PRINCIPAL INVESTIGATORS: Jonathan Moorman, M.D.

TITLE OF PROJECT: COE Inflammation, Infectious Disease, and Immunity Repository

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EAST TENNESSEE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD INFORMED
CONSENT DOCUMENT

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether to volunteer for a research study that is unfunded and is intended to create a repository of human specimens for use in research. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to establish a large repository of patient specimens related to human diseases for use in future research studies. Such specimens help us to learn how your body's immune system deals with infections and inflammation. Your participation in this research will last only until you have provided a specimen to be placed in the repository.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will not directly benefit from this study, but the collection of your specimens may contribute to key research conducted in future health-related studies.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study if you do not want your specimens used for research. The alternative is not participating in this research study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Jonathan Moorman, MD, PhD of the COE Inflammation, Infectious Disease, and Immunity (CIIDI). If you have questions, suggestions, or concerns

regarding this study or you want to withdraw from the study his contact information is Jonathan Moorman, MD, PhD, phone # (423) 439-4768.

RESEARCH DETAILSWHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn how your immune system responds to human disease, in particular infections and inflammatory disease. Your specimen can be stored and later used in research studies along with other volunteers' specimens to study how your immune system works when challenged by diseases. Collection of umbilical cord samples and cord blood samples could be used to improve clinical management of medication assisted therapy in pregnancy. Collection of liver tissue samples could be used to improve clinical management of hepatic diseases.

HOW LONG WILL I BE IN THE STUDY?

This research study is an ongoing repository of specimens that expands over time, and has no end date. Your individual participation in the project, however, is only as long as it will take for you to provide your specimen (generally blood, but occasionally bodily fluids or tissue including urine, stool, sweat, saliva, placenta and/or umbilical cord).

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you take part in this study, you will be asked to consent to provide a blood sample, and perhaps other bodily fluids or tissue including urine, stool, sweat, saliva, placenta and/or umbilical cord). The blood draw will generally occur at the time you are already getting blood drawn for your routine health care. If you are a routinely seen patient of ETSU or Ballad health providers, you may be asked to participate in repeat sampling, but is not a requirement of your participation. This study does not include whole genome sequencing. The Biospecimens collected for this study, even if identifiers are removed, may be used for commercial profit but there is no plan for CIIDI to share any commercial profit from such developments. Your sample along with your specific medical information will be transported to the research laboratory at the Center of Excellence Inflammation, Infectious Disease, and Immunity. Your name will not be recorded on the sample or your data form, and will only be needed for this consent document, which will be stored on a HIPAA-compliant ETSU RedCap server and accessible only to specific study personnel. **Your samples will be released in the future to researchers following approval, but your name and identifying information will never be released**.

Results of certain studies could produce information that's relevant to the participant. Subjects interested in receiving results can make the request at the time of consent. After the informed consent process is complete, a note will be made for the request by the research coordinator, the subject's address will be recorded, and the "honest broker" will mail those results to the participant upon receipt. By signing this informed consent, you are giving permission to C.I.I.D.I.'s honest broker to receive and release these results to you by mail.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

Your involvement as a research subject may include:

●A blood draw from an arm vein by a trained technician after your

permission, and/or your donation of a body fluid or tissue sample such as liver tissue, stool, urine, sweat, saliva, placenta, and/or umbilical cord into a sterile specimen container that we will provide.

- For blood draws, less than 50mL of blood will be drawn and transferred into appropriate tubes.
  Any bleeding can usually be controlled with a chemical that stops bleeding and by applying pressure. The blood draw site is then covered with a bandage.
- Other body fluids or tissue samples such as liver tissue, stool, saliva, sweat, urine, placenta, and/or umbilical cord may be requested but you can choose to provide any or all of these specimens and still participate in the study.

• Collection of liver tissue samples is routinely done at the time of your scheduled surgical procedure for lab tests performed by pathology to assess your current health status, and all remaining tissue is otherwise discarded. For the purposes of this research, all biologic tissue samples are obtained from that remaining tissue that would otherwise have been discarded.

