Official Title: **Garmin PACT (Physical Activity Tracking)**

NCT: 05992350

Date:3/11/2025

PROTOCOL TITLE:

Garmin PACT (Physical Activity Tracking)

Study ID: STUDY00002582

PRINCIPAL INVESTIGATOR:

Mark Clements, MD, PhD
Endocrinologist
Pediatric Clinical Research Unit
The Children's Mercy Hospital
Email: maclements@cmh.edu
Phone: 816-983-6982

VERSION NUMBER/DATE:

Version 1.0 4.12.22

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Version 3.0 2.23.2023

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Version 5.0 3.21.2023

Version 5.1 4.5.23

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Version 5.3 4.11.23

Version 5.4 4.14.23

Version 5.5 6.7.23

Version 5.6 7.27.23

Version 6.0 8.23

Version 7.0 11.23

Version 7.1 03.24

Version 7.2 4.24

Version 8.0 5.24

Version 9.0 12.24

Version 10.0 1.25

Version 11.0 2.25

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
3	1.2	Correcting section 9.3 to specify that we will be looking at subjects with a predicted rise of 0.3 points or are >8.5% HbA1C as candidates for the intervention	no
4	2.0	Updated protocol and consent letters per IRB suggestions. Updated section 9.3 to remove >8.5% HbA1c to streamline enrollment. Updated Section 8 to reflect accrual goals. Updated section 24 to clarify use of private information for study subjects.	Yes
5	3	Updated protocol per IRB comments, including the study summary, study calendar, enrollment goals, tangible property, and data collected, per IRB comments. The ICF letters included creating an entirely new adult information letter, and updates and editing in the information collected, data sharing, the study schedule, the study calendar to make the information shared clear and concise.	Yes
6	4	Updated section 23.3 chart per IRB comments. Updated information letters per IRB comments to record correct identifying information storage and data collection.	Yes
7	5.1	Updated section 5, 21.0, 21.2, and 22.3 to include a mid-study survey to provide the participants with the information letter and facilitate a discussion of any questions they have. The information letter study calendars have been updated with the new survey Created recruitment flyer and text and email messages for text, email, newsletters, clinic recruitment, event recruitment, etc.) Included device manuals, REDCap survey instructions, REDCap survey inviations	Yes
8	5.2	Moved the section 21 description of the mid-point survey to section 10 but retained the	

		reminder that the mid-point survey was intended to facilitate a continuing consent discussion in section 21.0 and 22.3 per IRB comments (moved from 21.2 to 21.0).	
9	5.3	Clarifying section 9.3 to make the where how and why clear	No
10	5.4	Updated sections 9, 21, & 22 to affirm that patient recruitment methods are approved by CM	No
11	5.5	Updated Garmin Health App title to Garmin Connect app for accuracy in sections 5, 6.3, 12, 23.2, 26, and 32 Updated sections 5, 12 and 26 to clarify that data from the Garmin Connect app will be uploaded by the Garmin Health API developed by Children's Mercy Research Informatics. Updated sections 26 and 29.1 to specify that a copy of data will be kept in the diabetes data mart (D-dock), used for CGM uploads, and clarified that data collection would be completed by the diabetes data mart developed by CMH. Also updated ICF to better reflect data collected, privacy statements, account status after study completion, etc. Per IRB comments. Added in a clarification that the Glooko and Dexcom apps will only be used for data collection if the participant uses the apps.	Yes
12	5.6	Added language to section 9.3 to include the recruitment flyer in CM Find a Study	
13	6.0	Added in payment for completing surveys to section 18. Updated Garmin Connect wording in the information letter to current edition. And added insurance type as information collected to sections 23 and 26 and the information letter	Yes
14	6.1	Updated section 9.3 to include putting the study flyer in the clinic intake form Updated sections 26 & 29 to clarify that the Diabetes Data Mart (or RTDA Data Warehouse) is the Diabetes Data Dock	Yes

