Informed Consent Document

A Double-Blind, Randomized, Placebo Controlled, Clinical Trial of an Antiplaque Chewing Gum (30 mg) - Phase 2 Proof of Concept in a Generally Healthy Patient Population

Participant: _____

CONTACT INFORMATION: The contact information is a resource if you have questions about the study, your participation in the study, the study product, any adverse event that you may experience, possible compensation, your rights as a study participant, and the safety of this clinical trial.

Principal Investigator (PI): (for questions about an injury related to the research study, adverse events, the study product, compensation due to injury, or to revoke in writing the HIPAA Authorization)

Jeffery Milleman, DDS, MPA

Salus Research
1220 Medical Park Dr, Bldg #4
Fort Wayne, IN 46825
260-755-1099;

The contact telephone number for after work hours is: 260-413-7777

Sub-investigator(s): (for questions relating to the research study, adverse events, or the study product)

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Study Coordinator:

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Research Monitor: (for questions relating to the safety of this study)

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Institutional Review Board: (for questions about your rights as a participant in research)

U.S. Investigational Review Board, Inc.
Chairperson: Ms. Rosa M. Fraga

6400 S.W. 72nd Court
Miami, Florida 33143
786-473-3095

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And

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What Is Informed Consent

You are being given the opportunity to participate in a research study to assess the safety and response to an anti-plaque chewing gum (APCG). The study will be conducted at Salus Research, in Fort Wayne, Indiana. The research study is approved by: U.S. Investigational Review Board (Central IRB) and the Human Research Protection Office US Army Medical Research and Material Command (HRPO USAMRMC). The study will be conducted at Salus Research under the direction of the Principal Investigator, Dr. Jeffery Milleman. The study is sponsored by The Surgeon General, Department of the Army.

Please take your time when making your decision about participating in this study. Dr. Milleman or another member of the study team will explain the study to you and answer any questions you may have. Study personnel will wait to continue the informed consent discussion with you until you have had at least 24 hours to read this document. It is important that you understand what will be done and the possible risks to you, so please ask questions at any time. To give informed consent, you must understand that:

- You will be given detailed information about the research study.
- You are free to ask any questions that will enable you to understand the nature of the study.
- You will be asked to read, sign, and date this informed consent after you have an understanding of the study and decide to participate.
- Taking part in this study is completely voluntary.
- Refusal to participate will involve no penalty or loss of any benefits to which you are otherwise entitled.

- You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- You will be given a signed and dated copy of this consent document to keep.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results of the study. You can search this website at any time. You can get information by typing the name of the investigational compound or protocol title into the website's search field.

The clinical staff will talk with you about the information in this document. The study investigators will encourage you to ask questions about this study at any time. You can take as much time as you need to review this document and take it home if you would like to discuss your study participation with your family, friends, and related community.

This investigational product has not been licensed for sale by the United States of America but has been approved by the Food and Drug Administration (FDA) for human research.

Why Is This Investigational Product Being Offered?

Sometimes there are situations where daily oral hygiene (teeth brushing, flossing and mouth rinses) cannot be followed. This investigational product is being offered as a chewing gum which can be used in place of daily oral hygiene to reduce the buildup of plaque on the teeth...

What Is the Purpose of the Study?

We are testing a new medication called Anti-Plaque Chewing Gum (APCG) which we think may be effective in helping patients reduce the amount of plaque that forms on their teeth. Poor oral hygiene and diet can lead to a build-up of bacteria, which then leads to a buildup of plaque on the teeth. The buildup of plaque on the teeth may cause tooth decay (cavities), gum disease and other oral infections. This chewing gum may help reduce plaque buildup on the teeth and prevent gingivitis (gum disease).

Sometimes we don't know which form of treatment is best. We want to know if the APCG is able to reduce plague buildup on the teeth and is safe to use. To find out, we will compare the APCG treatment to a placebo treatment. In this case, a placebo is a chewing gum that looks exactly like the APCG, but has no active ingredients and has no physical effect on the patient. In this study, patients will be put into 2 groups. One group will get the active drug (APCG) treatment and the other group will get the inactive drug (placebo) treatment.

What Is the Investigational Product?