●Collection of umbilical cord samples and cord blood samples is routinely done at the time of delivery for lab tests performed by the obstetricians and pediatricians to assess maternal and neonatal status, and all remaining tissue is otherwise discarded. For the purposes of this research, all biologic tissue samples are obtained from that remaining tissue that would otherwise have been discarded. No biologic specimens are collected directly from the fetus or neonate.

●All samples will be stored in a secure locked building on the Quillen College of Medicine campus, building 6, room 224. No other procedures will be necessary. We will also obtain access to your medical records to obtain your age, social security number (SSN), race, gender, email, address, diagnoses, medical history, complete blood count, comprehensive chemistries, coagulation assays, and microbiology results, results of physical exam, x-ray results, and immunologic assay results.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

This study may involve collection of a blood specimen. This collection will almost always involve collecting the specimen at the time you are already having blood drawn so that there is not an additional needlestick. There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood.

Collection of umbilical cord samples and cord blood samples is routinely done at the time of delivery for lab tests performed by the obstetricians and pediatricians to assess maternal and neonatal status, and all remaining tissue is otherwise discarded. For the purposes of this research, all biologic tissue samples are obtained from that remaining tissue that would

otherwise have been discarded. No biologic specimens are collected directly from the fetus or neonate.

- Collection of liver tissue samples is routinely done at the time of your scheduled surgical procedure for lab tests performed by pathology to assess your current health status, and all remaining tissue is otherwise discarded. For the purposes of this research, all biologic tissue samples are obtained from that remaining tissue that would otherwise have been discarded.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

The alternative is not participating in this research study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Every attempt will be made to see that my study results/data are kept confidential. A copy of the consent and data collection form will be stored on a HIPAA-compliant ETSU RedCap server in accordance with the record control schedule. The results of this study may be published and/or presented at meetings without identifying me as a subject. Your information and biospecimens may be de-identified and used for future research studies without your additional informed consent. Although your rights and privacy will be maintained, both the research records and signed consent form that identify you may be looked at by others that have the legal right to see that information. This may include the ETSU IRB overseeing this research, other individuals at the University with the responsibility for ensuring we follow the rules related to this research, the federal Office of Human Research Protections (OHRP) that protects participants like you, and the Principal Investigator and research team. Your medical records will be kept completely confidential according to current legal requirements, and will not be revealed unless required by law, or as described in this form.

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HIPAA Authorization for Disclosure of Protected Health Information for Research

The purpose of this authorization is to authorize Dr.Jonathan Moorman, MD, PhD, CIIDI research staff¸and an unbiased 3rd party known as the "Honest Broker" to collect, use, and disclose your protected health information for the purpose of research.

East Tennessee State University, Medical Education Assistance Corporation and Ballad Health have rules to protect your private health information. There are also federal and state laws that protect the privacy of your health information.

By signing this authorization, you authorize Dr.Jonathan Moorman, MD, PhD, CIIDI research staff,¸and an unbiased 3rd party known as the "Honest Broker" to collect, use, and disclose your health information as described in this form. ***You do not have to sign this form***. Your decision not to sign this authorization will not affect your treatment, healthcare, enrollment in health plans, or eligibility for benefits. However, your decision not to sign this form will result in your not being allowed to participate in this research study.

Dr. Jonathan Moorman, MD, PhD, CIIDI research staff, and an unbiased 3rd party known as the "Honest Broker" working on the study will collect information about you.

By signing this form, you give your authorization for your healthcare providers, to disclose the following protected health information to the research team:

- your name, SSN, race, email, address, date of birth, and information from your medical records including your age, gender,

  diagnoses, medical history, complete blood count, comprehensive chemistries, coagulation assays, microbiology results, results of physical exam, x-ray results, and immunologic assay results.

• Specimens collected: blood, stool, urine, sweat, saliva, placenta, umbilical cord, and/or various human tissues collected as part of routine procedure, as it relates to inflammation, infectious disease, and immunity.

Certain types of health information require special permission. In order to conduct this research study, the research team requires your special permission to obtain the protected health information listed below.