		And 29.1 & 23.3 to clarify data will be kept in the CMH Microsoft Azure Cloud which includes Sharepoint (originally stated as the drive), and will be stored per CM policy Corrected the payment schedule in the information letter Added in the CCPay handout for participant knowledge	
15		Updated Section 5 Study Calendar to make study visits approximately the days stated in the protocol. Updated section 5.0 and 12 to make it clear any additional visits to troubleshoot Garmin issues will occur at Visit 2, Visit 3 and Visit 4 (approximately at days 14, 28, 56).	Yes
16		Updated sections 23 to correctly document that the study database isn't only in the Onedrive/ Microsoft Teams Updated information letters to clarify the study objectives	Yes
17		Updated section 9.3, 24, and 26 to include the Health Device Portal texting system in communication. Updated section 21.4 to clarify how to handle data collection during and after the reconsent of a participant who turns 18. Updated section 23.3 to remove language about study coding study information with a study ID, as this is incorrect. Added in that the prescreening/ enrollment log and study data sheets are kept together in the study database. Updated section titles in section 26 to make it clear data is collected from both child and adult participants. Also removed language about coded data from section 26. Also updated language about parent demographics data including T1D information, as this is incorrect (includes data such as shipping information for sending Garmins which was added to the child/ adult participant section as well).	
18		Clarified the sections 21, 21.2, 27.2on consent/ assent, because following the P/A/C	

		policy with a waiver of documentation of assent/ consent would not be a telephone consent as stated in the P/A/C policy we cited. However, we state we waive assent/ consent but perform telephone consents. Also updated section 22.4 and 27.2 to remove the titles/ numbers of policies to ensure outdated/ renamed policies are not being cited. Updated section 32 to include electronic (email, text) communication in the consent discussion.	
19		Updated section 6.4 to allow participants to keep Garmins when they withdraw, and allow evaluating participants when they lose/ break a Garmin more than two times to see if they should be allowed more replacement Garmins.	No
20		Corrected protocol section 25 to note that participants may be lost to follow up if they are actively contacted three times, which does not include contacts like automatic text alerts.	No

Key Words: Type 1 diabetes (T1D), youth, physical activity monitors, HbA1c

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enSTUDY INFORMATION

1. Study Summary*

This is an observational study tracking physical activity for up to 200 youth wearing a Garmin physical activity tracker for up to 6 months, and tracking the attitudes on hypoglycemia of up to 100 parents of children with T1D.

Study Title	Garmin PACT (Physical Activity Tracking)
Study Design	Clinical observational study
Primary Objectives	Measure physical activity and sleep for up to 365 days using a Garmin physical activity tracker among youth and young adults with T1D. Evaluate the impact of physical activity and sleep related variables on rate of DKA admission over 90 and 180, and 365 ± 30 days Evaluate the impact of physical activity and sleep related variables on change in Time in Range (TIR) and other continuous glucose monitor-derived metrics of glycemic control over 90, 180, and 365 ± 30 days Test the impact of physical activity and sleep related variables on machine learning models to predict change in HbA1c, DKA admissions, and change in Time in Range over 90, 180, and 365 ± 30 days
Secondary Objectives	Examine for correlations between self-reported physical activity (IPAQ), hypoglycemia fear (HFS-II), and parent hypoglycemia fear (HFS-P) at 0, 6, and 12 months after study enrollment. Evaluate any change in physical activity levels via self-report with the IPAQ survey (to allow comparisons to external cohorts). Evaluate any change in how participants feel about episodes of hypoglycemia while wearing the Garmin physical activity tracker via the Hypoglycemic Fear Scale II (HFS-II) Evaluate any change in how parents feel about episodes of hypoglycemia in their children wearing the Garmin physical activity tracker via the Hypoglycemic Fear Scale II for Parents (HFS-P)
Research Intervention(s)/	Garmin physical activity tracker

Investigational Agent(s)	
IND/IDE #	NA
Study Population	Youth (8-21 YO) diagnosed with T1D and parents of youth (8-17 YO)
Sample Size	1000 pre-screened for total enrollment goal of 300 (200 youth 100 parents)
Study Duration for Individual Participants	365 Days (± 30 days)
Study Specific Abbreviations/ Definitions	T1D = Type 1 diabetes DKA= Diabetic Ketoacidosis IPAQ=International Physical Activity Questionnaire HFS-II=Hypoglycemic Fear Scale II HFS-P= Hypoglycemic Fear Scale II for Parents HbA1c= Hemoglobin A1c

2.0 Objectives*

2.1 Primary Objectives:

1. Measure physical activity and sleep for up to 365 (± 30 days) days using a Garmin physical activity tracker among youth and young adults with T1D.
2. Evaluate the impact of physical activity and sleep related variables on rate of DKA admission over 90 and 180, and 365 ± 30 days
3. Evaluate the impact of physical activity and sleep related variables on change in Time in Range and other continuous glucose monitor-derived metrics of glycemic control over 90, 180, and 365 ± 30 days
4. Test the impact of physical activity and sleep related variables on machine learning models to predict change in HbA1c, DKA admissions, and change in Time in Range over 90, 180 and 365 ± 30 days

