VA Consent Document

This study is being conducted with funding from <<sponsor name>>.

You are being asked to take part in a research study, but before you decide, it is important for you to understand why the research is being done and what is involved. Please take the time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research coordinators, research staff, and the principle investigator questions if anything is not clear or if you would like more information. Take time to decide whether or not to take part in this research study.

The purpose of the study is to understand why female Veterans are more prone to chronic lung inflammatory conditions as compared to male Veterans. Allergic-asthma is a chronic airway disease, commonly defined by chronic coughing, shortness of breath, and wheezing. In more severe forms of the disease, bronchoconstriction, tightness in the chest and/or limited ability to breathe are common, and lead to need for emergency medical attention.

Over the past few decades, Gulf War on Terror (GWOT) Veterans returning from deployments have a higher incidents of respiratory illnesses, and importantly, an even higher percentage of female Veterans returning from deployments develop respiratory symptoms and chronic airway conditions in comparison to male Veterans. This is increasingly important as more females are enlisting for military service every year.

In this study we are specifically examining an important innate immune cell (called ILC2) that is 1) increased in asthmatic people, and 2) our group has now shown that more of these cells are present in females, and that they are more highly activated in females in comparison to males. Given these recent studies we wish to examine the ILC2 in male and female participants to establish whether future therapies can target these cells to reduce asthma symptoms and end life threatening exacerbations. To accomplish this, we are looking for volunteers to undergo a single blood draw which poses only minimal risk. The total time involvement should be no more than one hour and your involvement in the study is completely voluntary. At this time, we don't anticipate any therapeutic benefit from taking part in the study, but future therapies for respiratory illness may be improved because of this study and others like it.

Although not anticipated, personal information and biospecimens collected on behalf of this study may be used for future research. As an example, we might determine that whole genome sequencing is a relevant step for understanding the complexities of male and female differences in asthma, as such the cryopreserved biospecimens can be used for this type of research in the future. We do not anticipate clinically relevant research results will be determined at this stage of the research; however, this information will be disclosed to subjects if it becomes relevant to your health. Lastly, subject biospecimens will not be used for commercial profit.

STUDY PROCEDURES

Commented [AS1]: Informed consent should begin with a **concise and focused presentation of the key information** that is most likely to facilitate understanding of the reasons why one may or may not want to participate in research.

In general, the beginning of an informed consent would include a concise explanation of the following: 1) The fact that consent is being sought for research, and participation is voluntary; 2) Purpose of the research, expected duration, and procedures; 3) Reasonably foreseeable risks; 4) Benefits that may be reasonably expected; 5) Appropriate alternative procedures or courses of treatment, if any.

Elements included in a concise summary need not be repeated. For example, if the purpose of the study is explained in the concise summary, it does not need to be repeated later to satisfy the required elements of informed consent.

Commented [AS2]: Is there a statement that the study involves research? Yes.

Commented [AS3]: Is there an explanation of the purposes of the research? Yes.

Commented [AS4]: Is there a statement about the collection of identifiable private information or identifiable biospecimens? Yes.

Commented [AS5]: For research biospecimens, is there a statement about whether the research may include whole genome sequencing? Yes. This is an additional element of informed consent. Since the study does involve biospecimens, this statement is appropriate to include.

Commented [AS6]: Is there a statement about whether the participant's biospecimens may be used for commercial profit? Yes.

If you decide to participate in this study we will require one visit that should take less than one hour in duration. During this visit you will be asked to fill out a short questionnaire followed by a single blood draw where we will collect up to 100 mL of blood; 100 mL is equivalent to 6-7 tablespoons. After this single visit we will direct deposit $20 into your bank account. This will complete your involvement in the study although we are still more than happy to answer questions if they come up after the visit.

Commented [AS7]: Is there a description of the procedures to be followed including the identification of any procedures that are experimental? Yes.

RISKS

The risks associated with a blood draw are minimal. Slight momentary discomfort can be expected and the only side effect may be minor bruising. The risk of infection is small and unlikely as the blood draws will only be completed by trained phlebotomists. There is only a minimal risk for breach of confidentiality as medical records and information collected over the course of the study will remain in password-secured file boxes/filing cabinet and locked within a pass-code protected room. Your medical information will remain securely locked on a VA-owned and protected server.

Commented [AS8]: Is there a description of any foreseeable risks or discomforts to the participant? Yes.

BENEFITS

There are no direct benefits to you from your taking part in this study, but the information we gather may help us treat future patients with asthma and respiratory illnesses.

Commented [AS9]: Is there a description of any benefits to the participants or others? Yes.

CONFIDENTIALITY

Results of this study may be published, but your identity will not appear in any such publication. We will keep all research records that identify you private. Records about you will be kept in locked filing cabinets and on computers protected with passwords. Only those who are approved by the Institutional Review Board to work on this study and are performing their job duties for the University of Utah and the Department of Veterans Affairs will be allowed access to your information on an as needed basis as part of the study.

Commented [AS10]: Is there a statement describing the confidentiality of records? Yes.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history related to pulmonary function testing and past pulmonary illnesses (upper respiratory tract infections, asthma exacerbations), allergies, lab results, prescription drug use, contraceptive use and body mass index information (height, weight).

Commented [AS11]: HIPAA authorization for VA studies may be included within the consent document or as a separate document. Verbatim language is required and can be found on the IRB website.

If a study includes optional tissue/data banking or impaired decision making individuals (using LAR) a combined authorization may not be used. Rather, the VA Form 10-4093 HIPAA Authorization Form must be used.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the University of Utah Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

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. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, <<Investigator Name>> and her 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.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact <<Contact Name>> at <<phone number>>.

Commented [AS12]: Is the necessary contact information provided? Yes.

INSTITUTIONAL REVIEW BOARD

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Commented [AS13]: This statement is required for all studies. This language should be included verbatim.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

Commented [AS14]: For studies conducted at the VA, the statement that the VA will provide treatment for the research related injury is required.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

Commented [AS15]: Is there a statement that participation is voluntary? Yes.

Commented [AS16]: Is there a statement that individuals may refuse to participate or discontinue participation without penalty or loss of benefits? Yes.

COSTS TO PARTICIPANTS AND COMPENSATION

A veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Commented [AS17]: When appropriate, is there a statement that informs VA subjects that insurance will not be charged for costs related to the research? Yes. This is an additional element required by the VA.

As a participant in this study you will be compensated with a direct deposit of $20 at the completion of your visit.

NUMBER OF PARTICIPANTS

We expect to enroll 84 participants at the VA Salt Lake City Health Care System (VASLCHCS).

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. I agree to participate in this research study and disclose health information about me for this study, as you have explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of Person Obtaining Consent and Authorization	_____ Signature of Person Obtaining Consent and Authorization	_____ Date