The investigational product is a medication that has active ingredients that kill micro-organisms or prevent their growth in the mouth, thus helping to prevent the buildup of plaque on the teeth that leads to gingivitis (gum disease) and periodontitis (diseased tissues around the teeth). This investigational product has been made into a chewing gum. The active ingredient in the test gum is called KSL-W.

How Will the Medication Be Given?

The medication will be given as a chewing gum. Neither you nor the study staff will know whether you will be given the APCG test gum or the placebo gum. This is called a double-blind treatment. You will chew the gum, preferably after meals three times a day for four consecutive days. You will chew the gum on both sides of your mouth for 20 minutes.

What Are the Requirements to Be in the Study?

To be eligible for this research study, you must meet all of the following conditions:

- Males or females between 18 and 64 years of age (inclusive at time of screening)
- A negative urine pregnancy test (females of child-bearing potential only)
- A negative urine drug test
- On a reliable form of birth control for at least 30 days prior to the start of the study and willing to use a reliable form of contraception for the duration of the study (Females of childbearing potential only), with reliable contraception defined as:
  - Abstinence which has been the customary lifestyle of choice (acceptable only if this has been your usual method of contraception)
  - Oral contraceptive (birth control pills), either estrogen progesterone combined, or progesterone alone
  - Injectable progesterone
  - Implants of levonorgestrel
  - Estrogenic vaginal ring (containing estrogen)
  - Percutaneous contraceptive patches (birth control patches)
  - Intrauterine device (IUD) or intrauterine system
  - Double barrier method [condom or occlusive cap (diaphragm or cervical vault caps) plus spermicidal agent (foam, gel, film, cream, suppository)]
  - Male partner sterilization at least 6 months prior to the female subject's entry into the study, and this male is the sole partner for that subject
  - Post-menopausal for at least two years
- Good health, as determined by pertinent medical history, physical examination, and vital signs (heart rate, respiration rate, blood pressure and body temperature).
- A minimum of 20 natural teeth with 6 scorable surfaces per tooth (6=the number of surfaces on your tooth that the dental examiner can look at and determine the amount of plaque buildup)
  - Sufficient number of opposing posterior (back) teeth to chew on both sides of the mouth as determined by the examining dentist
  - Teeth that have gross caries (excessive decay), full crowns or extensive restorations on facial and/or lingual (front and/or back) surfaces, orthodontic bands (braces), and third molars are not included in the tooth count
- Subject must have refrained from all oral hygiene procedures 12 to 16 hours prior to screening visit.
- Plaque Index of 1.95 or greater {Quigley Hein Turesky Plaque Index} (Turesky et al-1970) (a value measured by the dental examiner to determine the amount of plaque buildup on your teeth)

- Willing to forgo any optional dental procedures during the study period, such as dental prophylaxis (preventative dental procedures or teeth whitening).
- Ability to comprehend and a willingness to sign an informed consent, which includes the Authorization for the Release of Health Information (HIPPA) document.
- Ability to access the internet to complete the drug compliance information (electronic diary of when you chewed the test gum)
- Willingness to comply with (follow) all study procedures

You will be excluded from the study if you are/have:

- Phenylketonuria (a condition in which one is unable to metabolize phenylalanine, found in NutraSweet® also known as Aspartame)
- Acute or chronic medical conditions, organ system disease, or medications that, in the principal investigator's opinion, would impair the subject's ability to participate
- Temporomandibular Disorders (conditions that cause pain and dysfunction of the jaw joint and muscles of the jaw that control movement)
- Self-reported allergy to sucralose or mint flavors (peppermint powder, isomalt)
- Self-reported use of tobacco products including e-cigarettes
- Use of any type of anticoagulant medications (blood thinning drugs)
- Routine use of proton pump inhibitors (such as Omeprazole (Prilosec®), Lansoprazole (Prevacid®), Dexlansoprazole, Esomeprazole (Nexium®), Pantoprazole (Protonix®), Rabeprazole
- Allergic to any component of the study drug (components include: cetylpyridinium chloride, isomalt, peppermint powder, sucralose, colloidal silicon dioxide or magnesium stearate)
- Gross oral pathology, including widespread caries (cavities) or chronic neglect, extensive restoration, pre-existing gross plaque or calculus, or soft or hard tissue tumor of the oral cavity (mouth)
- Orthodontic appliances (braces) or removable partial dentures (false teeth) that will compromise the ability of the potential subject to participate in the study
- Periodontitis (gum disease) as indicated by periodontal pockets (tissues around the tooth) greater than 4 millimeters on more than one site
- Receipt of any investigational drug/test product within 30 days prior to study entry with study entry defined as Day 0 or currently participating in either the active or follow-up phase of any other Investigational Study or planning to participate in any other Investigational Study during participation in this trial
- Participation in the Phase 1/2a anti-plaque study
- Receipt of antibiotics within 30 days prior to study entry
- Need for antibiotic prophylaxis prior to invasive dental procedures

