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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
06/14/2023
APPROVAL EXPIRATION DATE

Consent Approval Date: 6/15/2022

Protocol Number: 2019P000274

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Effect of a rationally defined microbial consortia on functional and taxonomic parameters of the gut microbiota in Irritable Bowel Syndrome (IBS)DS-01.
PRINCIPAL INVESTIGATOR: Anthony Lembo, MD
PROTOCOL NUMBER: 2019P-000274

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 on in this form.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are a premenopausal adult female or male with stomach complaints.

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.
- Your participation is completely voluntary.
- 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.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Why is this research being done?
This research study is being done to see whether taking a specific multi-strain synbiotic (probiotic + prebiotic/fiber combination) will change the gut microbiome (bacteria composition).

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A person's body naturally contains billions of strains of bacteria. Probiotics are often called the "good bacteria" and are commonly thought to improve gut health. They are available as nutritional supplements and found in some foods like yogurt and fermented foods. Prebiotics are a type of fiber that act as food for the bacteria in the human gut. In other words, prebiotics are the food for probiotics. Prebiotics are also available as nutritional supplements and found in some foods such as whole grains and bananas.

The probiotic/prebiotic (or synbiotic) capsule used in this research study contains probiotic strains that have been shown in previous research studies to improve both overall female health and digestive health.

How long will the research last and what will I need to do?
We expect that you will be in this research study for up to 20 weeks.

You will be asked to take this study supplement (synbiotic) or placebo every day for 16 weeks and provide blood and stool samples. You will also be asked questions about your overall health and wellbeing and your digestive health.

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

Is there any way being in this study could be harmful to me?
It is possible that you may experience upset stomach, gas, diarrhea, or bloating.

More detailed information about the risks can be found under ***"*RISKS AND DISCOMFORTS*".***

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, possible benefits include improved digestive health.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

You will receive the synbiotic at no cost for the duration of the study. An alternative to participating in the research study is purchasing the synbiotic on your own.

DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Anthony Lembo and is funded by Seed Health. The funding agency in this study, Seed Health, is paying Beth Israel Deaconess Medical Center to perform this research. BIDMC or Dr. Lembo have no additional interests in this research project.

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WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Anthony Lembo at [617] 667-2138.

PURPOSE

This research study is being done to see whether a synbiotic changes a person's gut microbiome (bacteria composition).

This study is specifically evaluating whether taking this synbiotic for 12 weeks changes the composition/profile of your gut microbiome.

The drug involved in this study, DS-01 is a supplement. This means that the study drug is not regulated by the Food and Drug Administration [FDA].

STUDY PARTICIPANTS

You have been asked to be in the study because you are a premenopausal adult female or male with stomach complaints.

Approximately 150 people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be in this research study for up to 20 weeks and of that, you will take the study supplement or placebo for 16 weeks.

After you sign the consent form, the following things will happen:

Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include one visit that will last approximately one hour. It will occur either in person at BIDMC or remotely via video conferencing:

- Review of your medical history and current medications/supplements including any digestive complaints
- You will be asked to answer questionnaires on your GI and GI-related symptoms, including food, water, and medication intake via a secure Internet website. This questionnaire will be competed daily and will take no longer than 15 minutes each time
- If you are taking any probiotics or antibiotics at this time, we will ask you to discontinue the probiotics during the 7 days prior to Visit 2.

Randomization Procedures: It is not clear at this time which of the treatments in this study would be better for you. For this reason, the treatment plan offered to you will be picked by chance [like the flip of a coin]. You will not be able to choose which treatment you receive. The chances of receiving either of the treatments are approximately equal. After the randomization, you will be assigned to one of the following groups:

A) Synbiotic (2 capsules daily)

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B) Placebo (2 capsules daily)

You will take either the symbiotic or the placebo capsules for 12 weeks. In addition, you will also receive a placebo capsule for 4 weeks. You will not know which 4 weeks you will be receiving the placebo. In total, you will be taking a capsule for 16 weeks (4 weeks will be a placebo and 12 weeks will either be the symbiotic or a placebo).

A placebo is an inactive pill that looks like the supplement, but a placebo contains no live probiotics. Placebos are used to help determine if the results of the study are truly from the supplement. You will not know whether you will be receiving the supplement or the placebo. However, this information can be learned in case of an emergency.

Neither you nor your study team will know which product you are receiving. However this information can be learned in case of an emergency.

Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures that include three clinic visits and one phone call:

Visit 2. This visit will last approximately one hour.
- Review of your medical history and current medications/supplements
- Questionnaires about any digestive and digestive-related complaints including food, water, and medication intake
- Vital signs including weight, heart rate, respiratory rate, and blood pressure
- You will be given enough study medication for the next two weeks.
- If you are a female of child-bearing potential, you will have a urine pregnancy test performed.

Visit 3. This visit will last approximately 20-30 minutes.
- Review of your medical history and current medications/supplements
- Questionnaires about any digestive and digestive-related complaints including food, water, and medication intake
- Physical exam
- Vital signs including weight, heart rate, respiratory rate, and blood pressure
- Collection of blood (approximately 4 Tbs) for blood count and measurement of chemicals related to gut health. The excess blood will be saved for future studies related to how this synbiotic works in the human body. Your blood sample will not be saved with any identifiable information and will not be discarded if you withdraw from the study.
- You will be given a stool collection kit for stool collection at your own home.
- You will return the unused study medication from your last visit and receive enough study medication for the next 6 weeks.

Visit 4. This visit will last approximately 20-30 minutes and occur via telephone call.
- Review of your medical history and current medications/supplements
- Questionnaires about any digestive and digestive-related complaints including food, water, and

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medication intake
- You will return the unused study medication from your last visit and receive enough study medication for the next 6 weeks.

Visit 5. This visit will last approximately 20-30 minutes.
- Review of your medical history and current medications/supplements
- Questionnaires about any digestive and digestive-related complaints including food, water, and medication intake
- Collection of blood (approximately 4 Tbs) for measurement of chemicals related to gut health. The excess blood will be saved for future studies related to how this synbiotic works in the human body. Your blood sample will not be saved with any identifiable information and will not be discarded if you withdraw from the study.
- You will return the unused study medication from your last visit.
- You will be given a stool collection kit for stool collection at your own home.

Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures can be done at home one week after Visit 5 and include the following procedures.
- Review of your medical history and current medications/supplements
- Questionnaires about any digestive complaints

Study Visit Timeline	Visit 1 Screening	Visit 2 Day 1	Visit 3 4 weeks	Visit 4 10 weeks	Visit 5 16 weeks	Visit 6 17 weeks (at home)
Consent	X					
Vital signs		X	X			
Blood Draw			X		X	
Stool Collection			X		X	
Questionnaires	X	X	X	X	X	X

Individual Research Results

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The research testing done in this study is just a stepping stone to learning more about digestive health.

You will not receive any results from the research testing.

Information and Biological Samples

Your information and biological samples will be used and shared with the sponsor and the researchers involved in this study to conduct the research including outside institutions. The consent form provides

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information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

Storing of Identifiable Information and Samples for Future Use

At the completion of this research, we would like to store any remaining sample(s) and information collected from or about you for this research for possible future use. Your sample will be stored with identifiers, such as your name or medical record number. The remaining samples and information may be stored indefinitely and may be used for future unspecified research uses. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified by the other researchers or institutions.

If you have questions about storing samples or information, or would like to request that samples or information be removed from storage, please let us know. It is not always possible to remove samples or information from storage or to retrieve samples or information that have/has already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above: (please check and initial one to indicate your choice)

_____ YES _____ NO

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

- Upset stomach

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- Gas
- Diarrhea
- Bloating

Blood Drawing
The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw; occasional feeling of lightheadedness; and rarely, infection at the site of the blood draw.

Surveys/Questionnaires
Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

Loss of confidentiality
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

PREGNANCY

Because of the effects of this (these) study medication(s) on the developing fetus is (are) not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first dose of the study medication(s).

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant

The methods of highly effective birth control for this study are below:

1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately.

If you are a man capable of fathering children, you must use adequate contraception while participating in this study. For the purposes of this study, adequate birth control means:

1. use of a condom
2. your partner must use an approved method of birth control as listed above.

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CONFIDENTIALITY

Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by federal and state regulatory agencies, and by the drug manufacturer, Seed, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary.

It is important to note that it is possible to get the synbiotic even if you do not take part in the study.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your

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relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for any of the tests, procedures, or supplements that are part of this research study.

PAYMENTS TO YOU:

You will receive $25 for each in-person visit and a parking voucher for visits you attend in person. In addition, you will receive an additional $25 for returning the pre-treatment stool sample and $50 for returning the post-treatment stool sample.

It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section "Who to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]

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By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study (Seed) and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

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PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Anthony Lembo, MD at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____