



## **CONSENT FORM - Telementored Lung Ultrasound on Healthy Volunteers**

**TITLE:** The Marriage of Advanced Surgical Simulation Training with Tele-presence  
Mentoring: Training for Damage Control Surgery in Austere Environments:  
Part B) Telementored versus non Telementored Non Surgeons

**SPONSOR:** Department of National Defence, the Royal College of Physicians and Surgeons of Canada, and the Canadian Space Agency

**INVESTIGATORS:** Principal Investigator: Professor Andrew W Kirkpatrick  
Co-Investigators: Jessica McKee BA MSc  
Juan Wachs PhD  
Colonel Anthony J Laporta MD FACS  
Elon Glassberg MD MHA  
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This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

### **BACKGROUND**

You are being asked to give consent for participating in a research study led by Dr. Andrew Kirkpatrick. You will be asked to perform a lung ultrasound on yourself using an ultrasound probe that will plug directly into your smart phone or tablet. Using a platform similar to skype or ZOOM a trained surgeon/critical care medicine specialist will walk you through exactly how to get the images that he needs to see of your lungs to assess the general health of your lungs.



The reason that we are trying to see if you as a healthy volunteer are able to get images of your lungs is to potentially help those who have been infected with COVID 19. A practical question during the COVID 19 pandemic is how to quickly figure out which patients are in trouble from the majority who will just have inconvenient COVID-19 symptoms. Early Chest CT has been recommended as a screening tool for suspected COVID-19 but a chest CT is clearly impractical for home isolated patients. However, lung ultrasound in the home could be used to quickly and remotely identify those at risk of clinical deterioration to severe pneumonia at an early stage of illness.

So by starting with ultrasound in healthy volunteers if we are able to get images that would be sufficient to rule out pneumonia. Then the next steps would be to help those who are actually isolated with COVID 19.

### **WHAT IS THE PURPOSE OF THE STUDY?**

The overall purpose of this study is to evaluate the equipment and organization necessary to allow non-medical people who are isolated at home to perform a simple and potentially life-saving lung ultrasound using only an ultrasound probe that plugs into technology already in the home

### **WHAT WOULD I HAVE TO DO?**

An sterilized ultrasound probe that will plug into your phone or tablet will be left on your doorstep. Once you have the probe inside your house you will be given instructions over the phone on how to hook up the probe and communicate with the surgeon who will tell you what to do. Even though it is a lung ultrasound you will be able to leave your shirt on if it is loose fitting. It will simply be moved up and down to get the needed images. Once the ultrasound is over you will simply place the probe back onto your porch outside and it will be retrieved. You will also be asked to complete a short questionnaire online about your experience and basic information about yourself.

Your participation in this study will at all times be completely voluntary, and you may decline to answer any and all questions, you may refuse to participate altogether, and you may withdraw from the study at any time without penalty.

### **WHAT ARE THE RISKS?**

While there are no risks associated with conducting an ultrasound we are performing this study during the COVID 19 pandemic. The following things are being done to decrease transmission.

1. Only healthy volunteers that have been isolating at home for a least 14 days will be used.
2. Only healthy volunteers that are totally symptom free will be used
3. Only healthy volunteers that have not had a exposure will be used.



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4. The study coordinator who is running the study has been isolating at home for a minimum of 14 days, does not have any symptoms and has had no exposures.
5. The study coordinator will not be entering your house.
6. When you bring the ultrasound probe into your house it will be clean already and strict decontamination procedures will be followed when you leave the ultrasound probe outside. Including but not limited to a new, clean plastic bag will be covering the entire surface of the ultrasound probe.

### **ARE THERE ANY REPRODUCTIVE RISKS?**

No medication or treatment used in this study.

### **WILL I BENEFIT IF I TAKE PART?**

If you agree to participate in this study there may or may not be a direct benefit to you. The purpose of this study is to collect data in order to further the mission of advancing telemedicine. This is not intended as a training exercise for the participants. However, we expect that you will still learn and have fun in the process.

### **DO I HAVE TO PARTICIPATE?**

No, participation is purely voluntary. If you choose to give consent now, but then change your mind, you should call Dr. Kirkpatrick as soon as possible.

Dr. Kirkpatrick may also withdraw you from the study at any time if he feels it is in your best interests. For example, if you feel not comfortable by performing the procedure or other situations, you will be asked to stop participating.

If the researchers learn any new information during the study that might affect your willingness to continue to participate, you will be informed as soon as possible. This may include new information about the risks and benefits of being part of the study.

### **WHAT ELSE DOES MY PARTICIPATION INVOLVE?**

You will be asked to answer a short anonymous questionnaire regarding your medical training background in general and your ultrasound training background in particular.

### **WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

You will neither be paid nor have to pay for participating in this study.

**WILL MY RECORDS BE KEPT PRIVATE?**

All of the information will be kept private and confidential. The principle investigator and the data analysis team will have access to the anonymous data you provide, but which cannot be linked back to you in any way. All data related to any participant who withdraws prior to study completion will be destroyed. The CHREB has approved this study, and will only be allowed to access the records under the supervision of Dr. Kirkpatrick.

**IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?**

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by Department of National Defence, the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.



## SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without penalty. If you have further questions concerning matters related to this research, please contact:

Dr. Andrew Kirkpatrick (403) 944-2888

Or

Jessica Mckee (780) 906-4947

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Virginia Slater

Participant's Name

DocuSigned by:

*Virginia Slater*

4/23/2020

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Signature and Date

Andrew Kirkpatrick

Investigator/Delegate's Name

DocuSigned by:

*Andrew Kirkpatrick*

4/23/2020

80AE0B172E524DB...

Signature and Date

Jessica Mckee

Witness' Name

DocuSigned by:

*Jessica Mckee*

4/23/2020

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Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.