

## Consent to Participate in a Research Study

### *Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes*

1 Today, you are being asked to take part in this **research** study because you have type 1 diabetes  
2 and use an insulin pump. The goal of this research is to get new knowledge that may help other  
3 people, but it is not the same as treatment of type 1 diabetes. We want to find what works best  
4 for treating you and others with this condition.

5  
6 Your study team will be talking with you about this research and this document. Please take  
7 your time deciding whether you want to participate in this research and please carefully read this  
8 document. To take part in the study, you will need to carefully read and sign this document.

9  
10 Before you decide to take part in this research study, we encourage you to speak with friends and  
11 family members about it. If you do not understand all the information, please ask your study  
12 doctor or nurse to explain. If you are taking part in another study, please tell us right away.

#### **NON-PARTICIPATION STATEMENT**

15 Participation in this study is voluntary and you must agree to take part. If you decide to stop  
16 participation in this research, that will happen immediately. No penalty or loss of medical care  
17 will result from your decision. While the study is occurring you may continue to receive medical  
18 care not related to this study.

#### **WHO IS DOING THE STUDY**

21 Your study team will carry out this study. Their names are listed on the Cover Page of this form.  
22 The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is part of  
23 the federal government, is paying for this research. This funding will be used by your doctor's  
24 office and other clinical centers to conduct the research study and by the Jaeb Center for Health  
25 Research to coordinate the study

#### **WHY ARE WE DOING THIS STUDY?**

28 The purpose of this study is to see if the use of an automated insulin delivery system ("study  
29 system") can safely and successfully manage blood sugars. This type of system is also referred  
30 to as an artificial pancreas or a closed-loop system. The name of the study system is inControl.  
31 The system consists of (1) an insulin pump that delivers insulin, (2) a continuous glucose  
32 monitor or CGM that measures your sugar level, and (3) software that determines how much  
33 insulin will be given.

34

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57

58

#### **HOW MANY PEOPLE ARE WE EXPECTING TAKE PART IN THIS STUDY?**

59 We expect about 126 people will take part in this study at 7 different clinical centers in the  
60 United States.

62

#### **WHO CAN PARTICIPATE IN THIS STUDY?**

63 To take part in this study, you will need to:

- 64 1. Be at least 14 years old
- 65 2. Have type 1 diabetes and have used insulin for at least one year
- 66 3. Have used an insulin pump for at least the last 6 months
- 67 4. Have an HbA1c level <10.5% (a test of blood sugar control over the last 3 months)
- 68 5. Be willing to connect the study smartphone to the internet at least once per week either  
69 using your Wi-Fi or using a cell phone data plan provided to you
- 70 6. Not take any medicine but insulin to lower blood sugar either now or during the study

The CGM sensor has a thin needle that is inserted just under the skin. It measures the glucose in the fluid under the skin and shows this information every 5 minutes. The sensor needs to be changed about every 7 days. The insulin pump has a catheter that is inserted under the skin. It needs to be changed about every 3 days. This may be similar to the insulin pump infusion set you are already using.

The study system is experimental and can only be used for research. The U.S. Food and Drug Administration has approved its use in this research study.

We previously tested a version of this system in about 400 individuals. They used a similar version of the system in other studies for shorter periods of time at home. We did not find an increased risk for high or low blood sugars or other problems. We are now ready to further test the system at home with more people for a longer period.

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72     7. Not be employed by or have immediate family members employed by TypeZero  
73       Technologies, LLC.  
74     8. Not have a boss or an immediate family member who is directly involved in the study.  
75     9. Be willing not to participate in another study at the same time as this study  
76     10. Be willing to follow the procedures that will be described in the next sections

77  
78     There are some conditions that may prevent you from being part of the study. Your study doctor  
79       will check if you have these or not. Pregnant women cannot participate. If you are a woman who  
80       has the potential to get pregnant we will do a urine test to be sure you are not pregnant before  
81       you enter the study.

### **WHAT HAPPENS IF I AGREE TO TAKE PART IN THIS STUDY?**

82     About half of the individuals in the study will use the closed-loop study system. The other  
83       individuals will use the CGM and insulin pump only, which we refer to as sensor-augmented  
84       pump (SAP).

85     This study will take about 13-17 weeks for you to complete. The next sections list what will  
86       happen during the study.