- Receipt of prescription antibacterial oral products (eg products containing chlorhexidine) within 30 days prior to study entry
- Pregnant or breast-feeding female
- An employee of the study site directly involved with the study
- Inability to comply with assigned treatment regimen

What Precautions Should I Take During the Study?

The effect of this study medication on unborn babies is currently unknown. If you are a female, you should not breastfeed or become pregnant during the study or within 3 months after receiving the last dose of study drug. If you are a male, you should not have unprotected sex for at least 3 months after receiving the last dose of study drug.

What is the Potential Benefit of the Study and is there an Alternative to Participating?

There is no benefit from participating in this study other than the potential for added protection against gingivitis (gum disease) and periodontitis (diseased tissues around the teeth). You will receive oral examinations as part of the dental examination and you will have all your teeth polished at Baseline (Visit 2). Research is designed to benefit society by gaining new knowledge.

The alternative to participating is to choose not to participate and to practice oral hygiene as you normally would each day.

What Are the Potential Risks and Discomforts?

There are potential risks and discomforts in any medications you take. Some of the side effects that you may experience taking APCG are: coated tongue, tooth discoloration, a change in taste, a loss of taste, tongue pigmentation (color), throat tightness, abdominal discomfort (stomach ache) and flatulence (gas).

Study Event Schedule:

The procedures that will be completed during the course of the study are shown in the following Table.

Study Events Schedule

	Study Visit/Day					
	Visit 1	**Visit 2**				**Visit 3**
	Screening (-14± 2)	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**
General Procedures						
Written Informed Consent/HIPAA	X					
Evaluation Inclusion/ Exclusion Criteria	X	X				
Demographic Data	X					
Medical History	X					
Vital Signs (BP, HR, RR Temperature)	X	X				X
Physical Exam	X					X[a]
Urine Drug Screen	X					
Urine Pregnancy Test	X[b]					X[b]
Periodontal Examination	X[c]					
Intraoral Exam (OHT, OST)	X	X				X
Oral Hygiene Check	X[d]	X[d]				X[d]
Randomization (1:1 stratified by evaluator)		X				
Plaque Index Score	X	X[e]				X
Teeth Polishing		X				
Dispense Study Drug for Supervised and Unsupervised Use		X[f]				
Study Drug Administration		X[g]	X[g]	X[g]	X[g]	
Collect Used Study Drug		X[h]				X[h]
Electronic Diary Information System		X[i]	X[i]	X[i]	X[i]	
Adverse Event Reporting		X				X
Concomitant Medications	X	X				X
Study Discharge						X

BP-blood pressure, HIPAA-Health Insurance Portability and Accountability Act, HR-heart rate, RR-respiration rate, OHT-oral hard tissue, OST – oral soft tissue, QHT-Quigley-Hein Turesky Plaque Index

[a] Brief symptom oriented physical exam (based upon reported adverse events)

[b] Pregnancy test for females of childbearing potential

[c] Includes determination of number of teeth, score-able surfaces and pocket depths around teeth

[d] Confirm subject has refrained from all oral hygiene procedures (flossing, brushing of teeth, mouth wash rinse) for 12 to 16 hours prior to Screening and Day 0 (Baseline). On Day 4, confirm subject has refrained from all oral hygiene procedures since chewing their last dose on Day 3

[e] Measured after randomization, but before teeth polishing

[f] Subject will be allocated 14 tablets of gum for the 4 day study period

[g] Subject will chew one tablet of gum for 20 minutes preferable after a meal (breakfast, lunch, dinner) or every 4 to 6 hours for a maximum of 3 chews per day. Chewing will be balanced as equally as possible between both sides of the mouth. The first tablet will be given under supervision in the clinic. Oral hygiene is not allowed at any time during the 4 day treatment. Oral hygiene cannot resume until after the determination of the Plaque Index Score on Day 4

[h] After each chewing period, the gum is disposed of in individual labeled bags. Subject records time/date of gum disposal on each bag

[i] Subject records all start /stop times of gum chewing via the internet using the electronic diary information system (ePRO).

