Cover Page for Protocol with Statistical Plan

Official Title:	Preserving Lean Body Mass During Weight Loss In Elderly Obese Patients With GLP-1 Receptor Agonist Treatment
NCT number:	NCT05302596
Document Type:	ICF
Date of the Document:	03/06/2023

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Preserving Lean Body Mass During Weight Loss In Elderly Obese Patients With GLP-1 Receptor Agonist Treatment

Version Date: 1.15.2022 (Protocol Version 1)

Investigator: ***Dr. Husam Ghanim, PhD***
1000 Youngs Rd
Suite 105
Williamsville, NY 14221

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

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

You are being invited to take part in a research study because you might meet the criteria for this study investigating effect of semaglutide on body weight and body composition in elderly obese patients.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Both obesity and aging are associated with increased risk of chronic diseases such as type 2 diabetes, hypertension, cardiovascular diseases, and cancer. Therefore, weight loss is typically recommended to lower many of these risks. However, in the aging population approximately 25% - 33% of all weight lost in older adults during intentional weight loss interventions is fat-free mass (lean body mass and bone mass, which further contributes to weakening of the muscles and bones and increases risk for impaired activity, disability, and frailty. Therefore, there is a need for a weight loss intervention that can cause significant fat mass loss while preserving lean body mass, especially in the older obese patients.

Glucagon-Like peptide receptor agonists (GLP-IRAs) are a class of drugs approved by FDA to lower blood sugars in type 2 diabetes and for weight loss in obesity. We also showed that it can lead to significant weight loss in obese type 1 diabetic patients. The weight loss was observed was attributable to the loss of total body fat, including visceral fat, while there was no change in lean body mass when imaged by dual-energy x-ray absorptiometry (DEXA). Therefore, we are planning to test if semaglutide (a weekly injectable GLP-1 RA) will work in similar way in older obese patients. Therefore, the purpose of this study is to learn how semaglutide works and its effect in weight loss and body composition in older obese patients.

Permission to Take Part in a Human Research Study

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

We expect that you will be in this research study approximately 16 weeks and include up to 3 study visits to the study site.

You will be assigned in random way in one of two groups:

Control group: Standard of care weight loss program that includes lifestyle changes and personalized exercise and dietary education.

Semaglutide group: semaglutide (up to 1mg) once weekly injection added to the standard of care weight loss program. Semaglutide dose will be started at 0.25 mg dose during the baseline visit and doubled every 2 weeks up to 1mg dose or up to maximum tolerable dose. Patients will be instructed on how to inject themselves with the drug and how to increase the dose. At every visit, number of injections taken and doses will be collected.

All patients will receive instructions at the beginning of the study on weight loss nutritional program and appropriate physical activity to be performed for the next 16 weeks. You and the study team will know which treatment group you will be assigned to.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

All drugs and devices have the potential risk of an allergic reaction, which, if not treated, could become life-threatening. Potential side effects of GLP-1 RA, like semaglutide, include GI side effects including nausea (especially when you start using semaglutide); vomiting, stomach pain, loss of appetite; diarrhea; or constipation. The risk of hypoglycemia (low blood sugar) appears to be low with semaglutide, however, it could increase when combined with exercise or lower food intake as proposed in this study. There are other risks related to study procedures as well.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, you will benefit from the routine medical and laboratory examination results and you could lose weight as part of your participation in the study. Your participation in this research study may provide very important new information regarding the effects of this new product.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. You will have to sign and date this participant information and informed consent form to indicate you choose to take part. You may change your mind and withdraw without giving any reason, at any time. If you choose to not participate or you withdraw from the study, you will not lose any medical benefits to which you are entitled, and it will not have any effect on your future medical care.

Instead of being in this research study, your choices may include other treatments available to you, like diet and exercise, medications, stomach balloon, and surgery, as applicable to your condition. The study doctor will discuss with you the risks and benefits of the alternative treatments.

Permission to Take Part in a Human Research Study

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at The Diabetes Endocrinology Research Center of WNY, 716-535-1850. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

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

If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, you should call the number listed above.

How many people will be studied?

We expect about 16 people will be in this research study.

What happens if I say yes, I want to be in this research?

Before agreeing to participate in this research study, it is important that you read and understand why this research is being done and what it will involve for you. This participant information and informed consent form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. Please take time to read the following information carefully. You may want to talk to others before making your decision. Ask the study personnel if there is anything that is not clear or if you would like more information. Take the time you need to decide whether or not you are willing to take part in this study. After you read and understand this consent form, you and one of the research team will sign and date it. A copy will given to you.

