Brief Title: Garmin PACT (Physical Activity Tracking in Type 1 Diabetes Using Garmin Vivosmart)
Official Title: Garmin PACT (Physical Activity Tracking)

NCT: 05992350
Date: 1/10/2025

Garmin PACT (Physical Activity Tracking)

PI: Dr. Mark Clements

STUDY00002582

Adult Information Sheet

WHO IS DOING THIS REASERCH STUDY?

This study is being carried out by researchers at Children's Mercy Hospital.

Dr. Mark Clements is involved in research for the Garmin company. However, this study is not being funded by the Garmin company. He also has a separate financial agreement with Glooko and receives research support from Dexcom. These two applications are used to help collect data for this study if the participant uses these apps. He is a consultant for Glooko and personally receives income from them. The hospital and the IRB have reviewed this arrangement and determined that this relationship presents a potential conflict of interest for Dr. Mark Clements. Therefore, Dr. Mark Clements relationship is being disclosed to you. If you have questions, contact the Office of Research Integrity (816-731-7474) or the COI Administrator at MyCOI@cmh.edu.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see how the Garmin physical activity tracker, a watch worn on your wrist, records activity and sleep and if they improve control over Type 1 diabetes (T1D). Another purpose is to see if activity and sleep changes how people feel about managing their diabetes. The study records your activity levels, (T1D) outcomes (blood sugar, admissions, time in range, A1c), and activity levels you report. The study also records your feelings about T1D and managing T1D.

WHY AM I BEING ASKED TO PARTICIPATE IN THIS STUDY?

We are asking you to participate in this study because:

- You are 18-21 years of age
- Have been diagnosed with Type 1 Diabetes (T1D)
- You are a patient at the Children's Mercy Kansas City network

WHAT WILL HAPPEN IF I DECIDE TO BE IN THIS STUDY?

- Wear the Garmin watch for at least eight (8) hours every day and when you sleep
- The total time on the study is one year (give or take 30 days) from when you start wearing the watch.

Data Collection:

- We will review your medical history (including insurance type), health, medicines, diagnosis, A1c results, and demographics.
- We may collect other diabetes related information from your medical record and continuous Glucose Monitor (CGM).
- We will ask for your email and telephone number to check for any health changes over time.

Surveys:

- You will be asked to complete surveys three (3) different times

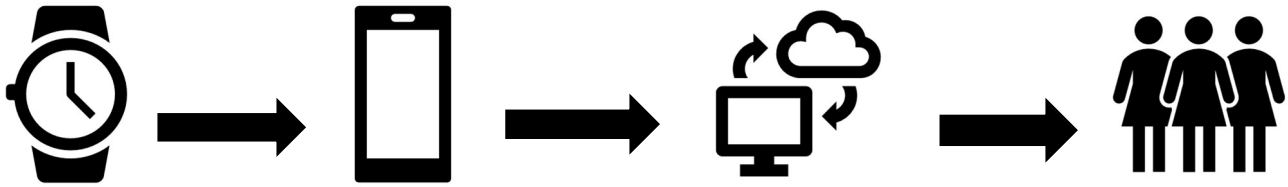
- The surveys will be sent to you electronically to your personal email and will take about 15-25 minutes to complete.
- You will be asked about T1D. This will include feelings and actions about hypoglycemia episodes, T1D management, and physical activity. There will be one survey in the middle of the study providing you with up-to-date study information and asking about any questions you may have. These answers will not identify you.
- The surveys may contain questions about topics you do not feel comfortable talking about. You do not have to answer questions if you do not want to.

Virtual/ in-person study visits:

- You may ask for virtual/ in-person visits for issues and information on the Garmin watch and/or Garmin Connect app.