2.2 Secondary Objectives:

1. Examine for correlations between self-reported physical activity (IPAQ), hypoglycemia fear (HFS-II), and parent hypoglycemia fear (HFS-P) at 0, 6, and 12 months after study enrollment.
2. Evaluate any change in physical activity levels via self-report with the IPAQ survey (to allow comparisons to external cohorts).
3. Evaluate any change in how participants feel about episodes of hypoglycemia while wearing the Garmin physical activity tracker via the Hypoglycemic Fear Scale II (HFS-II)
4. Evaluate any change in how parents feel about episodes of hypoglycemia in their children wearing the Garmin physical activity tracker via the Hypoglycemic Fear Scale II for Parents (HFS-P)

3.0 Background*

3.1 Physical activity is an important aspect of Type 1 Diabetes (T1D) management. However, very little investigation has specifically targeted the use of physical activity monitors in T1D management in youth. In a recent literature review of physical activity research using wearable devices in T1D, only three studies have been identified, all since 2019. It is important to establish the utility of physical activity trackers in T1D to identify patients who would benefit from interventions to increase physical activity.

There is also interest in predicting clinical outcomes like future glycemic control, hospitalization, mental health, etc. No studies have examined the utility of physical activity data from wearable devices in making such predictions.

3.2 Small studies have shown that it is feasible for people with T1D to wear physical activity trackers in non-clinical settings, and the devices show accuracy (Cescon et al., 2021). Additionally, T1D adolescents (7-19 Y.O.) can wear physical activity trackers while recording diet, although in this study the minimum device use time was three days (Jaggers et al., 2021). Physical activity trackers have also been used to study mealtime glucose control (Ozaslan, Patek, & Breton, 2020). Overall, there is support in the literature for the use of physical activity trackers in T1D management.

3.3 There is a need for accurate and timely record of longitudinal physical activity which affects the overall health of youth (8-21 Y.O.) with T1D (variables include DKA admissions, time in range, HbA1c, etc.). It is necessary to confirm the feasibility and utility of physical activity trackers for predicting near-term T1d outcomes. This study builds on previous studies that establish the feasibility of tracking physical activity and T1D and the accuracy of such devices for doing so.

4.0 Study Endpoints

1. Minutes/day of Moderate-to-vigorous physical activity (MVPA) – from Garmin device over 30, 90, 180, and 365 ± 30 days
2. Sleep minutes/day– derived from Garmin device over 30, 90, 180, and 365 ± 30 days
3. Other activity metrics derived from Garmin device over 30, 90, 180, and 365 ± 30 days
4. HbA1c – collected from Electronic Medical Record, obtained via standard care (binned as 46-135 days, 136-225 days, 226-305 days, and 306-410 days
5. Hospital admissions for DKA (0-180 days and 181-365 ± 30 days)
6. 14-day Time in Range and other CGM-derived metrics of the quality of glycemic control over 30, 90, 180, and 365 ± 30 days
7. Model performance characteristics (e.g. precision, recall, F1) of predictive models for the outcomes listed in 4.1-4.6

5.0 Study Design

*Participants with T1D treated at the Children's Mercy Endocrine clinic aged 8-21 years old will be asked to wear a Garmin VivoSmart 4 (or later) physical activity tracker for at least 6 months. This tracker will collect detailed physical activity and sleep data as measured by moderate to vigorous physical activity (MVPA) and sleep minutes/day. The tracker collects heart rate and accelerometry data, collected into the Garmin Connect application. The diabetes center will use the Garmin Health API connection developed by Children's Mercy Research Informatics to extract the data into a data warehouse in Microsoft Azure (CMH account). As noted in previous studies, MVPA is automatically measured by the tracker when the wearer runs for >1 minute or walks for >10 consecutive minutes. The weekly MVPA and step count are both weighted by multiplying the mean of weekday activity by 5, adding it to the mean of weekend activity and dividing the sum by 7.

Weighted MVPA= $\frac{[(MVPA)\times 5]+(MWVPA)}{7}$

Weighted step count= $\frac{[(MSC)\times 5]+(MSC\ weekend)}{7}$

If the subject wears the tracker for >8 hours between 9 AM and 9 PM, the day is used in the weighing calculation (Grimes et al., 2022). Clinical data will be collected from the medical record and coded (labeled with the study ID to minimize use of personal data). Also, self-reported personal health will be collected from the CMH-approved vendor software to which they upload their self-management device data. Baseline and end of study surveys including International Physical Activity Questionnaire (IPAQ), the Hypoglycemic Fear Scale II (HFS-II) for participants, and Hypoglycemic Fear Scale for parents (HFS-P) will be collected from participants/ parents. Surveys will be given to participants based on their ages and the ages surveys are validated for.

