CONSENT FORM AND HIPAA AUTHORIZATION FOR RESEARCH
LEFTOVER CLINICAL SAMPLES PLUS BLOOD AND OTHER SAMPLES FOR RESEARCH

For Adult Participants Only

Sponsor / Study Title:	**iSpecimen / "Collection and Distribution of Remnant and Research Use Only Biospecimens for Novel Research Uses"**
Protocol Number:	**ISPC-160630-REM/RUO**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	[redacted]

If you are in California, before you read this consent form, you should read and sign a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you haven't already received one.

A person who takes part in a research study is called a research or study participant. In this consent form "you" always refers to the research participant. If you are a legally authorized representative, please remember that "you" means the research (study) participant.

We want to know if you would like to take part in biological sample collection, and then allow your information and samples to be used for research. You will not receive the results of any tests done on the samples you provide.

This form gives you the information you need to decide whether you would like to take part. Please read it carefully and take the time you need to make your choice. Whether you take part in this research sample collection is your choice. Your decision will have no effect on your regular medical care.

If you have any questions about or do not understand something in this form, you should ask the study staff. You should also discuss your participation with anyone you choose in order to better understand this research.

WHAT IS THE PURPOSE OF THIS RESEARCH?

Researchers are trying to find new ways to detect, treat, prevent, and cure health problems. These efforts require the collection and use of biological samples from many people. A company called iSpecimen is trying to lead this effort by contracting with hospitals, medical centers, and other healthcare organizations to collect and distribute samples and information for use in research studies in the U.S. and other countries. iSpecimen is the “sponsor” of the collection of samples.

We are seeking samples from people who are willing to provide them for use by other researchers (“research use only” samples).

WHO WILL PARTICIPATE IN THIS RESEARCH?

We are asking many people to participate in the research. We don’t know how many people will participate.

For this research, “participating” means providing samples and information.

You do not have to participate in this research if you don’t want to.

WHAT TYPES OF SAMPLES ARE REQUESTED?

As a part of your regular medical care today, there may be leftover biological samples (like blood or tissue) which otherwise would be discarded after all necessary testing is done. With your consent, we would like to make your leftover clinical samples available for research or educational purposes, including research on genetic material (DNA). Your samples may be provided with health information to make them as useful as possible for research, but if this happens, they will not include any information that directly identifies you.

You may also be asked you to provide one or more additional fresh samples on the list below as part of this research. At the end of the consent form, you will be able to check the sample types that you agree to provide. Any sample type that is not checked by you will not be taken. If additional samples are requested from you in the future and if you agree, you will need to sign and date another consent form with the newly requested sample type(s) checked.

Below is the list of all possible sample types you could be asked to provide.

a) blood by finger stick, ear stick, or venipuncture (from a vein). Blood volume could include up to 550mL or about 2.5 cups within an 8 week period, if you are healthy and weigh at least 110 pounds, or up to 50mL, which is a little over 3 tablespoons within an 8-week period, if you are not healthy;
b) small number of hair or nail clippings;
c) teeth if already being pulled for medical or dental reasons;
d) sweat that your body naturally produces;
e) saliva (spit into a cup); the study staff may ask you to chew gum to produce more saliva;
f) If you are pregnant, researchers may request placenta after delivery;
g) If you are pregnant, researchers may request amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
h) dental plaque and calculus (hardened plaque) on the gums and teeth, removed with usual sterile dental tools like the ones your dentist uses or with toothpicks;
i) skin cells on your body or cells inside your mouth, collected by scraping or swabbing the inside of your cheek, mouth washings, or lightly scraping/swabbing your skin;
j) sputum (mucus) collected by coughing into a cup; the study staff may ask you to inhale a saline mist solution (similar to mist from a humidifier) to produce more;
k) urine or stool samples collected in a cup or toilet device;
l) nose swabs (placing a swab just inside your nose);
m) nasopharyngeal swab (placing a swab into the nasal cavity to collect samples from the back of the nose and throat)

n) ear swab (placing a swab just inside the opening of your ear canal);
o) vaginal swabs that do not go beyond the cervical os;
p) rectal swabs that do not go beyond the rectum

The study staff will explain the process of collecting each specimen you are asked to provide. You should agree only to the samples you wish to provide, and you will indicate your choices later in this form.