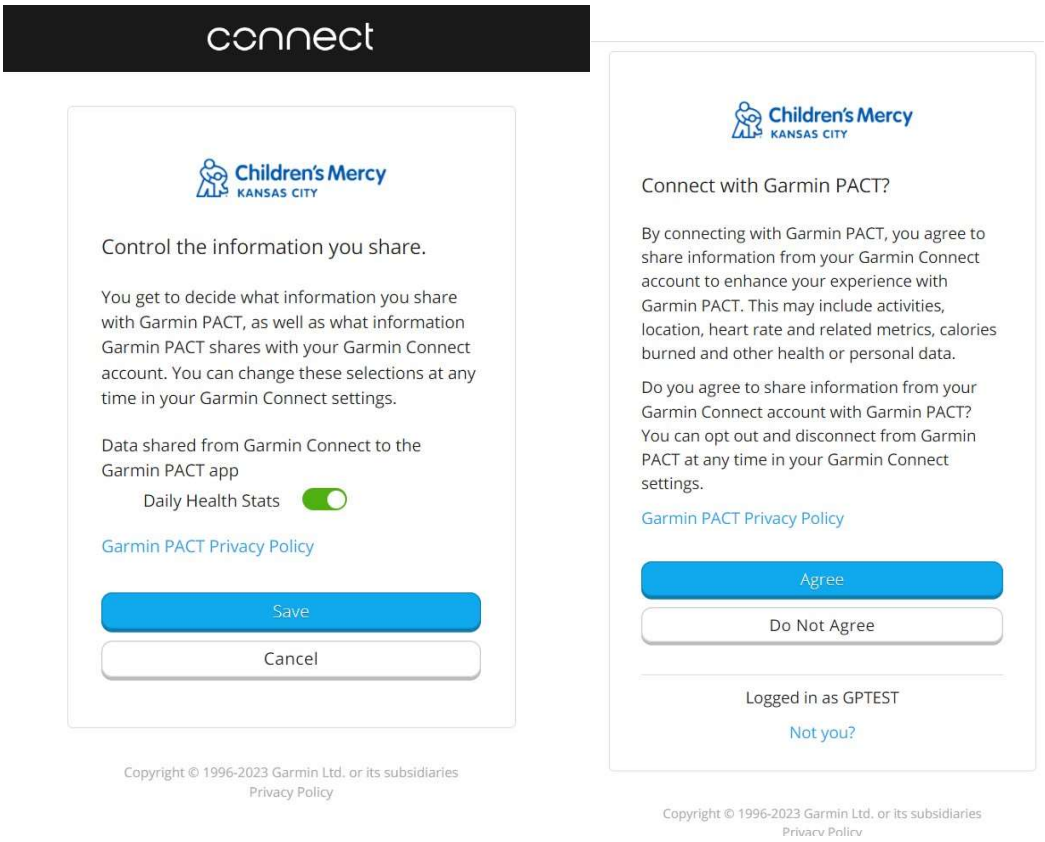
Garmin watch and Garmin Connect app:

- You will be asked to wear and use the watch and the watch app when you receive the watch. You will set up the Garmin Connect app with an anonymous account the study team will set up and provide to you.
- The watch app will be used by the study team to monitor the information collected by the watch.
- You will be asked to wear the watch for at least eight hours every day, between morning and night, and when you sleep.
    - The watch will encourage regular movement throughout the day and track sleep and oxygen at night. As you increase your activity, adjustments to your insulin regimen may need to be made.
- The information collected through the Garmin watch and Garmin Connect app will include the device ID, activities, location, heart rate and related metrics, calories burned and other health or personal data, such as sleep data.



Watch gets data Garmin Connect App Garmin PACT Researchers

To set up your Garmin PACT connection with the anonymous Garmin study account the study team must acknowledge the CM Notice of Privacy Practices for you. This Notice is given to you when you first become a patient at Children's Mercy, which you may request at any time. This is what the connection looks like ("Garmin PACT Privacy Policy"= CM Notice of Privacy Practices):



When the Garmin Connect app is downloaded to your smartphone, there will be additional privacy policies to accept. The Terms of Use can be found at https://www.garmin.com/en-US/legal/terms-of-use/

NOTE: the Garmin Connect app is not a HIPAA covered entity and will not protect private information in the same way as Children's Mercy. The HIPAA Rules generally *do not* protect the privacy or security of your health information when it is accessed through or stored on *your* personal cell phones or tablets. Once Children's Mercy downloads data from the Garmin device it becomes private data protected by HIPAA.

After All Study Procedures are Complete:

- If you choose to continue to use the Garmin watch once you have completed the study, you will need to set up a new personal Garmin Connect app account that is separate from the study.

