SAMPLE PATIENT CONSENT FORM

NOTE TO PHYSICIAN: Medtronic is providing this sample "Patient Consent Form" to support your patients' use of the iPro™2, including your use of the CareLink iPro website for their benefit. By signing this Consent Form, your patients are consenting to their medical and personal data being uploaded to the CareLink iPro database (server), and agreeing to certain standards for wearing the iPro™2.

Please note that this is only a sample form and should be customized to meet any specific needs of your office. Medtronic cannot guarantee that the language contained herein is exhaustive and addresses all legal, regulatory and operational requirements and standards. THIS SAMPLE CONSENT FORM IS provided on an "AS IS" basis and Medtronic disclaims all warranties, express or implied, regarding it.

PATIENT CONSENT FORM

Medtronic iPro™2 & CareLink™ iPro™

Dear Patient,

Please read this Patient Consent Form carefully, as you will be asked to provide your agreement and consent to the terms and instructions below regarding your use of the Medtronic iPro™2 digital recorder ("iPro2"), a continuous glucose monitor, and this office's use of the CareLink iPro web-based application for your diabetes therapy. If there is anything in this Consent Form that you do not understand or have concerns with, please contact our office. Please note that if you do not agree to the terms of this Consent Form, our office cannot place an iPro2 on you, nor use the CareLink iPro application for your diabetes treatment.

This Consent Form is separate from, and in addition to, any other consent or authorization form you have received from our office.

iPro2

The iPro2 is a continuous glucose monitor placed on your body for a period of a few days (as specified by our office and/or your physician), that will continuously record your glucose levels. The results of the recordings can be recorded, placed in a report, analyzed, etc. (through the CareLink iPro website), and will assist our office in helping you manage your diabetes more effectively. The iPro2 should only be used pursuant to our instructions. When wearing the iPro2, you agree and commit to the following:

(a) You agree to collect at least 4 blood glucose fingerstick tests per day.
(b) You agree to enter all meals, medication, and other relevant activities on a log sheet.
(c) You agree to check the insertion site daily, to verify the sensor is fully inserted and that the site is not irritated, excessively red or painful. (You understand that the possible risks include inflammation, infection, and/or bleeding at the sensor insertion site.)
(d) You agree to return the iPro2 within _____ days of completing the wear period.
(e) You agree to take every precaution when handling the iPro2, and understand it is a sensitive medical device. You may be responsible for the loss or theft of the iPro2, or any damage or malfunction caused by any unreasonable or unusual activity.
(f) In addition, you agree to follow any other specific instructions we provide regarding the iPro2, and to call our office immediately if you experience problems or have questions.

If you have any questions about the iPro2, please contact our office and, if necessary, your physician or health care professional.

CareLink iPro – General Information & Patient Privacy

The iPro2 uses a software application called CareLink iPro. This is a centralized, web-based software from Medtronic used by health care professionals to upload, store and analyze glucose readings from patients who have worn an iPro2. In addition to the glucose readings from the iPro2, we may also upload certain background information for identification purposes, including your name, date of birth, a patient ID number, and limited information regarding your type of diabetes (collectively referred to as "Protected Information"). Once your Protected Information is uploaded through the CareLink

iPro website (http://www.carelinkipro.com in the U.S.; http://ipro.medtronic.com outside of the U.S.), it will be stored on a secured computer server (database) located in a U.S. Medtronic facility (Minnesota) for patients in the U.S., or a secured computer server located in a Medtronic facility in Heerlen, Netherlands, for all non-U.S. patients. Accordingly, please note that your Protected Information may cross country borders when transmitted to a CareLink iPro server.

Our office and Medtronic place great importance in maintaining the privacy and confidentiality of your Protected Information (i.e., your medical and personal information). Medtronic has established significant security measures and safeguards for your Protected Information when used with the CareLink iPro website and stored on the CareLink iPro server. All Protected Information sent through the CareLink iPro website will be transmitted to the CareLink iPro server using HTTPS protocol and strong (128-bit) encryption. In addition, each CareLink iPro server features a secure architecture consisting of a three-tier firewall system, as well as password protection, designed to protect the privacy of your Protected Information.

Medtronic Access to Protected Information

Please note that Medtronic is responsible for hosting and maintaining the CareLink iPro servers, and therefore will have access to your Protected Information that this office has or will upload through the CareLink iPro website. Medtronic may also study your Protected Information for purposes of advancing or improving its products, therapies or services for the benefit of future patients. Medtronic may do this by analyzing, studying, conducting education, and/or monitoring the data (usually in aggregate form) stored on the CareLink iPro servers. Please note that Medtronic will not review any Protected Information for purposes of identifying clinical or medical issues regarding you or other individual patients.

In addition to the system protections mentioned above, Medtronic as a company enforces important patient privacy safeguards and policies internally to protect your Protected Information, including restricting access to only those employees (and certain contractors) who may need access to this information to do their jobs. Medtronic will take all appropriate steps to ensure that any contractors utilized will comply with applicable standards and policies for maintaining the privacy of patient data.

Your Protected Information stored on a CareLink iPro server will never be used to market to you, place you on any mailing lists, or sold to anyone for marketing purposes. Also, Medtronic will not share your Protected Information with any outside entity or third party. Limited exceptions exist to this prohibition, such as where the Protected Information is (1) completely de-identified (made anonymous) so that you (or any other individual patient) cannot be identified in any way, (2) requested by a government office or agency, court order, or a similar authority, or (3) disclosed to protect an individual's health, safety or welfare.

By signing below, I acknowledge that I have read, fully understand, and agree to the above terms of this Consent Form, including those terms regarding the use of the iPro2 and the storage and use of my Protected Information (as described above) through the CareLink iPro website. I have had an opportunity to ask questions and to receive answers. I realize that my consent is voluntary, and I may refuse to participate or utilize the iPro2 and the benefits of CareLink iPro.

Signature of Patient (or Legal Representative) _____ Date _____

Print Patient Name _____