Your medical history and current medications will then be obtained as well as your blood pressure and vitals. A physical examination will also be done. Blood samples (about 25 ml, about 1.7 tablespoons) will be taken to evaluate HbA1c (hemoglobin A1c, for diabetes assessment), CBC (complete blood count) and CMP (complete metabolic profile). Patients daily eating and exercise habits will be collected and reviewed for determining lifestyle intervention. Patients meeting all the inclusion and exclusion criteria based on all screening tests will be enrolled in the study.

At the baseline visit, and for all other visits, you will be expected to come fasting (10 -12 hours) to the research center. During the baseline visits blood (about 25 ml), body weight and other vitals will be collected. Other tests that will be performed at the baseline visit include Fat biopsy aspiration, DEXA scans, muscle strength measurement and a quality-of-life questionnaire.

Permission to Take Part in a Human Research Study

At the end of the baseline visit, a treatment group will be assigned to you by chance. You and the study team will know which treatment group you will be assigned to.
You will be assigned in random way into one of two treatment groups:
Control group: Standard of care weight loss program that includes lifestyle changes and personalized exercise and dietary education.
Semaglutide group: semaglutide (up to 1mg) once weekly injection added to the standard of care weight loss program. Semaglutide dose will be started at 0.25 mg dose during the baseline visit and doubled every 2 weeks up to 1mg dose or up to maximum tolerable dose. Patients will be instructed on how to inject themselves with the drug and how to increase the dose. At every visit, number of injections taken and doses will be collected and any side effects will be monitored

There will be three more additional visits at the research center at 4 weeks (safety visit), 8 weeks and at 16 weeks (final study assessment visit). During these visits blood (25ml) will be collected, weight and vitals measured, and information regarding any adverse events including hypoglycemia (blood sugar <70 mg/dl) events will be recorded.

During the final visit at 16 weeks there will also perform another fat biopsy aspiration, DEXA scans, muscle strength measurement and age-appropriate quality of life questionnaire.

All patients will receive instructions at the beginning of the study on weight loss nutritional program and appropriate physical activity to be performed for the next 16 weeks. The program will be based, in-part, on dietary and exercise habits collected at screening visit. For the entire duration of the study, participants will maintain a daily diary to document food and exercise activities to ensure compliance with lifestyle program provided.

You will be provided with glucose meter and glucose strips to measure fingerpick blood glucose. For the entire duration of the study, patients will be asked to measure their blood sugars at least one time after exercise and to record any hypoglycemic events (glucose <70mg/dl) in their diary, you will be instructed to record any other untoward side effects like nausea, vomiting, changes in appetite and other experiences in the diary. You will also be instructed to call the Diabetes Center to speak to a study investigator directly in case of any problem or untoward side effects.
You will receive phone calls at 2- and 12-weeks following start of treatment to collect any safety data and at 2 weeks after the end of the treatment. You will then be discharged from the study. Patients will be instructed to call the research center anytime they have a question or side effects.

At the 4- and 8-weeks visits, the daily diary will be reviewed for food and exercise activities, and instructions will be provided again to reinforce intervention.

Standard of care weight loss program:
You will be instructed to implement dietary and exercise program for the next 16 weeks and to record their activities on daily food and exercise diary provided.
1- Energy intake should be reduced by 500–750kcal/day.
2- Dietary fat should be reduced to 30% of total energy intake maximally.
3- Meal replacements (if used) will be consumed during breakfast and lunch.
4- Dinner consisted of conventional food and participants will be encouraged to eat fruits and vegetables within their calorie limit.
5- You will be instructed to ingest 1.0–1.5g of protein/kg/day and spread consumption equally throughout the day. A leucine-enriched balanced amino acid supplement can be used.

6- Subjects will be instructed to perform aerobic, muscle-strengthening, flexibility, and balance exercises. Minimally, this should include moderate-intensity aerobic activity for 30 minutes five days per week or vigorous-intensity aerobic activity for 20 minutes three days a week, 10–15 repetitions of 8–10 major muscle group strengthening exercises two or more nonconsecutive days each week, 10 minutes of flexibility activities at least two days a week, and balance exercises three times a week for fall prevention.

Blood collection:

The study requires collection of blood and urine samples. Throughout the course of the study, the total amount of blood taken will be approximately 100 mL (6.5 tablespoons).