WHAT ARE THE BENEFITS OF THIS STUDY? There may not be a benefit to being in this study. By being in this study, you may help researchers find better ways to manage T1D in the future.

WHAT ARE THE RISKS?

- There's a small risk of a breach of confidentiality. Your confidentiality will be protected to the greatest extent possible.
- The questions asked may be uncomfortable or embarrassing. You do not have to give any information you do not want to give.

- Because you are going to be exercising more, you may start to have more hypoglycemia episodes. Please review how to avoid/treat hypoglycemia and change insulin to avoid hypoglycemia with your T1D care team. The frequent insulin changes may mean you need to talk to your diabetes team more often.
- Because the watch must be worn for at least 8 hours, needs to be charged, and tells when to get up and move around, there may be some inconvenience in wearing the watch.
- There are rare risks with improper use of the tracker. These include fire, chemical burn, electrolyte leak, and/ or injury, and health risks such as interfering with pacemakers, triggering seizures, and irritating skin.
- If you have any of these problems or changes in the way you feel, you should tell the investigator or other study personnel as soon as possible.

We also offer the option of receiving study information, updates, link to surveys, and check- ins via SMS text message. Text messages are sent directly to the personal phone number that is provided. Text messages are sent from study-related Children's Mercy Hospital phone numbers within approved platforms. There is a potential risk of loss of confidentiality when using text messaging, as it is hosted by a third party. Please be aware that these communications can be intercepted in transmission or misdirected. You acknowledge that you have been informed and understand that we cannot guarantee text messages will be confidential.

WHAT ABOUT CONFIDENTIALITY?

You have rights regarding the privacy and confidentiality of your health information. Federal laws require that your information be kept secure, private, and under your control. We strive to keep your information confidential. Agreeing to be in this study allows the research team to access your medical record and use your private information for the research purposes described in this letter. Agreement also allows the following people access to your information (if necessary):

- The research team, which includes persons involved in this study at Children's Mercy Hospital
- The Institutional Review Board at Children's Mercy Hospital
- People from organizations that provide independent accreditation and oversight of hospitals and research
- Government/regulatory agencies (both US and international), such as the Office for Human Research Protections, the Food and Drug Administration, and/or National Institutes of Health offices who protect human subjects and oversee research

Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. We will share your necessary health information only when we must and will ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of CMH, we cannot promise that it will remain private.

There will be a separate database, in which all study information is collected. This database will be used to analyze the study information and find out the study results.

You may cancel the use and sharing of your information at any time. If you want us to stop using and sharing your information, contact the study worker listed under "Problems or Questions?"

Results of this study may be made public. If made public, you will not be identified in any publications or presentations.

HOW WILL THIS STUDY BE SHARED?
In addition to the use of data described above, a description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
If you choose to stop the study, the link between your identifiable information and the collected information will be destroyed (de-identified). No identifiable information will be saved. The anonymous account and de-identified information collected will remain with the study team and will be kept in the study database.

CAN I STOP THE USE OF MY INFORMATION?
You may stop us from using and sharing your information at any time by contacting the people in "Problems or Questions?". Information that has already been collected for the study may still be used. But no new information will be collected except information related to any safety issues.

If you do not cancel your permission, your information may be kept until the entire study is finished. This may take years. Any study information recorded in your medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your research record or research test results.

WHAT IDENTIFIABLE INFORMATION WIL BE USED FOR THE STUDY?

- Name, assigned study ID number, home street address, telephone number, medical record number, date of birth, social security number, dates of service, CGM device number (for downloading T1D information), and email address.

HOW WILL MY INFORMATION BE USED IN THE FUTURE?
Your information, even if de-identified, will not be used for future research.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?
You may choose not to be in this study and continue with your normal clinical treatment for T1D. You may change your mind at any time. Your decision will not impact your standard care at Children's Mercy.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY? You will get to keep the Garmin watch for being in this study. You will be paid $15 every time you complete the study surveys for a study visit:

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

WHAT SHOULD I DO IF THE DEVICE IS BROKEN OR LOST?

- Contact the study team (information is below) if your watch is broken/ lost to talk about possible options (including fixing/replacing the watch).

Problems or Questions? Please contact either Dr. Mark Clements 816-983-6982 maclements@cmh.edu or Priscilla Connell 816-601-4543 or pcconnell@cmh.edu if you have any questions about this study.