#### ***Screening Visit***

87     If you agree to participate, you will sign this consent form before any study-related procedures  
88       take place. You will have some tests done to make sure you qualify and that it is safe for you to  
89       be in the study.

90     These include the following:

- 91       • Collection of information about you: This may include contact information, diabetes  
92           history, the past and current medical conditions, surgical procedures, menstrual history  
93           (females), allergies, medications and supplements, family history, social history  
94           (drinking, smoking, and drug habits), and whether or not you have various symptoms.  
95           You also will also be asked about your pump settings and average daily insulin use over  
96           the past week.
- 97       • Physical exam (height and weight, blood pressure)
- 98       • HbA1c test unless you have had one within the past 2 weeks
- 99       • Additional blood tests if your study doctor has any concerns about medical conditions  
100          that might put you at risk in the study
- 101       • A urine pregnancy test if you are a woman who can become pregnant. The pregnancy test  
102          must be negative for you to participate and will be repeated at some follow-up clinic  
103          visits during the study.

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110 We will give you a study blood glucose meter and blood ketone meter to use during the study.  
111 You will need to perform a ketone test if your glucose level is higher than 300 mg/dL for more  
112 than 1 hour, or greater than 400 mg/dL at any time. We will give you instructions on how to use  
113 and maintain your meters.

114  
115 You will be asked to keep a glucagon emergency kit on hand at home. If you need a prescription  
116 for the glucagon emergency kit, you can ask your study doctor.

117  
118 The Screening visit will last 1 to 2 hours.  
119

#### Initial CGM Use

120 If you have used a CGM that is the same as the study CGM for at least 21 out of the last 28 days,  
121 you will skip to the Main Phase of the study described below. Otherwise, you will use the study  
122 CGM as described here.

123  
124 First, you will wear the study CGM for 2 weeks without being able to see the glucose values it  
125 records. This is called “blinded” CGM.

- 126 • You will be taught how to use the CGM including putting in a new sensor after 7  
127 days (or sooner if the sensor comes out).
- 128 • You will use the CGM at home for 2 weeks. You should follow your normal  
129 routine during this time for meals, fingersticks, and insulin boluses. If you were  
130 using a personal CGM before entering the study, you may continue to use it.
- 131 • You will return for a follow-up clinic visit after 2 weeks.
- 132 • Study staff will download the “blinded” study CGM data to determine if you wore it  
133 often enough to continue in the study—at least 11 out of 14 days. They will also  
134 check for any skin reaction in areas where you wore the CGM.
- 135 • Study staff may suggest changes to help you improve your blood sugar control.

136  
137 If you are eligible to continue, study staff will change the CGM settings so you can see the CGM  
138 glucose values. You will wear the study CGM for 2 more weeks at home. This is called  
139 “unblinded” CGM.

- 140 • You will be trained how to use CGM information in your diabetes management.
- 141 • Study staff will download the “unblinded” study CGM data to determine if you  
142 wore it often enough to continue in the study—at least 11 out of 14 days. They  
143 will also check for any skin reaction in areas where you wore the CGM.
- 144 • Study staff may suggest changes to your insulin pump settings to help you  
145 improve your blood sugar control.

146  
147

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148 **Main Phase**  
149 If you skipped the CGM Use phase above, the procedures described below could occur as part of  
150 the Screening visit. Otherwise, a separate visit will occur at least 4 weeks after the Screening  
151 visit.  
152  
153 If you qualify to start the main phase of the study, you will again be asked if you have any  
154 questions about the study. We want to make sure that if you continue, you understand the study  
155 and feel that you could follow the procedures needed in either study group.  
156  
157 We will draw blood for another HbA1c test. The blood will also be used for a C-peptide test.  
158 This measures whether your body makes any of its own insulin. Everyone in the study will  
159 complete some questionnaires. Topics will include a personality assessment, hypoglycemia  
160 awareness, low and high blood sugar, and your feelings about managing your diabetes.  
161  
162 At this visit, a computer program will be used to select whether or not you will be given the  
163 closed-loop study system or use the study CGM with your own insulin pump. Through a process  
164 similar to flipping a coin, you will be assigned to either the closed-loop group or the SAP group  
165 for the rest of the study. You will have a 50/50 chance of being in either group. Neither you nor  
166 the study staff will have a choice in which group you will be placed.  
167  
168 You will receive diabetes education. The education will cover key parts of diabetes  
169 management.  
170  
171 **SAP Group**  
172 If assigned to this group, you will use your personal insulin pump along with the study CGM at  
173 home. We will call you after the first week to see how you are doing with the CGM. You will  
174 come back to the clinic after your second week so we can answer any questions you may have  
175 and review your glucose data. Study staff may suggest changes to help you improve your blood  
176 sugar control. You will then continue to use the study CGM and your personal pump for about  
177 13 weeks at home. You will have a series of phone contacts and clinic visits during this period  
178 as shown in Table 1 below.  
179  
180 You will be asked to upload data from study devices at different times during the study. You  
181 will be given all necessary equipment to do this.  
182  
183 **Closed-Loop Group**  
184 If assigned to this group, you will be trained to use the study pump on its own. You will also be  
185 trained to use the closed-loop study system to control the study pump. You will be taught how to

