Consent Cover Letter & Authorization

Follow-Up Care for Ankle and Foot Injuries

The purpose of this research study is to learn how to provide the best health care support to patients who have been treated for ankle and foot injuries. This study will help us improve the care we give to our patients.

If you agree, you will complete a survey 4 times over the next year. You will complete this survey on your computer or smart phone. Each survey will take approximately 10 minutes to complete. You will get a text message or phone call each time you need to complete the survey. We will use the survey information with information from your medical record to see how your care was received.

Your participation is completely voluntary. You may choose not to answer a question or are free to withdraw consent and discontinue participation in the interview at any time for any reason without penalty or loss of benefits. There are no known risks associated with participating in this study. You may experience a benefit in the form of increased insight and awareness into your research practices and support needs.

This is the information we will use and include in our research records:

- Demographic and identifying information like *name, address telephone number, and email address*
- Related medical information about you like *<<family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results*

How we will protect and share your information:
We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team and University of Utah Health
- The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;

If we share your information with groups outside of University of Utah Health we will not share your name or identifying information. We will label your information with a code number, so

Commented [A1]: Does the consent process begin with a concise and focused presentation of key information? Yes. A Consent Cover Letter generally provides all the key information in a concise form.

Commented [A2]: Is there a statement that the study involves research and an explanation of the purposes of the research? Yes.

Commented [A3]: Is there a description of the procedures to be followed including the identification of any procedures that are experimental? Yes, there is a description of the procedures. There are no experimental procedures.

Commented [A4]: Is the expected duration of participation stated? Yes.

Commented [A5]: Is there a statement that participation is voluntary? Yes.

Commented [A6]: Is there a statement that individuals may refuse to participate or discontinue participation without penalty or loss of benefits? Yes.

Commented [A7]: Is there a description of any foreseeable risks or discomforts to the participant? Yes.

Commented [A8]: Is there a description of any benefits to the participants or others? Yes.

Commented [A9]: Is there a statement describing the confidentiality of records? Yes.

Are HIPAA Authorization provisions included? Yes.

they will not know your identity. The information collected in this research will not be used for future research studies.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health.

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

If you have any questions complaints or if you feel you have been harmed by this research please contact <<researcher name>>, University of Utah Marriott Library, at <<phone number>>.

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.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

By participating in the surveys, you are giving your consent to participate in this research and your authorization to allow us to use your medical record information. Thank you for your willingness to participate!

Commented [AS10]: Is there a statement about the collection of identifiable private information or identifiable biospecimens? Yes.

Commented [A11]: Is the necessary contact information provided? Yes.

Commented [AS12]: This statement is required when the study is conducted at the University of Utah. The language should be included verbatim.

Commented [IRB13]: If the study is conducted at the University of Utah, include this statement.

Commented [AS14]: A Waiver of Documentation of Consent is approvable because the research presents no more than minimal risks of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Therefore, this cover letter does not require a signature from the participant or participant's legally authorized representative. The participant should receive a copy of the consent cover letter.