Table of Events:

	Pre-screening (Pre-consent)	Visit 1 Day 1 appx.	Visit 2[a] Day 14 appx. (PRN)	Visit 3[a] Day 28 appx. (PRN)	Visit 4[a] Day 56 appx. (PRN)	Visit 5 Day 180 appx.	Visit 6 Day 365 appx.	Unscheduled Visit
EMR Review Eligibility	X							
Verbal Consent		X						
Demographics		X						
Clinical history[b]		X					X	
Send Garmin tracker		X						
Surveys[c]		X				X	X	
Mid-Study Check-In Survey						X		
Garmin Troubleshooting Visits			X	X	X			

a. Additional virtual or in person visits may be scheduled at Visit 2, Visit 3, and Visit 4 as needed for device troubleshooting and additional education, depending on the needs of the subjects

b. A1c will be drawn SOC as a part of the clinical history, in the absence of A1c results, GMI will be deduced from CGM data

c. The IPAQ (for>15 YO) and HFS-P/HFS-II (HFS-II child for 11-18 Y.O., HFS-II adult for >18 YO)

6.0 Study Interventions*

6.1 Description: The Garmin VivoSmart 4 (or later) physical activity tracker is worn like a watch on the user. The tracker assesses several physical states (I.e., HRV, sleep, and activity) to provide the participants with a "Body Battery" measure. This measure indicates either when the body is at optimal time for activity, or if the individual needs to rest. The tracker also monitors stress levels using heart rate variability (HRV) and provides a reminder alert to *"Take a moment to breathe."* The tracker utilizes behavioral principles to set goals with participants based on previously completed activity. To meet these goals the tracker alerts participants after a period of inactivity, encourages regular movement throughout the day, and decreases the amount of time spent sedentary.

6.2 Behavioral Intervention*:* The Garmin VivoSmart 4 (or later) physical activity tracker will be part of a behavioral intervention with accepted standard of care that will help improve activity behaviors and decrease stress. This is done by prompting the participant to engage in activity when sedentary and/or stressed.

6.3 Drugs, Biologics, or Devices:

Drug/Biologic/Device Name	Describe how the article is being used under current FDA approved labeling
Garmin VivoSmart 4 (or later)	This device will be continually used to monitor participants activity and sleep.
Garmin Connect App	This app will be used by the diabetes team interventionists to monitor the data collected via the device.

6.4 Device Handling: The trackers will be kept securely locked up in the office of the investigator. No one will have access to the trackers besides those involved in this study. An inventory log will be kept of all tracker serial numbers and which tracker is sent to each participant. The tracker will be shipped to the participant after they verbally consent to the protocol and have their eligibility confirmed by the study team. Participants will activate the tracker and Garmin app upon receipt of the tracker. If the participant experiences any issues with tracker activation or use, additional study visits will be scheduled at Visit 2, Visit 3 and Visit 4 (approximately Day 14, 28, or 52). If the device is broken, the study team will schedule a virtual session to troubleshoot any issues per study calendar. If issues cannot be fixed, the participant will be offered a prepaid envelope to return the device. The study team will replace lost/ broken devices twice while the patient remains on study (during the 365 ± 30 days from enrollment). If the device is broken/lost a third time, we will evaluate if the patient should be taken off study, if the circumstances appeared to be out of the participant's control we will offer to let them stay on the study and replace the Garmin again.

PARTICIPANT MANAGEMENT

7.0 Inclusion and Exclusion Criteria*

7.1 Inclusion Criteria

- Participants aged 8-21 years of age and/or parent of participant aged 8-17 years of age
- Participants diagnosed with T1D greater than 6 months ago
- Participants must be patients at the Children's Mercy Kansas City network

7.2 Exclusion Criteria

- Participants who do not meet age criteria above
- Participants who do not have T1D
- Participants who are unwilling to wear the device for at least 6 months

7.3 Equitable Selection*:*

Participants will be accrued to the study from the patient population at Children's Mercy. No participant will be excluded based on sex, race, or ethnicity. However, if a non-English speaking participant speaks a language not supported by the Garmin device, they will not be able to participate.

7.4 Vulnerable Populations: *Check any vulnerable populations <u>that are being targeted</u> for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☐ Children/Minors (under 7 years of age)
☒ Children/Minors (7-17 years of age)
☐ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☐ Wards of the State
☐ Fetuses
☐ Pregnant Women
☐ Adults with impaired decision-making capacity
☐ CM Employees
☐ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

Children under age 18 are a vulnerable population. Because children recruited for this trial will be between 8 and 21 Y.O., adult parents will provide verbal consent for their child's participation who are <18 Y.O.

If a child participant reaches the age of majority (18 years old) during the study, he/she will be asked to again provide verbal consent if they wish to remain on the study.

8.0 Local Number of Participants

We will pre-screen up to 1000 participants, depending on the patients coming to the diabetes clinic. If patients meet the requirements for the study, they will be sent the information letter.

	Group 1: Pre-screening/screen failures	**Group 2: participant**	**Group 3: parent of participant**	**Totals**

Enrollment Goal: *Number of participants to be enrolled = the number of participants to be consented*	1000	200	100	1000 pre-screened for a tot enrollment goal of 300

9.0 Screening and Recruitment Methods*

9.1 Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☒ Chart reviews

☒ By their treating physician who will then provide the study team's contact information to the potential participant/family

☒ By their treating physician who will obtain patient/family permission to share contact information with the study team

☒ Self-refer in response to IRB approved advertisements or websites

☒ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☐ List of candidates provided through the Data Report Request Form

☐ Registry of individuals interested in research opportunities

☐ Past participant list

☐ Participants will roll-over from another research study: Study #

☐ Other:

9.2 Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☒ Yes

☐ No

- *If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete* ***Addendum E: Waiver/Alteration of HIPAA Authorization***

9.3 Recruitment of Potential Participants:

Participants will be recruited from the CMH diabetes clinic, at diabetes events CM participates in (such as T1D walks or camps), by identifying youth 8-21 Y.O. with T1D who have a predicted rise in HbA1c of 0.3 points, by CM approved electronic communication (emails or texts- including the Health Device Portal Messaging) or by physician referral to the study. Flyers describing the study generally (discussing who researchers are looking for, what they would have to do, and receiving the Garmin devices) will be posted in the diabetes clinic, CM study lists (I.e. Find a Study, the clinic intake form), and at T1D events. Also, the flyer/ link to the flyer can be sent to T1D patients via email (via CM approved email servers)/ text (CM approved SMS servers including the Health Device portal messaging). The flyers will contain the study coordinator and PI contact information so the participant can reach out for information/ screening. After the initial screening to confirm eligibility, participants will be contacted via telephone and asked if they want to be emailed the consent letter to obtain verbal consent. Participants will be called up to three times, and all visits will be virtual unless a participant requests to be in person, if so the study visit will be coordinated with their standard of care clinical visit.

10.0 Surveys and Psychometric Testing:

Participants will be administered the International Physical Activity Questionnaire (IPAQ) to measure the amount and type of physical activity each participant reports per a usual week (or last week in the short form). The Hypoglycemic Fear Scale II (HFS-II) measures attitudes and fears of diabetics towards episodes of hypoglycemia. There will be two HFS surveys used for diabetics- the Child Hypoglycemic Fear Scale (C-HFS) for participants 11-18 Y.O., and the Hypoglycemic Fear Scale for Adults >18 Y.O. The Hypoglycemic Fear Scale for Parents (HFS-P) measures the fears and actions taken by parents of children with T1D concerning hypoglycemic episodes. All surveys have been used in multiple T1D studies previously.

At the mid-point of the study (day 180) participants will be asked to complete a REDCap survey. The survey will provide the current information letter and ask if they have any follow-up questions about the study.

11.0 Additional Study Activities NA

Blood and Other Specimen Collection: NA

12.0 Follow-up

After the V1D1 visit, physical activity information will be collected from the participant trackers via the Garmin Connect app and uploaded into storage via the Garmin Health API connection developed by Children's Mercy Research Informatics. If the participant experiences any issues with tracker activation or use, additional study visits will be scheduled at Visit 2, Visit 3 and Visit 4 (approximately Day 14, 28, or 52).

Participants will have information collected from the devices until 365 (+/- 30 days) days following start of study, at which point they will have one more SOC clinic visit, complete surveys, and then will have completed the study requirements. There will not be any research follow up after this point, and if the participants elect to discontinue from the study, there will be no follow up. When participants complete the study requirements or elect to discontinue, they will be marked as such in the RedCap database of study participants. We will ask the patients if they are willing to complete the surveys prior to discontinuing the study.