You may also call the Children's Mercy Hospital' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee that ensures that a research study is ethical and that the rights of study participants are protected.

Marking "I agree" on the REDCap study form means that you agree to stay on this study.

WHAT DO I DO AFTER READING THIS LETTER?

If you agree to be in this study, you will:

- Mark "I agree" on the REDCap survey containing this letter
- The study team will confirm you are eligible, then mail you the Garmin watch and send you the baseline surveys in your personal email via REDCap
- When you get the Garmin Device, you will set up the Garmin Connect app to connect the Garmin watch to the data storehouse. The research team will provide an anonymous email to you so that you do not need to use your private email
- Once your Garmin watch is set up, complete the REDCap surveys sent to you
- The study team will send you the Visit 5 surveys when 180 days have passed

STUDY CALENDAR:

	Visit 1 Day 1 appx.	Visit 2[a] Day 14 appx. (if needed)	Visit 3[b] Day 28 appx. (if needed)	Visit 4[c] Day 56 appx. (if needed)	Visit 5 Day 180 appx.	Visit 6 Day 365 appx.
Consent	X					
Demographics	X					
Medical history[b]	X					X
Send Garmin tracker	X					
Surveys[c]	X				X	X
Mid- Study Check- In Survey					X	

Device fixing Visits (if needed)		X	X	X		

a. *Additional online or in person visits may be scheduled as Visit 2, 3, or 4 as needed for any issues with the Garmin watch*
b. *A1c information will be collected from regular clinic visits, extra labs will not be needed*
c. *This includes the International Physical Activity Questionnaire (for>15 YO) (IPAQ) and Hypoglycemic Fear Survey (HFS) for children, parents, or adults*

Garmin PACT (Physical Activity Tracking)

PI: Dr. Mark Clements

STUDY00002582

Parent and Child Information Sheet

WHO IS DOING THIS REASERCH STUDY?

This study is being carried out by researchers at Children's Mercy Hospital.

Dr. Mark Clements is involved in research for the Garmin company. However, this study is not being funded by the Garmin company. He also has a separate financial agreement with Glooko and receives research support from Dexcom. These two applications are used to help collect data for this study if the participant uses these apps. He is a consultant for Glooko and personally receives income from them. The hospital and the IRB have reviewed this arrangement and determined that this relationship presents a potential conflict of interest for Dr. Mark Clements. Therefore, Dr. Mark Clements relationship is being disclosed to you. If you have questions, contact the Office of Research Integrity (816-731-7474) or the COI Administrator at MyCOI@cmh.edu.

WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research study is to see how wearing the Garmin physical activity tracker, a watch worn on the wrist, records activity and sleep and if they improve control over Type 1 diabetes (T1D). Another purpose is to see if activity and sleep changes how people feel about managing their diabetes. The study records your activity levels, (T1D) outcomes (blood sugar, admissions, time in range, A1c), and activity levels you report. The study also records your feelings about T1D and managing T1D.

WHY AM WE BEING ASKED TO BE IN THIS STUDY?

We are asking you and your child to be part of this research study because your child:

- Is 8-17 years of age
- Has been diagnosed with Type 1 Diabetes (T1D)
- Is a patient at the Children's Mercy Kansas City network

WHAT WILL HAPPEN IF WE DECIDE TO BE IN THIS STUDY?

- Your child will wear the Garmin watch for at least eight (8) hours every day and when they sleep.

- You and your child will be part of the study for 1 year (give or take 30 days) from when your child starts wearing the watch.

Data Collection:

- We will review your child's medical history (including insurance type), health, medicines, diagnosis, A1c results, and demographics.
- We may collect other diabetes related information from your child's medical record and Continuous Glucose monitor (CGM).
- We will ask for your email and telephone number to check for any changes in your child's health over time.

Surveys:

- You and your child will be asked to complete surveys three different times.
- The surveys will be sent electronically to your personal email and will take about 15-25 minutes to complete.
- You and your child will be asked about T1D. This will include feelings and actions about hypoglycemia episodes, T1D management, and physical activity. There will be one survey in the middle of the study providing you with up-to-date study information and asking about any questions you may have. These answers will not identify you or your child.
- The surveys may contain questions about topics you or your child do not feel comfortable talking about. You and your child do not have to answer any questions you do not want to.