Fat aspiration procedure: Fat tissue sample will be collected during baseline and 16 weeks visits. Subcutaneous fat (under the skin fat) aspiration will be performed on abdomen at a 10 cm distance from the belly button under sterile conditions and local anesthesia.

DEXA scans: Patients will visit an off-site imaging center (Seton Imaging, Amherst, NY) for this non-invasive test.

Muscle strength: Biceps and quadriceps muscle strength will be collected as the average of 3 measurements using the MicroFET2 dynamometer. For these assessments, participants will be asked to take a seat and either lift an arm or kick a leg straight while be restrained by the MicroFet2 device allowing collection of force generated. This will be performed at baseline and at 16 weeks.

Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF) will be performed at 0- and 16-weeks visits.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Disclose all medical history to the Investigator and staff.
- During the entire study, you must carefully follow any instructions given to you concerning the study.
- You should not eat or drink anything for 10 to 12 hours before all study visits (you may drink water up to 2 hours before you arrive), and not perform moderate or intense physical activity within 12 hours of study visits where blood samples will be collected.
- You must take the semaglutide injections according to the study doctor's instructions.
- For the entire duration of the study, you will maintain a daily diary to document food and exercise activities to ensure compliance with lifestyle program provided.
- For the entire duration of the study, you will be asked to measure your blood sugars at least one time after exercise and to record any hypoglycemic events (glucose <70mg/dl) in your diary.
- For the entire duration of the study, you will be asked to record any untoward side effects like nausea, vomiting, changes in appetite and other experiences in the diary.
- You should tell the study doctor about any side effects that occur during the study.
- Some medications are not permitted during the study, so you must discuss and obtain approval of any new medications with the study doctor before you begin its use.

- For any illnesses or injuries, you should contact the study doctor immediately or, in a medical emergency, seek appropriate care.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, you are required to notify the study doctor of your decision. If you have some unresolved health problems when you leave the study, the study doctor may, if you agree, need to collect information about your health until the problem resolves. If you choose to withdraw before the planned final visit, you might be asked to complete an end of study visit for your safety. DEXA scan and fat biopsy procedures and QOLQ may be performed if you agree.
If you withdraw, no new data will be added to the study database. However, the study investigators may still use already collected information. If you decide to withdraw, you may also ask for identifiable samples to be destroyed to prevent further analysis.

Is there any way being in this study could be bad for me? (Detailed Risks)

- **Blood Draws:** The risks associated with the study blood draw are generally considered to be minimal. All subjects will be informed of the complication of venipuncture, which includes mild bruising at the site, which should resolve in few days. They will also be informed about the possibility of infiltration at the time of performing blood draws in which case another venipuncture at different site will be performed and this may lead to bruising at more than one sites. Serious risks associated with venipuncture may also include infections and thrombosis. If any of these serious side effects is observed, the patients will be asked to call us immediately or seek immediate medical help.
- **Fat tissue collection:** The risks involved with fat biopsy procedure are also very minimal. This procedure is performed under local anesthesia and therefore study subjects might experience momentary discomfort at the time of giving local anesthesia. There is a small risk of bleeding at the site of incision, but this will be controlled with cotton gauzes and pressure. The risk of infection is very rare as the procedure is done under sterile conditions.
- **Semaglutide side effects:** Potential side effects of semaglutide include GI side effects including nausea (especially when you start using semaglutide); vomiting, stomach pain, loss of appetite; diarrhea; or constipation.
- **Low blood sugar:** The risk of hypoglycemia (low blood sugar) appears to be low with semaglutide, however, it could increase when combined with exercise or lower food intake as proposed in this study.
- **Semaglutide and risk of thyroid tumors:** In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. However, it received FDA-approval for the treatment of type 2 diabetes in 2017 following large Phase 3 trials including the cardiovascular safety trial SUSTAIN-6. Based on the above rodent studies, semaglutide is contraindicated in those with a personal or family history of medullary thyroid carcinoma and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). However, following review of human data with GLP-1RAs, FDA does not require or suggest routine monitoring of serum calcitonin/ thyroid ultrasound in people treated with semaglutide.
- **Injection-site reactions:** Serious injection-site reactions, with or without bumps (nodules), have happened in some people who use GLP-1RAs but are less frequent with semaglutide. Injection-site reactions have rarely required surgical intervention. Participants will be instructed to report any injection site reactions including nodules to study investigators.
- **Kidney injury:** GLP-1 RA might cause acute kidney injury in patients without underlying renal disease especially in patient who had experienced nausea, vomiting, diarrhea or dehydration.