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186 use the study system in all modes of operation similar to your personal insulin pump. Using the  
187 study system in closed-loop mode will automatically adjust your insulin delivery based on the  
188 CGM glucose readings. You can always stop the study system at any time and take over control  
189 of your insulin pump.

190  
191 Training may happen during a single visit or two visits to the clinic. By the end of training, you  
192 will be expected to perform certain tasks without help from study staff members. You will be  
193 given a printed User Guide as a reference. You will also wear a blinded CGM sensor as  
194 described above during your first two weeks of home use

195  
196 ***At-Home Study Procedures***  
197 You will use the study system at home day and night for a 1-week period and then have a phone  
198 call with study staff to review your experience. You will continue to use the system for another  
199 week followed by a clinic visit to review your training and answer any questions you have.  
200 Study staff may suggest changes to help you improve your blood sugar control. Then you will  
201 use the study system at home for about 13 weeks. You will have a series of phone contacts and  
202 clinic visits during this period as shown in the table below.

203  
204 You should use the study system in closed-loop mode whenever possible. In the following  
205 situations you should contact study staff to determine whether temporarily to stop closed-loop  
206 use:

- 207 • You have a fever above 101.5 degrees Fahrenheit
- 208 • You have a major illness
- 209 • You need to use certain medications including epinephrine (e.g. for the  
210 emergency treatment of a severe allergic reaction or asthma attack) or oral or  
211 injectable glucocorticoids; details will be provided to you in a written guide

212  
213 You will be provided with an Emergency Card with information regarding the study system to  
214 carry with you at all times while participating in the study in the event you need emergency  
215 medical care.

216  
217 The study system will transfer CGM and pump data to a central database every few minutes  
218 when the study smartphone is connected to the internet. The system must be connected to the  
219 internet at least once per week.

220  
221 You will be able to contact study staff at any time with a question, problem, or concern.

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223 ***Scheduled Clinic Visits***

224 The schedule for clinic visits is the same for everyone in the study. The main reason for these visits  
225 is to troubleshoot any problems and ask you about any changes in your health.

226

227 Follow-up visits will occur at 5 weeks, 9 weeks, and 13 weeks.

228

229 The following procedures will be performed in both groups at each visit, unless otherwise listed  
230 below:

231     • Assessment of study device use (*except 9-week visit*)  
232     • Review of any problems or events that have occurred (*except 9-week visit*)  
233     • Download of study device data  
234     • Blood draw for HbA1c (*13-week visit*)  
235     • Insertion of a blinded CGM device as described above (*9-week visit*)

236

237 ***Scheduled Phone Calls***

238 In addition to the 1-week phone call described above, study staff will call you at 3 weeks. The  
239 schedule for these calls is the same for everyone in the study.

240

241 **3-Week Phone Call Procedures**

242     • Discussion of your use of the study devices  
243     • Discussion of any changes in your health  
244     • Review of available study device data to identify any safety issues

245

246 ***Final Visit (13-week Visit)***

247 The final study visit will be at least 13 weeks after the Screening visit. Procedures will be similar  
248 to those described for the Screening and follow-up visits. You will return some or all study devices  
249 as instructed by study staff. If needed, you will be switched back to the insulin pump you were  
250 using before entering the study. You will complete another set of questionnaires with similar  
251 topics as before. There will be a final blood draw for HbA1c tests. You will have weight and (if  
252 you are under 21 years old) height measurements taken again.