13.0 Genetic Analysis Information NA

14.0 Sharing of Results with Participants NA

15.0 Risks to Participants*

The anticipated increase of activity places the participant at greater risk for hypoglycemia. As the participants increase their activity they should be aware of the guidelines to avoid/treat hypoglycemia and frequent adjustments to their insulin regimen may need to be made. The frequent adjustments may also lead to increased contact with the diabetes team. Participants will be surveyed about their level of stress, potentially leading to emotional discomfort. The participant must wear the watch every day throughout the study, must follow prompts provided by the watch, and charge it as frequent as every 2-3 days. These elements may cause inconvenience and/or discomfort. Per the device manual, there are additional risks if the device is not used appropriately, including rare risks of fire, chemical burn, electrolyte leak, and/ or injury, and health risks such as interfering with pacemakers, triggering seizures, and irritating skin. Because the research requires the collection of identifying data, there is a risk of breach in confidentiality.

16.0 Potential Benefits*

There may not be direct benefits from taking part in the research. However, as the participants with T1D react to the watch interventions, they may become more active and more aware of stress throughout the day. As these elements improve, participants may see improvement in self-care, diabetes management, HbA1c, and decreased potential for long-term diabetes complications. There is no direct benefit for the parents of participants with T1D. The knowledge gained from this study may help other healthcare providers know how to better serve their patients by utilizing Garmin trackers or similar products to promote activity.

17.0 Investigator Assessment of Risk/Benefits Ratio*

17.1 *Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.*

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the propect of direct benefit to the individual participants. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

18.0 Payment, Reimbursement and Tangible Property Provided to Participants*

18.1 Is payment, reimbursement, or tangible property part of the study?

☒ Yes ☐ No *(If No, delete the following subsections)*

18.2 Payment to Participants:

☐X CCPay
☐ Gift Card: (Merchant:_____)
☐ Other: _____

Note: "Gift Card" and "Other" options require approval by Research Administration. Upon submission in myIRB, ORI staff will initiate the Research Administration approval process.

18.3 Payment Schedule:

Day 1 Surveys	Day 180 Surveys	Day 365 Surveys	Total Compensation Possible
$15	$15	$15	$45

18.4 Reimbursement: *NA*

☐ CCPay
☐ Check
☐ Other: _____

18.5 Tangible Property:

The participants will be given a Garmin tracking device (value 129.99$) when they begin the study, and we will let the participant keep the device after study completion.

19.0 Compensation for Research-Related Injury NA

20.0 Economic Burden to Participants NA

21.0 Parental Permission and Adult Consent Process*

Parents/ participants will be contacted and asked for verbal consent to participate in the study per CM policy.

We will call the parent/participant and ask if they want to be emailed the study information letter to read over (via a CM approved email server). We will ask that if they are interested in participation, that they call us back to discuss the study in more detail. We will ensure the participant has plenty of time to consider the study and ask questions. They will be told they don't have to participate. We will ask questions to

make sure they understand the study. We will follow the CM policy on obtaining p/a/c.
To facilitate an ongoing consent discussion, the Information Letter will be included with the mid-point (day 180) REDCap survey.

21.1 ***Indicate below all methods of Permission/Consent that will be used in this study.***

Waiver of Documentation of Permission/Consent

Permission/Consent form provided but signature will **NOT** be obtained (e.g. verbal consent)
Must complete *Addendum A: Waiver of Documentation of Permission/Consent*

☒ **Waiver of written documentation of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: Parent of Participants 8-17 years old

☒ **Waiver of written documentation of consent of adult participants**

Study group(s) to which this method applies: Participants 18 and above and Parent as a Participant

☒ **Waiver of written documentation of consent of participants turning 18**

Study group(s) to which this method applies: If a child participant reaches the age of majority (18 years old) during the study, he/she will be asked to again provide verbal consent if they wish to remain on the study.

Additional Methods

☐ **Obtaining permission/assent/consent of non-English speaking parents or participants**

Must compete *Addendum C: Non-English Speaking Participants*

Study group(s) to which this method applies:

21.2 Permission/Consent/Consent at 18 Discussion:

Permission/Consent Discussion:

Consent at 18 Discussion: Participants who turn 18 while active in the study will be contacted and asked for verbal consent to continue to participate in the study. We will contact the participant and email them the study information letter to read over (via a CM approved email server). We will ask that if they are interested in continuing participation, that they call us back to discuss the study in more detail. We will ensure the participant has plenty of time to consider the study and ask questions. They will be told they don't have to participate. We will ask questions to make sure they understand the study. We will follow the CM policy on obtaining p/a/c.