Screening – Visit 1

If you agree to take part in this study, the study staff will complete the following tests and procedures during a screening period to decide if you can take part in this study. You will be asked to sign a consent form before any tests or procedures are done. After the consent, the following assessments will occur:

- Study inclusion and exclusion criteria will be evaluated.
- Your medical history and demographic information will be collected.
- Your vital signs (diastolic and systolic blood pressure, respiration rate, heart rate and temperature) will be measured.
- A physical exam will be performed.
- A urine drug screen will be performed.
- If you are female and are able to become pregnant, you will take a urine pregnancy test.
- A periodontal exam will be performed. During this exam, the investigator will count your teeth, determine how many tooth surfaces and pockets depths in the tissues around your teeth can be measure.
- An intraoral examination will be performed. During this exam, the investigator will examine both the hard and soft tissues of your mouth.
- Oral hygiene check – You will be asked to confirm that you have not performed any oral hygiene procedures (flossing, brushing your teeth, using any mouth wash rinse) for 12 to 16 hours prior to the screening visit.
- The amount of plaque buildup on your teeth will be measured by the dental examiner. The dental examiner will rate your plaque buildup using a scoring system called the Quigley Hein Turesky Plaque Index. (A red food dye will be used to disclose (show) the plaque deposits on your teeth.)
- You will be asked to provide a list of any additional medications you may be taking.

Study Day 0 (Baseline) – Visit 2

After the screening period, if you are eligible to participate, you will be scheduled to return to the clinic for Visit 2 (Day 0 baseline) to begin treatment. The following assessments will occur at Visit 2:

- The study inclusion and exclusion criteria will be re-checked
- Your vital signs (blood pressures, respiration rate, heart rate and temperature) will be measured
- Intraoral exam (OHT and OHT) will be conducted. During this exam, the investigator will examine both the hard and soft tissues of your mouth.
- Oral hygiene check: You will be asked to confirm that you did not perform any oral hygiene procedures (flossing, brushing your teeth, using any mouth wash rinse) for 12 to 16 hours prior to the visit
- You will be assigned to a chewing gum group. You will be assigned to receive either active ACPG (containing 30 mg KSL-W) or to receive placebo gum. There is an equal chance that you will be assigned to either chewing gum group. (You will be assigned to a treatment group according to a randomization schedule and neither you nor the investigators will know whether you will receive active ACPG or placebo during the study).
- The amount of plaque buildup on your teeth will be measured by the dental examiner. The dental examiner will rate your plaque buildup using a scoring system called the Quigley Hein Turesky Plaque Index. (A red food dye will be used to disclose (show) the plaque deposits on your teeth.)
- A licensed dental hygienist will polish your teeth.
- You will chew your first piece of study gum while you are at the clinic. You will be instructed to chew one tablet of gum for 20 minutes and to balance your chewing on both sides of your mouth as equally as possible.
- After chewing the gum for the 20 minutes, you will be given a used product collection bag to store the chewed gum. The evaluator will tell you how to label this bag with the time and date that you chewed the gum.
- After the chewing gum is stored in the used product collection bag, you will enter the time you started and completed chewing the gum into the electronic diary information system. You will enter this information while in the clinic with assistance from the staff if necessary.
- Before leaving the clinic, you will be provided with the study medication to take home for unsupervised use. You will receive:
    - 13 tablets of gum along with 13 individual used product collection bags. (Note: this includes two 2 extra pieces of gum and used-product collection bags in case you mistakenly lose or misplace one of your doses. If you need more than 2 additional doses of gum, you will need to contact the study center).
    - You will be given the following instructions for chewing the gum as follows:
        a. Chew the gum for 20 minutes preferably after a meal or every 4 to 6 hours (3 times a day). Balance chewing as equally as possible between both sides of your mouth. Do not chew more than 3 pieces of gum each day.

b. After chewing a piece of gum for 20 minutes, place the used gum in its own used product collection bag that you were provided.

c. Label each used product collection bag with the date and time that you chewed the gum. (You must use a separate bag for each chew).

d. After each chew, record the start and stop time of the chew on the electronic diary information system.

e. You must bring all of the used product collection bags (containing your chewed gum) back to the clinic for Visit 3, 4 days later. You must also return any of the chewing gum tablets you did not chew.

