Parkland Health
Guidelines for Informed Consent Document

I. PURPOSE

Parkland Health serves as a primary research site for clinical and health services research. The purpose of this document is to provide guidance to UTSW research staff for requirements of the informed consent document during study submission.

II. REQUIRED LANGUAGE THAT MUST BE INCLUDED IN THE INFORMED CONSENT DOCUMENT THAT WILL BE UTILIZED AT PARKLAND (WHICH IS INCLUDED IN THE UTSW IRB INFORMED CONSENT TEMPLATE)

A. If UTSW is listed in the informed consent header then Parkland Health must be listed as well.

Consent to be part of a Research Study
To be conducted at
***Select** appropriate Study sites*
The University of Texas Southwestern Medical Center
Parkland Health & Hospital System

B. PHI section should always include Parkland Health as shown below:

How will your PHI be shared?
The Research offices at [select all appropriate, delete others:] the University of Texas Southwestern Medical Center, Parkland Health and Hospital System, Children's Medical Center of Dallas and any of its affiliated entities, Texas Scottish Rite, Texas Health Resources.

C. Research-related injury should always include a statement as shown below:

- We have no plans to give you money if you are injured.
- UT Southwestern and Parkland Health have no plans to give you money if you are injured.
- UT Southwestern and affiliate sites have no plans to give you money if you are injured.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

NOTE: If UT Southwestern is the only site listed the study team will be required to submit an IRB modification adding Parkland Health

D. The following insurance clause as shown below must be included:

Please do not remove the insurance clause section of the IRB template as this language is Parkland Health required.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

E. All of these areas listed above must be included in the informed consent before approval from the ORA.

Parkland Health
Guidelines for Informed Consent Document

III. REMINDERS

A. Parkland REQUIRES a fully translated Spanish consent prior to study approval (reference the Parkland Health policy "Research Consent Process" OSM.ORA.RSCH.101)

B. If you ADD "UT Southwestern Medical Center" throughout the consent, be sure to ADD "Parkland Health" if appropriate

C. Always print the informed consent directly from the IRB

D. Utilize informed consent forms with valid approval dates

E. All research participants must consent prior to any study related tasks or procedures being conducted

F. If a member of the study team is not listed on the study in the IRB they cannot obtain consent