WHAT WILL HAPPEN IF I AGREE TO PARTICIPATE?

Today you are being asked whether any leftover clinical samples from your clinical visit can be saved and used for research **and** whether you are willing to provide an additional blood collection for research.

If you agree to participate, we will ask you to sign and date this form. The study doctor or study staff will explain the process of collecting each additional blood sample you are asked to provide. Study staff may review your medical records and may ask you questions about your medical history, including whether you are pregnant or have recently acted as a blood donor. The study staff may also ask that you undergo routine tests or provide a sample for screening purposes only. This testing, if performed, will be limited to vital sign checks, a physical exam, health or lifestyle questionnaires, or collection of typical biological specimens like blood, urine, saliva, or stool. A screening blood sample would be limited to no more than 50mls.

The research samples collected from you may be provided to researchers at academic institutions, hospitals, clinical and government laboratories, corporations (including diagnostic, medical device, biopharmaceutical, and biotechnology companies), and/or life science companies and forensic laboratories. These researchers may use your samples to perform genetic testing (DNA), conduct testing related to COVID-19, or develop cell lines, or may even freeze and save your samples for many years. Research studies may be conducted to further the advancements made in the areas of forensic genetics, human identity testing, and the validation of forensic DNA testing methods, forensic testing laboratories in the U.S. and around the world may conduct studies using your blood and blood components. A primary intent of this collection is to share DNA extracts with law enforcement laboratories for the purposes of research and the validation of forensic DNA typing methods.

Your samples may be provided along with some of your demographic and health information, in order to make them as useful as possible for research. Only information that is relevant to the purpose of the research will be provided.

The hope is that these samples, combined with information about you, may help further research related to human health and may lead to new treatments and therapies.

All samples and health information will be coded, and neither iSpecimen nor the researchers who will use the samples will receive information that directly identifies you.

Your samples will be kept until they are used in their entirety for the research.

Results from research on your samples will not be shared with you or your medical professionals, and will not be added to your regular medical record.

HOW LONG WILL MY PARTICIPATION LAST?

If you agree to participate in this biological sample collection, your consent will last indefinitely, although you can decline to provide samples at any time. You may be approached again about whether you would like to continue to provide samples and asked to sign and date another consent form. You will have an opportunity at the end of this form to indicate whether you would like to be contacted by the study staff about opportunities to participate in additional sample collection.

ARE THERE ANY POTENTIAL BENEFITS?

Researchers may make discoveries that help people in the future; however, you will not receive any benefit from participating.

WHAT ARE THE POTENTIAL RISKS IF I PARTICIPATE?

There are no physical risks associated with providing left over clinical specimens.

Any fresh samples you provide will be collected in a way that should not expose you to invasive (deep) sampling procedures, and they are obtained in the way most samples are routinely obtained for clinical lab tests. However, it is possible that swabbing or scraping skin, nose, or ears could result in minor bleeding, irritation, or pain.

You may have some pain, bruising, or bleeding after a blood collection. Some people feel faint or dizzy. It is possible to get an infection as a result of a blood draw from a vein, but the risk is low.

There is a risk that your nostril may bleed or become irritated during the collection of a nasopharyngeal swab sample. You may feel some discomfort.

If you provide a sputum (mucus) sample collected through nebulization (saline mist), it is possible that if you have a current respiratory infection (such as COVID-19) this virus could be dispersed and expose people in the surrounding area to the virus.