253

254 Table 1 below summarizes what will happen at each call and visit during the main study phase.

255

256

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257 **Table 1: Main Phase of Study**

258

	Week of Study:	0	1w	2w	3w	5w	9w	13w
<b>Clinic Visit (V) or Phone Call (P)</b>		V	P	V	P	V	V	V
<b>Review if you can continue in the study</b>		X						
<b>Pregnancy Test</b>		X						
<b>Blinded CGM (2 weeks)</b>							X	
<b>Blood draw for HbA1c test</b>		X						X
<b>Blood draw for C-peptide test</b>		X						
<b>Study device download</b>		X		X		X	X	X
<b>Review diabetes management and any new medical problems</b>		X	X	X	X	X		X
<b>Study questionnaires</b>		X						X

259

260

### **Additional Study Procedures**

261

262 If you are a female and menstruating, you will be asked to keep a log of when your menses occur to see the impact it has on your blood sugars. You may choose not to participate in this part of 263 the study if you prefer. If you participate, you will be given a paper log to record this 264 information for the study team. This will help us to better understand blood sugar fluctuations 265 and insulin requirements during menses and the impact of the closed-loop system. Your decision 266 to participate, or to not participate, in these additional procedures will not affect your ability to 267 be in this study.

268

269

### **ARE THERE RISKS IN THIS STUDY?**

270

271 Taking part in research often involves some risks of physical or psychological injury or discomfort. 272 The most likely risks of this study are described below. These deserve careful thought. This study 273 may include risks that are unknown at this time.

274

275

276

Risks related to your normal medical care are not listed in this form. We encourage you to discuss these with your study doctor, your primary care provider, or another health care professional.

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277 **Risk of Low Blood Sugar**

278 As with any person who uses insulin, there is always a risk of having low blood sugar  
279 (hypoglycemia). Low blood sugar should not happen more often during the study than before the  
280 study. Symptoms of low blood sugar can include:

- 281 • sweating
- 282 • shaking
- 283 • not feeling well
- 284 • fainting
- 285 • seizures (convulsions)

286 In very rare cases low blood sugar can lead to brain damage or death. Even if low blood sugar does  
287 occur, it almost always goes away quickly with treatment to raise the blood sugar.

288

289 **Risk of High Blood Sugar**

290 High blood sugar also should not happen more often during the study than before the study. High  
291 blood sugar usually does not cause many obvious symptoms, but you may become thirsty or have a  
292 higher level of sugar in your urine. In severe cases, diabetic ketoacidosis (DKA) or coma may  
293 occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown, and  
294 even death.

295

296 **Fingerstick Risks**

297 About 2 drops of blood will be removed by fingerstick to test blood sugar levels. It hurts when the  
298 needle goes into your finger but not for long. In about 1 in 10 times, a small amount of bleeding  
299 under the skin will produce a bruise. A small scar may persist for several weeks. The risk of an  
300 infection is less than 1 in 1000.

301

302 **Blood Draw Risk**

303 Possible risks from blood draws include:

- 304 • Pain (common)
- 305 • Bruising (common)
- 306 • Redness (common)
- 307 • Temporary discomfort from the needle stick (common)
- 308 • Clotting (unlikely)
- 309 • Excessive bleeding (unlikely)
- 310 • Lightheadedness (rare)
- 311 • Infection (rare)
- 312 • Fainting (rare)
- 313 • Swelling of tissue (rare)

314 Total blood loss during this study is approximately 15 milliliters or about 3-4 teaspoons.

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315

#### Insulin Pump Therapy Risks

316 The risks of using an insulin pump may include:

- 317 • Discomfort during insertion of the infusion set (common)
- 318 • Bruising at the site of infusion set insertion (common)
- 319 • Bleeding at the site of insertion (rare)
- 320 • Infection at the site of insertion (rare)
- 321 • Allergy to the infusion set or adhesive (rare)
- 322 • Insulin pump malfunction and mechanical problems (rare)
- 323 • Allergy to insulin (very rare)
- 324 • Changes to your skin (very rare)

325

#### Continuous Glucose Monitoring Sensor Risk

326 Potential risks from using a CGM include:

- 327 • Discomfort when the sensor is inserted into the skin (common)
- 328 • Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- 329 • Tape allergies (rare)
- 330 • Infection at the site of sensor insertion (rare)

331

#### Study System Risks

332 There is a risk that parts of the closed-loop study system may not work properly. As a result, you could receive less or more insulin than you need and be at risk for high or low blood sugars. The following are some common ways the study system might not work correctly:

- 333 • CGM sensor reads higher or lower than your actual glucose level
- 334 • CGM sensor stops working or cannot communicate with the study system. If this occurs, the pump will start delivering your normal insulin rate within 30 minutes.