PARENTS:

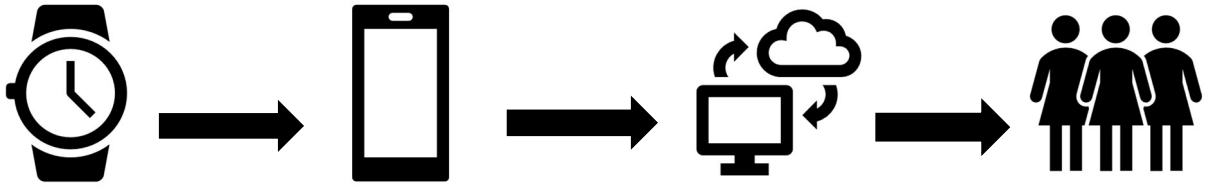
- We (the researchers) will be collecting your responses to a survey (hypoglycemic fear survey) because you are a parent of a child with T1D.
- By agreeing to have your child be in this study, you are agreeing to be in this study and allow us to collect this information from you.
- This survey will ask you your feelings and actions about your child's hypoglycemia episodes. This is the only information we will collect from you. Your responses will be kept confidential, although there is a small risk of this information being leaked.
- There is a risk that the questions asked may make you feel uncomfortable.
- You and your child do not have to be in this study, and you do not have to answer any questions you do not want to answer.
- There is no benefit to your participation in the survey, but your responses will provide information about feelings and actions for T1D management.

Virtual/ in-person study visits:

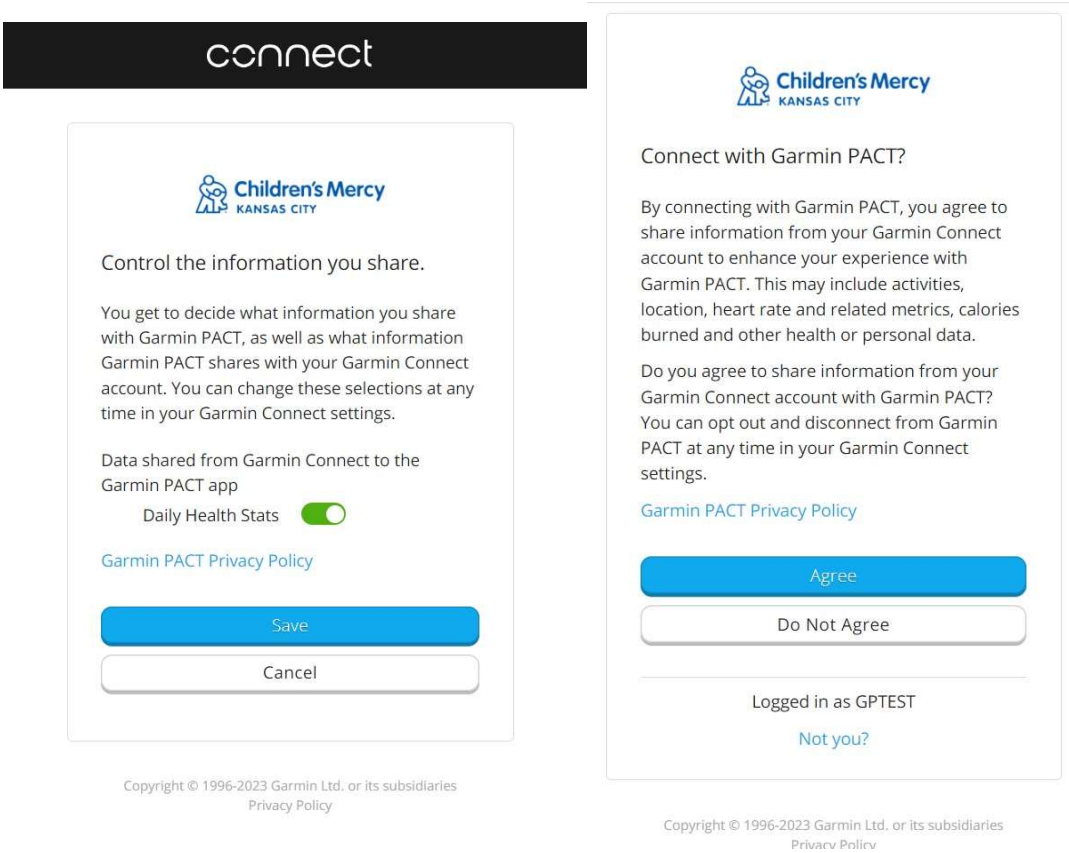
- You and your child may ask for virtual/ in-person visits for issues and information on the Garmin watch and/or Garmin Connect app.

