents, the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies and the Institutional Review Board (IRB).

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, we will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Once your personal health information is released it may be disclosed, at which point your health information will no longer be protected by federal privacy regulations.

The findings of this research will be presented at meetings or in publications; however, neither your name nor identity will be disclosed in those presentations.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your genetic information as described in this consent form. You should be aware, though, that if your genetic information were accidentally released to the wrong source, federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or by adoption agencies.

ClinicalTrials.gov is a website that provides information about clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Suzanne Craft that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Suzanne Craft
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest School of Medicine and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital medical record will be created for all study participants. Information about your participation in the study will be placed in this medical record, along with any routine medical test results that were obtained at North Carolina Baptist Hospital as part of this study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study drugs and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive up to a total of $310 upon completion of the study.

Pre-Study Drug Lumbar Puncture	Pre-Study Drug Memory Testing	Pre-Study MRI	6 Week Study Memory Testing	2, 4 & 10 Week Safety Check	Post-Study MRI	Post-Study Drug Lumbar Puncture	Post-Study Drug Memory Testing
$75	$30	$25	$20	$10 (each)	$25	$75	$30

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute on Aging. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year.

The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated does not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be due to unexpected reactions to the study drug, failing to follow instructions or if the study is stopped early.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Suzanne Craft at [redacted] (after hours number [redacted], ask for the Geriatrician on call and reference the SNIFF Quick study).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study ECG and/or laboratory tests to your personal physician?

[ ] Yes [ ] No

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Wake Forest®
School of Medicine

Study of Nasal Insulin to Fight Forgetfulness
Short-Acting Insulin Aspart
"SNIFF – Quick"

Informed Consent Form to Participate in Research
Suzanne Craft, PhD Principal Investigator

STUDY PARTNER INFORMATION & CONSENT

As the subject's study partner, you have important tasks that need to be carried out in order for the study to be conducted in the safest and best manner possible. These responsibilities include:

1) You must have direct contact with the subject for a minimum of 10 hours per week.
2) You must go along with the subject to at least 4 clinic visits.
3) You are an important source of information about the subject. You will be asked questions in order to find out whether there are any changes in the subject.
4) You must be able to assist in study drug preparation and administration or able to assure that another person (such a family member or friend or other) will be able to assist the subject in the study drug preparation and administration.

If for some reason you become unable to carry out your responsibilities, please tell the study coordinator immediately. You may be asked to help find someone else close to the participant who can take over your duties.

You will receive no payment or other compensation for taking part in this study.

You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction.

You voluntarily consent to participate in this study.

Study Partner Name (Printed):_____

Study Partner Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm