

W INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Clinical Trial Using an Insulin Dosing Calculator on Hospital Admission

Your legally authorized representative consented for you to participate in this study. The intervention is to start insulin dosing using our novel insulin calculator. This was already done when you came to the hospital. We would like to ask for your consent for us to continue collecting your medical record data during this hospitalization.

What is this study about?

The purpose of this study is to look at whether using a standardized calculator to compute insulin dosages results in acceptable rates of low blood sugar (hypoglycemia). Currently, hospitals rely on physician experience to calculate insulin dosage, and physician practices are variable.

How will we store, share, and protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and any individuals from the UW, National Institutes of Health (NIH), or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name.

This study is funded by the National Institutes of Health (NIH). We have a Certificate of Confidentiality from the U.S. federal NIH, which allows us to protect identifiable research information stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish. There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

Research information that is placed in your medical record may not be protected by this Certificate. Ask a member of the study team for information about what research information will be placed in your medical record.

The Certificate expires when the NIH funding for this study ends. Currently this is June 30, 2028. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, the information may then be used for future research studies or given to another investigator without getting additional permission from you.

Other information about this study.

If you have been injured or otherwise harmed by participating in this study, you will be treated or referred for treatment. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. Our study team may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, you can contact the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

A description of this clinical trial will be available on <https://clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What can you do if you want more information?

Talk to the study team. The doctor who admitted you to the hospital is part of our study team. If you have further questions after talking to your hospital doctor, the primary investigator, Dr. Hou-Hsien Tony Chiang, can talk to you in the hospital during work hours (htchiang@uw.edu). We are here to help you understand the study. Please ask us any questions you may have, even about things that are not in this document.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division (hsdinfo@uw.edu or 206-543-0098).