335

#### Risk of Reusing the Continuous Glucose Monitor

336 The FDA approved the continuous glucose monitor as a “single use device.” This means that they recommend that only one person use this device as there is a rare risk that a blood-borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. In the study, we may reuse CGM receiver or transmitter parts after careful cleaning. The sensors will not be reused.

337

#### Risk of Reusing the Blood Glucose Meter or Ketone Meter

338 The FDA approved these meters for “single-patient use.” This means that they recommend that only one person use this device as there is a rare risk that a blood-borne pathogen, such as

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352 Hepatitis B, may be spread if used with multiple patients. In the study, we do not plan to reuse  
353 these meters.

354

#### Risk of Reusing the Insulin Pump

355 The FDA approved the insulin pump for “single-patient use.” They suggest that only one person  
356 use this device as there is a rare risk that a blood-borne pathogen, such as Hepatitis B, may be  
357 spread if used with multiple patients. In the study, the insulin pump may be reused after careful  
358 cleaning.

359

#### Risks for Women

360 If you are pregnant now, or get pregnant during the study, please tell us. We do not know how the  
361 study may affect an unborn baby, so you will not be able to join or stay in the study. A urine  
362 pregnancy test will be done during the Screening visit and will be repeated during the study if you  
363 are a woman who can become pregnant. You and your partner must use an approved form of birth  
364 control during this study. Ask your doctor for more details about the proper birth control method  
365 for you.

366

#### Questionnaires

367 The questions asked on the questionnaires will include questions about your personal attitudes, and  
368 behaviors related to diabetes. It is possible you may find these questions to be upsetting. Similar  
369 questionnaires have been used in other studies, and this reaction is uncommon. You can refuse to  
370 answer any questions that make you feel uncomfortable. You can decide not to answer  
371 questions, take a break, or stop taking part in the study at any time. There are no physical risks  
372 present. Many precautions will be made to keep your information confidential, but this is not a  
373 guarantee.

374

#### Unknown Risks

375 There may be additional risks associated with the study system that are not known at this time.  
376 If we become aware of any new risks, you will be told about them. You will be able to decide if  
377 you want to continue to take part in this study.

378

#### Loss of Privacy

379 Study staff will do their best to make sure that your private information is kept confidential, but  
380 participating in research may involve a loss of privacy and the potential for a breach of  
381 confidentiality. Information about you will be replaced with a code. A list linking the code and  
382 your information will be kept separate from the research data.

383

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389 Information about your data uploaded from your study devices will be collected for the study and  
390 transmitted through a secure electronic system to the Jaeb Center for Health Research in Tampa,  
391 Florida. This center is coordinating the study. It reviews all of the study information that is  
392 collected. The Jaeb Center for Health Research will be reviewing the data, but will not have your  
393 personal information.

394  
395 The blood glucose meter used in the study is made by a company called Ascensia. Data from the  
396 meter will be downloaded by study staff during clinic visits using software at the clinic. You  
397 should not try to use any other software to download data from the meter. This includes software  
398 from Ascensia called the CONTOUR DIABETES app. Your data may not remain confidential if  
399 you use this app or other software to download the data. Study staff will remind you about this  
400 during the study.

401  
402 **WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?**  
403 There may be a possible medical benefit to you if you decide to take part in the study, but it is  
404 not a guarantee. For instance, it is possible that your blood sugar control will improve during the  
405 study using the study system or using just your insulin pump with CGM. If you are just using  
406 the insulin pump, the blood sugar information from the CGM along with the instructions given  
407 for management changes will be useful for your diabetes control.

408  
409 You may receive no direct benefit from being in the study. People who take part in this research  
410 study will add new knowledge that may help other people with type 1 diabetes.

411  
412 **WHAT ALTERNATIVE PROCEDURES OR TREATMENT ARE AVAILABLE IF I DO  
413 NOT TAKE PART IN THIS STUDY?**

414 If you do not take part in this study, you could continue using your current insulin pump. You  
415 could also talk with your doctor about other ways to take insulin. If you do not participate, your  
416 medical care will not be affected.

