

Do <u>YOU</u> have Cystic Fibrosis-Related Diabetes? Do you want to try a Bionic Pancreas?

Researchers at the [Site Name] Children's Mercy Hospital are looking for volunteers to test the Insulin-only iLet Bionic Pancreas from Beta Bionics.

The iLet Bionic Pancreas uses a continuous glucose monitor (CGM) and a computer program to automatically deliver insulin through a pump every 5 minutes. The iLet Bionic Pancreas is cleared by the FDA for people with type 1 diabetes ages 6 and older but is considered experimental in people with CFRD.

You may be eligible if:

- ✓ You are 14 years or older
- ✓ You have a documented diagnosis of Cystic fibrosis-related diabetes
- ✓ You have been on insulin therapy for at least the past 3 months
- ✓ You have been on the same insulin regimen for at least the past 1 month.

What will happen?

- ✓ A Screening visit to determine if you are eligible (about 2-3 hours)
- ✓ A 14-day period of CGM data collection if you don't regularly use a Dexcom G6 or G7 CGM.
- ✓ One of two arms
 - One 13-week main study period with the iLet Bionic Pancreas (BP arm), followed by another 13-week extension period with the iLet Bionic Pancreas OR
 - One 13-week main study period of your usual diabetes care with a Dexcom CGM (Usual Care arm), followed by one 13-week extension period with the iLet Bionic Pancreas
- ✓ The first 13-week study period has at least 5 virtual visits and 2 in-person visits
- ✓ The second 13-week study period has at least:
 - o 1 virtual visit and 1 in-person visit for the BP arm OR
 - $\circ\hspace{0.4cm}$ 5 virtual visits and 2 in-person visit for the Usual Care arm
- ✓ In person visits can be completed virtually over telehealth if necessary

Will I Be Paid?

- ✓ You will be given:
 - o \$80 for the screening visit
 - $\circ \;\;$ \$355 for completing main study & extension phase of the BP arm

<u>OR</u>

- \$415 for completing main study & extension phase of the Usual Care arm
- ✓ An additional \$210 will be given for your participation in the optional substudies

IF YOU ARE INTERESTED, PLEASE CONTACT

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