By initialing below, you are specifically authorizing the research team to collect, use and disclose your protected health information pertaining to:

_____ Sexually Transmitted Diseases
_____ Abortion
_____ AIDS or HIV
_____ Behavioral or Mental Health/Illness

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_____ Drug or Alcohol Abuse, Diagnosis, or Treatment _____ None of These

By signing this form you authorize *Dr.Jonathan Moorman, MD, PhD, his research staff, and the "Honest Broker"* to collect, use and disclose your protected health information as listed above *for an unlimited period of time to be used in future research. Results of certain studies could produce information that's relevant to the participant. Subjects interested in receiving results can make the request at the time of consent. After the informed consent process is complete, a note will be made for the request by the research coordinator, the subject's address will be recorded, and the "honest broker" will mail those results to the participant upon receipt.*

In general your health information will only be shared with Dr.Jonathan Moorman, MD, PhD, CIIDI research staff, and an unbiased 3rd party known as the "Honest Broker". However, in certain circumstances the following individuals or organizations may have access to your protected health information:

1. The Department of Health and Human Services
2. The ETSU Institutional Review Board
3. The ETSU Human Research Protection Program
4. The ETSU HIPAA Compliance Office
5. Other representatives of ETSU as reasonably required to carry out the research study
6. The Ballad Health HIPAA Compliance Office
7. Other representatives of Ballad Health as reasonably required to carry out the research study
8. Other Individuals/Organizations as required by law

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. If you revoke this authorization, Dr. Jonathan Moorman and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

In order to change your mind and revoke this authorization, you must send a letter to: Jonathan Moorman, M.D., Ph.D. at 6 Magnolia Avenue, Mountain Home, TN 37684 This authorization will remain valid unless and until it is revoked by you.

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Questions about Privacy: If you have any questions or concerns about your privacy rights you may contact the East Tennessee State University HIPAA Compliance Office via telephone 423.439.8533 or mail P.O. Box 70285, Johnson City, TN 37614.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for ETSU/Ballad care and medications, you will still pay these copayments for ETSU/Ballad care and medications that are not part of this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

You will not receive money or any other form of compensation for your participation in this study. Should unforeseen injury occur as a result of your participation in this study, appropriate medical care as determined by your physician will be provided. However, no financial reimbursement or any other form of compensation will be given. Your participation will not affect your care by your physicians.

East Tennessee State University (ETSU) will pay the cost of emergency first aid for any injury that may happen as a result of your being in this study. ETSU makes no commitment to pay for any other medical treatment. Claims against ETSU or any of its agents or employees may be submitted to the Tennessee Claims Commission. These claims will be settled to the extent allowable as provided under TCA Section 9-8-307. For more information about claims contact ETSU Office of University Counsel.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary and there are no penalties or loss of benefits to which you are entitled if you choose not to take part in the study.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, problems, or research-related medical problems at any time you may contact Dr. Jonathan Moorman at (423) 439-4768. This research is being overseen by an Institutional Review Board (IRB). An IRB is a group of people who perform independent review of research studies. You may also contact the ETSU Institutional Review Board at 423.439.6054 or irb@etsu.edu for any questions you may have about your rights as a research participant.

DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?

Because your samples contain cells, genetic information may be studied. This genomic data (information related to human DNA) along with portions of your samples and *health information will be stored for an unlimited period of time to be used in future research.* The samples and data will not be used for the study of population origins or ancestry.

Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this study.
- Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

TISSUE BANKING

All specimens will be stored in Dr. Moorman's secure laboratory at the Center of Excellence Inflammation, Infectious Disease, and Immunity in building 6, room 224 and only research team members will have access to them. The samples and their associated data will be kept until the study ends. Blood samples, body fluid/tissue samples, and collected data will be stored in a repository and shared in a deidentified fashion, potentially with other investigators and institutions.

If you give consent for the specimen(s) to be used in future research by the Quillen College of Medicine, Johnson City Medical Center, or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your unused specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

In order to change your mind and revoke this authorization, you must send a written letter to: Jonathan Moorman, M.D., Ph.D., 6 Magnolia Avenue, Mountain Home, TN 37684**.**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Jonathan Moorman or an approved study staff member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will be offered a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date (mo/day/yr)
_____ Legally Authorized Representative (LAR)	_____ LAR Signature	_____ Date (mo/day/yr)

_____

Signature of Person Obtaining Consent Date