There are laws to protect your privacy and to prohibit the misuse of your information, and each researcher must agree in writing to abide by these rules. iSpecimen also has protections in place to help keep your identity private. However, it is important to know that there is still a risk that someone could get access to the information we have stored about you, and that your samples or health information could be used to identify you or a family member, or reveal that you or a blood relative carry a genetic disease.

Researchers may learn information about groups to which you belong (race, ethnic group, gender) when using your samples and information for their research. This information can help researchers understand whether the causes and impact of health problems are the same for different groups of people. It is also possible that these findings could be used to support harmful stereotypes.

Ask the study doctor if you have questions about the side effects that you read about in this consent form.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

The study staff and iSpecimen will do their best to make sure that your information is kept confidential. None of your samples or health information will include your name or any other information that directly identifies you when sent to the researchers.

Your samples stored will not be labeled with your name or other directly identifying information. Your samples will have a code instead. The master list that links the code with your name will be stored separately.

Researchers who receive your samples and information will not have access to the master list that matches the code with your name. The researchers must sign an agreement that they will not try to find out who you are.

The information shared may include your DNA results. Because your DNA information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is small but may be greater in the future.

Researchers may share findings with others. For example, information may be shared between forensic testing laboratories within the law enforcement community. Your identity will not be known to the researchers or others, but you should consider this possibility when considering whether you would like to participate.
Genetic information collected for research purposes will not be stored in databases that are used for criminal searches and will not be used by law enforcement to investigate criminal acts.

If you are in the United States of America, a federal law called the Genetic Information Non-Discrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance and it does not guarantee privacy.

Be aware that your records (which may include your health information, your signed and dated consent form, and other information) will be shared as needed by law. For example, study staff, iSpecimen, Advarra IRB (an ethics review committee), and federal regulatory agencies such as the U.S. Food and Drug Administration (FDA) and Health and Human Services may have access to research data and records, to monitor the research or in the event of an audit.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There will be no costs to you or your insurance for participating in this research.

WILL I BE PAID?

For some collections, subjects will receive $25-50 reimbursement.You will be paid at the end of your participation in this study.

If any of the research leads to new tests, drugs, or other commercial products, there are no plans to pay you or for you to share in the profits.

DO I HAVE TO PARTICIPATE IN THIS RESEARCH? WHAT IF I CHANGE MY MIND LATER?

Participation in this research sample collection activity is voluntary, and the decision to participate is entirely yours. Should you decide not to participate, or if you change your mind about your participation at any time, there will be no penalty to you, and this decision will have no impact on your regular medical care or any other benefit you are entitled to.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

ALTERNATIVES TO PARTICIPATION

This research study is for research purposes only. The only alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

WHAT ELSE SHOULD I KNOW?

If you change your mind about participating, we will no longer make your samples and health information available to researchers. However, we will not be able to retrieve and/or destroy any samples or information that iSpecimen has already shared with researchers, and you cannot withdraw your samples and information from any studies that have already begun. You can discontinue participation at any time up until the start of blood collection.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:

  Study Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110

Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00035314.

FUTURE CONTACT

We may want to contact you in the future. You can still participate in the research use only sample collection even if you don't want to be contacted again. Or you can say you want to be contacted later, even if you choose not to provide samples for the research right now.

Do you agree to be contacted in the future for any of the following reasons? Please add your **initials** to indicate your decision:

_____ Yes _____ No I agree to being contacted in the future to request new samples as part of this research.

_____ Yes _____ No I agree to being contacted in the future to update my information.

_____ Yes _____ No I agree to being contacted in the future to hear about other opportunities to provide research samples.

CONSENT

I have read this form, and I have been able to ask questions about this research. The study staff has talked with me about this sample collection requested. They have answered all my questions. I voluntarily agree to the research activity I am indicating below.

By signing and dating this form, I do not give up any of my legal rights. I will get a signed and dated copy of this consent form.