417  
418 We encourage you to discuss these options with your study team, your general primary care  
419 physician, or another health care professional who has knowledge of type 1 diabetes.

420  
421 **WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO  
422 WITHDRAW FROM THE STUDY?**

423 You can stop participating in this study at any time. You may continue to receive medical care  
424 not related to this study. However, we encourage you to talk to a member of the study team so  
425 they know why you are stopping the study.

426

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427 If there are any new findings during the study that may affect your participation, you will be told  
428 about them so you can decide if you want to continue.

429  
430 No penalty or loss of medical care will result from your decision. You may continue to receive  
431 medical care not related to this study.

432  
433 The study doctor may decide to stop your participation without your permission if he or she  
434 thinks that being in the study may cause you harm. Some possible reasons for this include:

- 435 • the study doctor decides that continued participation is not safe for you, especially if you  
436 have a severe low blood sugar or DKA
- 437 • you need treatment not allowed in the study
- 438 • failure to follow instructions
- 439 • the study is canceled

440  
**441 ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?**

442 Testing that is specifically for this study will be paid for by the study. The costs of treatment,  
443 office visits, and tests that are part of your type 1 diabetes care will be your or your insurance  
444 company's responsibility. The study will pay for:

- 445 ➤ CGM-pump system, system supplies, and smartphone (closed-loop group)
- 446 ➤ CGM sensors (both treatment groups)
- 447 ➤ Blood glucose meter, test strips, and control solution (both treatment groups)
- 448 ➤ Blood ketone meter, test strips, and control solution (both treatment groups)
- 449 ➤ Blinded CGM (both treatment groups)

450  
451 At the end of the study, or if you decide to remove yourself from the study, you must return the  
452 study system parts to the study team listed on the Cover Page.

453  
454 All other tests and procedures, including your own insulin, and other medical problems that  
455 would happen even if you were not in this study are your or your insurance company's  
456 responsibility.

457  
**458 IS THERE COMPENSATION FOR TAKING PART IN THIS STUDY?**

459 If you take part in the study, you will be paid \$50 for each completed office visit required for the  
460 study to cover travel and other visit-related expenses. You will not receive any compensation for  
461 extra visits your doctor believes are needed for your usual care.

## Consent to Participate in a Research Study

### *Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes*

#### 462 **WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?**

463 Medical care is available if you have a research-related injury. If you have an emergency, you  
464 can get emergency care. If possible, you should tell the emergency care medical staff that you are  
465 in a research study. You should also tell your study team about the emergency as soon as  
466 possible.

467

468 The study will not provide costs for medical expenses or any other costs for research-related  
469 injuries. The costs of care are your or your insurance company's responsibility. Money for lost  
470 wages or direct or indirect losses is not available.

471

#### 472 **CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS**

473 If you have questions about this study, a research-related injury, have concerns, suggestions or  
474 questions about the study, contact your study team using the provided contact information on the  
475 Cover Page.

476

477 If you have unanswered questions about your rights as a research participant, wish to talk about  
478 your concerns or suggestions linked to the research study, want additional information about the  
479 research, or want to provide comments about the research, contact the Jaeb Center for Health  
480 Research Institutional Review Board (IRB) Office at 813-975-8690 or [irb@jaeb.org](mailto:irb@jaeb.org)

481

#### 482 **HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?**

483 As required by law, study related records with identifying information will be kept confidential.  
484 Safeguards for authorized access, security, and privacy of your information have been put in  
485 place by the Federal Privacy Regulations. Unless the law requires it, your name, address, social  
486 security number, telephone number, or any other direct identifying information will not be used  
487 to identify you.

488

#### 489 **A. Purpose of Authorization**

490 We have rules to protect information about you. Federal and state laws and the federal medical  
491 Privacy Rule also protect your information. By signing this form you provide your permission,  
492 called your "authorization," for the use and disclosure of information protected by the Privacy  
493 Rule.

494

495 You must sign the **Protected Health Information Authorization** at the end of this form if you  
496 want to be in the study. When you sign the form, you give permission for the use and disclosure  
497 of your Protected Health Information (PHI) for the study. PHI is health information that  
498 identifies you. Your authorization is beneficial and important for the study. Without your  
499 authorization, you will not be able to be in this research study.