21.3 Documentation of Permission/Consent/Consent at 18: *NA*

21.4 Identification of Participants turning 18: Participant age will be tracked on a master log. It will be assessed at enrollment if the participant will still be active in the study when they turn 18. A reminder will be put on the calendar for that day to contact and obtain verbal consent via the Adult consent. We will attempt to reconsent the participant as an adult up to three times. During the reconsent period we will mark the participant record as "reconsenting" and not collect any study data about the participant until they reconsent. If they have not consented after the third contact, we will remove the participant record from the study database.

22.0 Assent of Pediatric Participants

22.1 Select the option(s) that apply to the study:

☒ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.**

☐ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

- ☐ *The capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*
- ☐ *The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

☐ **Obtaining assent of pediatric participants is NOT PRACTICLE given the context of this study** (e.g., minimal risk, no direct contact with participants).
Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent*

☐

22.2 Assessment of Ability to Assent:

Ability to assent will be discussed with the parent/LAR and clinical care team to confirm the pediatric patient is able to understand the study and procedures.

22.3 Assent Discussion: The parent of the child will be contacted via telephone and asked if they want to be emailed the study information letter to read over (via a CM approved email server). The parent will be instructed to call back with the child if they are interested in participating to discuss the study in more detail. If the parent and child feel more comfortable discussing the study in person, the discussion will be conducted in person. The parent and child will have plenty of time to consider the study and ask questions. They will be told they don't have to participate. They will be asked questions to make sure they understand the study. The CM policy on obtaining p/a/c will be followed.

To facilitate an ongoing consent discussion, the Information Letter will be included with the mid-point (day 180) REDCap survey.

22.4 Documentation of Assent or Inability to Assent:

We will follow CM Research Policy on obtaining permission/ assent/ consent and research documentation in the Electronic Health Record

23.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

- The past, present, or future physical or mental health or condition of an individual;
- The provision of health care to an individual; **OR**
- The payment for the provision of health care, **AND**
- identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

23.1 HIPAA Authorization

a. ☐ *Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)*

☒ Partial Waiver of HIPAA Authorization (e.g. waiver for recruitment and pre-screening purposes only)

Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) We will need to access their MRN, name, DOB, email and phone number for prescreening/recruitment purposes.

☒ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g. signature will not be obtained)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) We will obtain verbal consent as this is minimal risk study.

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained)

☐ If Other, explain:

23.2 Specify the PHI for which accessing ("viewing") or recording ("writing down") is necessary for the purpose of this research:

1. Name/Initials	☐ Accessed only	☒ Recorded
2. All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded
3. Medical record number	☐ Accessed only	☒ Recorded
4. Account number	☐ Accessed only	☐ Recorded
5. Health plan identification number	☐ Accessed only	☐ Recorded
6. Social Security Number	☐ Accessed only	☐ Recorded
7. Device identifiers and serial number	☐ Accessed only	☐ Recorded
8. Certificate/License number	☐ Accessed only	☐ Recorded
9. Telephone number	☐ Accessed only	☒ Recorded
10. Fax number	☐ Accessed only	☐ Recorded
11. Email addresses	☐ Accessed only	☒ Recorded
12. Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
14. Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
15. Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
16. Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded

17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)	☐ Accessed only	☐ Recorded
18. Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
19. Other: Garmin Connect account token number, CGM device (for data collection), insurance type (public vs private)	☐ Accessed only	☒ Recorded

23.3 Information Security

Only those working on the study will have access to the study data. The master list will be stored securely on the secure CMH Microsoft Azure Cloud (including Teams, Sharepoint, and OneDrive) with access restricted to research team members. Some additional data (such as correspondence) will be kept in the secure study file drive on the CMH network domain, and also in CM approved platforms (such as the SSN in the payment system for study payments). The minimum amount of PHI will be used for this study, and will be destroyed at the earliest possible time at completion of study after data analysis. The access to the REDCap study database will be protected by limiting access to the study team only. The prescreening log and subject log will be stored in the secure limited access study database with the study data sheets. The subject log may include the child's name, date of birth, child's medical record number, date consented, date of service, email address, phone number and study ID number. After the minimum length of time has lapsed (one to two years post study closure depending on the space needs of the team) physical records may be transferred to hospital approved offsite facility.

23.4 Certificate of confidentiality:

No Certificate of Confidentiality has been issued for this study.