Please add your **initials** to indicate your decision:

_____ **I do not want to provide any samples for research purposes right now.** But you may contact me in the future (as I've checked in the section above called "Future Contact")

____ **I agree to allow my clinical samples that are left over from procedures I undergo at this facility to be used for research**

____ **I agree to provide the following additional research-only samples (please add your initials to indicate your decision):**

_____ Blood

_____ Saliva

_____ Urine

_____ Stool

_____ Skin scrapings/swabs

_____ Mouth scrapings/swabs/washings

_____ Sputum (coughed-up mucus from the lungs)

_____ Nose swabs

_____ Nasopharyngeal swab

_____ Ear swabs

_____ Sweat

_____ Hair clippings

_____ Nail clippings

_____ Teeth

_____ Plaque on teeth/gums

_____ Placenta after delivery

_____ Amniotic fluid after delivery

_____ Vaginal swabs

_____ Rectal swabs

____

Printed Name of Participant

____ ________________

Signature of Participant Date

I am the legally authorized representative of the participant named above and I consent to his/her participation in this research study.

____ ________________

Signature of Legally Authorized Representative Date

____

Relationship to Participant (for example, authority)

I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent Date

WITNESS STATEMENT

As an impartial third party, I witnessed the entire consent discussion and the signature of the individual providing consent on this form.

Printed Name of Witness

Signature of Witness Date

HIPAA AUTHORIZATION FOR RESEARCH

HOW WILL MY INFORMATION BE OBTAINED, USED AND SHARED FOR THIS STUDY?

This section explains who will use and share your confidential health information (often referred to as protected health information under federal law) if you agree to be in this study. This section also explains who you will be authorizing to provide your confidential health information to the study doctor and study staff. This study does not include research-related treatment. You may refuse to sign and date this authorization. However, if you do not sign this authorization, you cannot participate in the study and if you cancel this authorization you will not be able to continue in the study.

By signing and dating this HIPAA Authorization for Research, you agree that, during the study, the study doctor and study staff will use, collect, and share health information about you (your “record”). Your records may include any medical information about you that the study doctor needs to have in order to determine if you can participate in the sample collection activities. This includes identifying information about you, such as your name, date of birth, address, phone number, or social security number. Your records will include:

- Medical records

Your health information will be used or shared when required by law. You also agree that your records may also be used and shared with these people for the purposes described below.

- The study doctor and study staff to conduct the sample collection activities described in the consent form.
- iSpecimen, in order to provide your de-identified medical information and samples to researchers
- Researchers who request your samples from iSpecimen to conduct research
- Although your health information will generally be coded and not identify you by name, it is possible that the sponsor (iSpecimen); people who work with or for the sponsor and other associates of iSpecimen will have access to your identifiable personal health information.
- Others required by law to review the quality and safety of medical research, including representatives of the FDA, or other government

agencies in the United States and other countries. Advarra IRB may also review your records.

There are national and state laws that require the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the above described need to share your information to conduct the research. After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records. Also, if all information that can identify you is removed from your records, the remaining information may no longer be subject to this authorization and may be used or shared for other purposes.

Your information may be used in scientific publications or presentations. No publication or public presentation about the results obtained from the research described in this form will reveal your personal identity without specific permission from you.

The information developed as a result of this study will be kept separate from your medical record and designated record set and will not be used to influence your care. You will not have access to this information during or after the study.

You can cancel this authorization to use your leftover and/or blood specimens for the research or to share your medical records at any time. If you want to cancel your authorization, you must write a letter to the study doctor at the address listed on the first page of this consent form. If you cancel your authorization, you will not be able to continue in the study. However, if you cancel your authorization and leave the study early, the persons authorized in this form may continue to use and share information that has already been collected.

This authorization to use and share your records expires in 50 years.

I agree to allow the collection, use, and sharing of my information as described above.

Printed Name of Participant and Participant Date of Birth

Signature of Participant Date

I am the legally authorized representative of the participant named above and I authorize the collection, use, and sharing of the participant’s information.

Signature of Legally Authorized Representative Date

Relationship to Participant (for example, authority)