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#### 500 **B. Use and Disclosure of the PHI**

501 Your study doctor will collect information about you. This information includes things learned  
502 from procedures listed and described in this form as well as your name, address, date of birth,  
503 and information from your medical records. Your name, address, telephone number, and social  
504 security number are examples of identifiable information.

505  
506 A code number will replace your name, address, telephone number, or social security number in  
507 the results given to the study coordinating center which is the Jaeb Center for Health Research in  
508 Tampa, Florida.

509  
510 The study doctor's office will not disclose study results that have your identifiable information  
511 except as explained in Section C. or when required by law. The Jaeb Center and this doctor's  
512 office will guard the privacy of your study PHI.

513  
514 Study results without the protected information may be shared in medical journals and at  
515 scientific meetings. Your records will be confidential. No one will disclose your identity in a  
516 medical journal or at a scientific meeting.

#### 517 **C. Authorized Recipients and Users**

518 It is possible that people outside of this doctor's office and the Jaeb Center may need to see or  
519 receive your information from this study. Some examples include: government agencies (such as  
520 the U.S. Food and Drug Administration), committees that monitor safety, other sites in the study,  
521 and companies that sponsor the study.

522  
523 In most cases the information will have a code number with it instead of your name, address,  
524 telephone number, or social security number.

525  
526 There are some situations where the information will not have a code number but may include  
527 your name, address, telephone number, or social security number (PHI). If so, people outside this  
528 doctor's office who assist in your care may see your study PHI. They may not be covered by the  
529 federal Privacy Rule. Everyone who needs to see your information will be told it is confidential  
530 – but we cannot guarantee full confidentiality.

#### 531 **D. Other Considerations**

532 The data collected in the study may be provided to other researchers to use; however, the data  
533 that are provided will not contain any information that could identify you.

534  
535 When the results are made public, all of the study data collected may also be made public.

## Consent to Participate in a Research Study

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538 However, there will be no identifying information included.

539

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

543

#### **E. Cancellation of HIPAA Authorization**

544 You may cancel your permission for the use and disclosure of your study PHI at any time. You  
545 need to contact your study doctor and give him/her a notice of cancellation in writing. When you  
546 cancel your permission or when you withdraw from the study directly, you are no longer part of  
547 the study. No new information about you will be gathered for the study except when there is an  
548 adverse (unfavorable) event that is related or potentially related to the study. If an adverse event  
549 happens, your entire medical record may need to be reviewed.

550

551 The Jaeb Center will receive all the information that was collected for the study up to the time of  
552 cancellation or withdrawal. The Jaeb Center will receive any new information about any adverse  
553 (unfavorable) event that is related or potentially related to the study.

554

#### **F. 50 Year Expiration Date and Indefinite Expiration Date**

555 Some of your study PHI does not have a code number with it. Your permission for the use and  
556 disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study,  
557 whichever is sooner.

558

559 The rest of your study PHI does have a code number with it. When it is collected, it becomes a  
560 research report. Your permission for the use and disclosure of these coded data will never end.  
561 These coded data do not have your name, address, telephone number, or social security number.

The above supports the HIPAA Privacy Rule – 45 CFR 164.508

562

563

564

565

**Consent to Participate in a Research Study**

***Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes***

566 Your Full Name (printed) \_\_\_\_\_

567

568 **Description of Representative's Authority to Act for the Subject**  
569 \_\_\_\_\_ (if applicable)

570

571 **Protected Health Information Authorization**

572

***By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of your participation in this study.***

Signature \_\_\_\_\_

Date \_\_\_\_\_

573

574 **Study Enrollment**

575

***By signing, you agree to take part in this study. Your signature means that:***

- ***you have read this informed consent form about the study named below;***
- ***you have been given the chance to discuss the study and to ask questions;***
- ***you have verbally summarized your understanding of the study to the person who is explaining it to you; and***
- ***you freely choose to participate.***

**Name of Study: A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes**

Signature \_\_\_\_\_

Date \_\_\_\_\_

***I certify that to the best of my knowledge the participant understands the nature, demands, risks, and benefits involved in his/her participation in this study.***

Investigator's Printed Name \_\_\_\_\_

Investigator's Signature \_\_\_\_\_

Date \_\_\_\_\_

576

**You will be given a signed copy of this document in case you want to read it again.**