24.0 Provisions to Protect the Privacy Interests of Participants*

24.1 Participants will be contacted via phone to discuss enrollment into the study. If they prefer an in-person discussion, they can be approached and consented at the CM endocrine clinic. They will be given as much time needed to review the study information sheet and ask questions before deciding whether to participate. They

will be told this is voluntary, and enrolled subjects will be informed that they may withdraw at any time without penalty or loss of benefits. Any new information gathered during the study that may impact the subject desire to continue in the study, will be revealed as soon as it becomes available. Communication may include emails (per CM communication policy) or texting (via the Health Device Portal Messaging system). Follow up visits will be conducted remotely via phone, unless the patient requests in person visits, which will be held in the endocrinology offices. Follow-up may also occur via emails (per CM communication policy) or via texts (via the Health Device Portal messaging system). Recruitment may occur via the clinic intake form asking if the participant would like to join the observational study (see attached form).

The subject study ID will be used to set up the Garmin account for all participants, with no personal information (PII or PHI) used. This will keep private information used in the study will remain secure in the study database.

25.0 Withdrawal of Participants*

Participants may withdraw from the study at any time at their own request, or they may be withdrawn at any time at the discretion of the investigator. Reasons for withdrawal may include:

- Participant no longer wants to participate in study visits/procedures/processes.
- Participant's clinical care deciding it is not in their best interest to continue participation
- Participant stops providing information and cannot be reached by the research staff. For example, lost to follow up after three active attempts to contact participant (not including automated alerts, for example the automatic texts triggered when watches are inactive)

If a participant is withdrawn or lost to follow up, this will be documented appropriately in the REDCap database developed for research documentation since this study may not be recorded in the medical record per CMH policy.

All data collected prior to the participant withdrawal will be retained.

DATA MANAGEMENT

26.0 Data Collection*

This study will be completely integrated into the Diabetes Data Dock at CMKC. Data will be collected and paired with the other wearable devices, such as pump and continuous glucose monitor readings.

Surveys (IPAQ, HFS-II/P) will be collected at baseline and EOS. Data collected from EMR will include medical history, lab results, demographics, clinical data, insurance type (public vs private).

Child/ adult participant data -

Demographic data: We will use the REDCap demographics survey to collect demographic data. We may use the Diabetes Data Dock and/or the child's electronic health record to verify or extend demographic data (e.g., T1D diagnosis, history of T1D-related complications, T1D regimen, shipping address to send the Garmin Device, shipping history).
HbA1c data: We will use routine T1D care POC HbA1c levels to at baseline and at post-treatment (~3 months post baseline).
CGM or SMBG data: Families will use their personal, prescribed CGM or standard blood glucose monitor (SMBG) throughout the study. Families will share CGM data with the study team using their personal, CM connected account. Data will be download automatically to the Diabetes Data Dock using API.
Insulin delivery data: Participants will use their personal, prescribed insulin delivery device throughout the study. Participants and parents/LARs of adolescents will share participants' insulin device data with the study team using their personal, CM connected account.
Questionnaire data: We will use REDCap to electronically collect any survey data, including participants' daily activity schedules. We will use a single REDCap database for all study participants. This REDCap data base will reside on a CM secured server.

Garmin data and activity monitor: Data will be downloaded and stored on the Diabetes Data Dock using API connection. Primary physical data will be gathered from the Garmin Connect platform. The anonymous participant Garmin data from the Garmin Connect platform will be loaded to a secure database through the Garmin Health API connection developed by Children's Mercy Research Informatics. The Garmin tracker will not collect personal information. Also, the patient study record will be linked to the Garmin tracker. The Garmin Health Portal attached to the Garmin Health API will also contain the communication texted to the participants (if any). The interventionist team will be able to pull the data to Microsoft Azure database to evaluate. Clinical data will also be collected from EMR.

Parent Data -

Demographic data: We will use the REDCap demographics survey to collect demographic data. We may use the Diabetes Data Dock and/or the child's electronic health record to verify or extend parent demographic data (e.g., shipping address to send the Garmin Device, shipping history, contact information, etc.).

Sensitive Data: Adult participants with T1D will be asked in the HFS if they avoided sex to prevent a hypoglycemic event. All participants will be asked about physical activity and efforts to prevent hypoglycemic incidents, which can be sensitive topics. Participants will be assured in the consent letters that they do not need to answer any questions they want to, and answers will be kept in confidence.

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27.0 Adverse Events and Unanticipated Problems*

27.1 Monitoring:

Participants/families will be instructed to contact the team if an adverse event or other unanticipated problem occurs.

27.2 Reporting:

We will follow the CM policy on reportable events to report adverse events and other unanticipated problems to the CM IRB.

28.0 Statistical Analysis*

28.1 Matched Cohort:

Where possible, the intervention group will be compared to a matched cohort identified using propensity score matching. The propensity score for the groups will take into consideration age, baseline HBA1c, duration of diabetes, insurance, race, device usage, and time in range.