- You will be told that no oral hygiene procedures of any kind (teeth brushing, flossing or using mouth wash rinse) are allowed while you are on study treatment (Day 0, 1, 2, 3 and 4).
- You will be asked about any adverse events that you may experience after your first gum chew.
- You will be asked about any other medications that you are taking.

Unsupervised Treatment, Study Days 0, 1, 2, and 3

After the first supervised chew is completed, you will be released from the clinic. Over the next 4 days, outside of the clinic, you will chew a total of 11 pieces of gum. You will chew one tablet of gum (study medication) for 20 minutes every 4 to 6 hours, preferably after a meal, for a maximum of 3 chews per day according to the schedule in the table below.

Schedule for Unsupervised Chews:

Time*	**Day 0**	**Day 1**	**Day 2**	**Day 3**
After Breakfast**	N/A	1	1	1
After Lunch	1	1	1	1
After Dinner	1	1	1	1
Total Chews per Day	**2**	**3**	**3**	**3**

* Chew gum for 20 minutes, preferably after a meal or every 4 to 6 hours for a maximum of 3 chews per day. Balance chewing as equally as possible between both sides of your mouth.
** You will chew your first tablet of gum at the clinic under staff supervision.

After completing each 20 minute chew, you will place the used gum in one of the used product collection bags provided to you. You will record the date and time of that you chewed the gum on the used-product collection bag. A separate bag will be used for each chew. You will record your chewing gum start and stop times on the electronic diary system after each chew. You will log onto the internet to enter in this

information. The study staff will explain how to do this after your first chew and before you leave the clinic. If you need help, contact Dr. Milleman at 260-755-1099 or after work hours at 260-413-7777.

Treatment, Study Day 4 – Visit 3

After 4 days of treatment, you will return to the clinic for Visit 3. The following events will occur at Visit 3:

- You will return all used product collection bags and any unused gum
- Your vital signs (blood pressure, respiration rate, heart rate and temperature) will be measured
- A brief, symptom-oriented physical examination will be performed
- If you are female and are able to become pregnant, you will take a urine pregnancy test
- You will be asked to confirm that you did not perform any oral hygiene procedures (flossing, brushing your teeth, using any mouth wash rinse) for 12 to 16 hours prior to the visit
- An intraoral examination will be performed. During this exam, the investigator will examine both the hard and soft tissues of your mouth.
- The amount of plaque buildup on your teeth will be measured by the dental examiner. The dental examiner will rate your plaque buildup using a scoring system called the Quigley Hein Turesky Plaque Index. (A red food dye will be used to disclose (show) the plaque deposits on your teeth.)
- You will be asked about any adverse experiences you had while taking the study medication (chewing gum).
- You will be asked about any other medications that you took since your last visit to the clinic.
- You will be dismissed from the study and paid a gratuity. (You will be allowed to brush your teeth just prior to leaving the research center.)

What Happens if I Get Sick?

If you get sick, you should call Dr. Milleman and your Primary Doctor for instructions.

What Happens if I Am Injured as a Result of Taking Part in This Treatment Protocol?

If you are injured and are affiliated with the Department of Defense: The US Department of Defense is funding this research study. If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge even if you are a contracted employee. You will be treated for injuries that are directly caused by the research study only. The Army will not pay for your transportation to and from the hospital or clinic. If you believe you have received a research-related injury, or if you pay out-of-pocket expenses for medical care elsewhere for injuries caused by this research study, contact Dr. Milleman. If you still are not satisfied, contact the US Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) (301-619-7663/2221).

Requests for other benefits are processed independent of this research study. Military members retain the right to pursue military disability benefits, and federal civilian employees retain the right to pursue relief through established workers' compensation processes; however, neither military disability benefits nor

workers' compensation benefits are guaranteed. This is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the Principal Investigator before you sign the informed consent to participate in the study.