- **Severe allergic reaction** (anaphylaxis) to study drug ingredients may accrue in rare cases.
- **Unforeseen risks:** There might be other unforeseen risks associated with the use of semaglutide in this age population. This research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.
- **Risks due to exercise:** Exercise related events including, falls, fractures, dizziness, and loss of balance.

- It is important that you tell the study doctor about any adverse changes in your health as soon as they occur, whether or not you think they are caused by the investigational product.

- **Loss of Confidentiality**

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy and therefore there is always the risk of losing confidentiality.

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

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

During your participation in this research study, the study doctor and study staff will collect or create coded (does not include your name, birth date, social security number, etc.) health information about you (for example, medical histories and results of any lab tests, examinations, or procedures you undergo while in the study) and record it on study documents. The study doctor will keep this health information in your study-related records (that we will refer to as "your study records"). These records will be kept locked in cabinets or in password protected computers and folders. In addition, the study doctor may obtain, and include in your records, information regarding your past, present, and/or future physical or mental health and/or condition. The study doctor may ask you to sign a separate authorization to obtain some or all your medical records from your regular doctor. Records that may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you will be kept locked in a separate location or cabinet from study records. Health information that could identify you is called "Protected Health Information" (or "PHI").

Permission to Take Part in a Human Research Study

Can I be removed from the research without my OK?

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

- You have or develop side effects or medical conditions that may jeopardize your safety if you continue in the study
- You do not comply with the requirements of the study (see section "What are my responsibilities..."above.

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

What else do I need to know?

Who is paying for this research?

This research is being funded by CTSI Translational Pilot Studies Program Grant.

What medical costs am I responsible for paying?

There will be no charge to you for your participation in this study. The study drug, study-related research procedures, and study visits will be provided at no charge to you or your insurance company. Cost of adherence to weight loss program (dietary and exercise needs) is the responsibility of the participant. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard of care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the study and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.
You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.
The University at Buffalo, Buffalo General Hospital and ECMC make no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including the University at Buffalo.
By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you for the study visits you complete according to the following schedule:

Visit 1: blood draw ($25), fat biopsy ($75), DEXA ($25)
Visit 2: blood draw ($25)
Visit 3: blood draw ($25)
Visit 4: blood draw ($25), fat biopsy ($75), DEXA ($25)

Permission to Take Part in a Human Research Study

Completed daily diary: $50/study (prorated if not fully completed)

If you complete all study visits, you will be paid up to $350 in a form of a check at the end of study. If you do not complete the study, for any reason, you will be paid for each study visit you do complete according to the schedule above.
Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds $600.00 in a calendar year, you will be issued a form 1099.

What are my alternatives to participating in this research study?

Instead of being in this research study, you can pursue other standards of care for weight loss interventions.

.

What will happen to my information and samples?

Your de-identified information and samples will be stored in locked cabinets or password protected computers and in samples kept in temperature-controlled freezers. It may be used to create publications and/or develop methodology and be relied upon for future research including some that may be sold and/or make money for others. If this happens, there are no plan to tell you, or to pay you, or to give any compensation to you or your family.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If this happens, you may want to get a second test from a certified clinical laboratory, consult your doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Primary Care Physician/Specialist notification option:

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.
_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.
_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.
Name of provider:_____
Telephone number of provider:_____

Permission to Take Part in a Human Research Study

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

___√__ Information from your full medical records: name, address, phone number, your email address, date of birth, medical history, information from your study visits, including all test results (height, weight, blood pressure, glucose, gut hormones and insulin levels, etc.), other health conditions, related tests/ procedures.

___√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

___√__ KALEIDA Health, Buffalo NY
___√__ ECMC Healthcare Network, Buffalo NY
___√__ University at Buffalo School of Medicine (UBMD)
___√__ Principal Investigator or designee
___√__ Other (identify): Diabetes and Endocrinology Research Center of WNY

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee
_____ Other(s) (identify):_____

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√___ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
___√__ The sponsor of this research study UB-CTSI
___√__ The organization(s) responsible for administering this research: **IRB and other representatives of UBIRB**

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New

York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

___√__ c. This authorization does not have an expiration date unless you revoke this authorization in writing.

__√___ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Dr. Husam Ghanim, PhD
1000 Youngs Road, Suite 105
Williamsville NY 14221

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	