If you are injured and are not affiliated with the Department of Defense: Your participation in this protocol is being provided as a service by the US Department of Defense under an agreement with another institution or agency. Only short-term acute or emergent medical care will be available at the clinic for illness or injury associated with participation in this protocol. However, if care for your research-related illness or injury is needed beyond that provided at the clinic, you are entitled to free medical care for such illness or injury at an Army hospital or clinic. It cannot be determined in advance which Army hospital or clinic will provide care. Transportation to and from Army hospitals or clinics will not be provided.

You may choose to seek care under your own health insurance, and it is also possible that you may have workers' compensation/disability coverage that applies to your injury. No reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. If you believe you have sustained a research-related injury, please contact the PI. You should understand that this does not constitute a waiver or release of legal rights.

What Happens if I Want to Leave the Study?

Your participation in this research study is completely voluntary. You may choose not to take part at all, or you may choose to stop your participation at any time after you have begun the research study. If you stop participating in this research study, you will not be penalized or lose any benefits to which you are otherwise entitled.

You may refuse to participate in or may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to leave this study early, we ask that you notify the PI or a designee as soon as possible. You may be asked to schedule a clinic visit.

What Are the Safeguards for My Protection?

All study procedures will be performed by qualified, trained personnel.

Volunteer Registry Data Sheet: USAMRMC requires that data sheets (Volunteer Registry Data Sheet, Form 60-R) be completed for entry into the Command's Volunteer Registry Database for all individuals participating in research trials. This information includes the volunteer's name, address, Social Security Number, study identity, and dates of participation. The intent of this database is twofold: first, to readily answer questions about an individual's participation in research sponsored by USAMRMC; and second, to ensure that USAMRMC can exercise its obligation to ensure that all research study participants are adequately warned (duty to warn) of risks and to provide new information as it becomes available. This information will be stored at USAMRMC for a minimum of 75 years and is kept confidential. The Volunteer Registry Data Base is separate from and not linked to the study database.

Will I Be Compensated for My Participation in the Study?

You will be compensated for participation in the study. You will be given a $25 gift card for the screening visit. If you are eligible for participation in the study and receive treatment you will receive gift cards worth $200. Total compensation will be $225 in gift cards.

What About My Confidentiality?

Confidentiality: All data and medical information obtained about you as an individual will be considered privileged and held in confidence. We may need to request your medical or hospital records to monitor your safety. You will not be identified by name in any published report or in any presentation of the results. Information bearing on your health may be required to be reported to appropriate medical or command authorities. Representatives from other regulatory agencies, such as the FDA, USAMRMC, and its subordinate commands, and study personnel are eligible to review research records as part of their responsibility to protect human participants in research and to carry out their obligations relating to the study. Representatives from the US Army Medical Material Development Activity may review your research record. By signing this consent document, you agree to such inspection and disclosure.

HIPAA Authorization: The Federal Health Insurance Portability and Accountability Act (HIPAA) requires that researchers obtain the participant's permission (called an Authorization) to use and disclose protected health information (PHI) about the participant that is either created by or used in connection with this research. This Authorization has no expiration date. **By signing this consent form, you are agreeing to the use and disclosure of your PHI by the PI and the research staff**, including results of physical exams, blood tests, and other diagnostic and medical procedures as well as vaccination and medical history. Your PHI may also be viewed and used by other regulatory and medical representatives, including but not limited to representatives from FDA and USAMRMC.

Your PHI may also be used by others who do not necessarily work under HIPAA rules. Subject records are maintained permanently.

If you choose not to authorize these uses and disclosure of your PHI by signing this form, you will not be eligible to participate in this research study. However, your decision not to sign this consent form will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits. You may also change your mind and cancel this Authorization at any time by sending a written notice to the PI. Cancellation of this Authorization will not alter disclosure of PHI that has already been collected; however, no further PHI about you will be collected by or disclosed to the researcher for this study.

Consent for Participation in the Research Study

Your signature on this form indicates that you have read this consent form, that the research study has been explained to you and your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

SIGNATURES

_____

Printed Full Name of Study Participant

_____ _____

Signature of Study Participant | Date

_____

_____

Permanent Address of Study Participant

Printed Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion and Obtaining Informed Consent

Date