Garmin watch and Garmin Connect app:

- Your child will be asked to wear the watch. You and your child will be asked to use the watch and health app when you receive the watch. You will set up the Garmin Connect app with an anonymous account the study team will set up and provide to you.
- The watch app will be used by the study team to monitor the information collected by the watch.
- Your child will be asked to wear the watch for at least 8 hours every day, between morning and night, and when they sleep.
    - The watch will encourage regular movement throughout the day and track sleep and oxygen at night. As your child increases activity, adjustments to their insulin regimen may need to be made.
- The information collected through the Garmin watch and Garmin Connect app will include the device ID, activities, location, heart rate and related metrics, calories burned and other health or personal data, such as sleep data.



To set up your child's Garmin PACT connection with the anonymous Garmin study account the study team must acknowledge the CM Notice of Privacy Practices for your child. This Notice is given to you when your child first become a patient at Children's Mercy, which you may request at any time. This is what the connection looks like ("Garmin PACT Privacy Policy"= CM Notice of Privacy Practices):



When the Garmin Connect app is downloaded to a smartphone, there will be additional privacy policies to accept. The Terms of Use can be found at https://www.garmin.com/en-US/legal/terms-of-use/

NOTE: The Garmin Connect app is not a HIPAA covered entity and will not protect private information in the same way as Children's Mercy. The HIPAA rules generally *do not* protect the privacy or security of your child's health information when it is accessed through or stored on *your* personal cell phones or tablets. Once Children's Mercy downloads data from the Garmin device it becomes private data protected by HIPAA.

After All Study Procedures are Complete:

- If you choose to continue to use the Garmin watch once you and your child have completed the study, you will need to set up a new personal Garmin Connect app account that is separate from the study.

When your child turns 18 years old, we will contact them to find out if they want to give verbal consent for continued participation in this study and/or use of the information.

If your child cannot be reached or chooses not to consent, the link between your child's identifiable information and the collected information will be destroyed. No identifiable information will be saved. The information without their identifiers will be kept in the secure study database.

WHAT ARE THE BENEFITS OF THIS STUDY?

There may not be a benefit to being in this study. By being in this study, you and your child may help researchers find better ways to manage T1D in the future.

WHAT ARE THE RISKS?

- There's a small risk of a breach of confidentiality. You and your child's confidentiality will be protected to the greatest extent possible.
- The questions asked may be uncomfortable or embarrassing. You and your child do not have to give any information you do not want to give.
- Because your child is going to be exercising more, they may start to have more hypoglycemia episodes. Please review how to avoid/treat hypoglycemia and change insulin to avoid hypoglycemia with your child's T1D care team. The frequent insulin changes may mean you and your child need to talk to your diabetes team more often.
- Because the watch must be worn for at least 8 hours, needs to be charged, and tells when to get up and move around, there may be some inconvenience in wearing the watch.
- There are rare risks with improper use of the tracker. These include fire, chemical burn, electrolyte leak, and/or injury, and health risks such as interfering with pacemakers, triggering seizures, and irritating skin.
- If your child has any of these problems or changes in the way they feel, you should tell the investigator or other study personnel as soon as possible.

We also offer the option of receiving study information, updates, link to surveys, and check- ins via SMS text message. Text messages are sent directly to the personal phone number that is provided. Text messages are sent from study-related Children's Mercy Hospital phone numbers within approved platforms. There is a potential risk of loss of confidentiality when using text messaging, as it is hosted by a third party. Please be aware that these communications can be intercepted in transmission or misdirected. You acknowledge that you have been informed and understand that we cannot guarantee text messages will be confidential.

WHAT ABOUT CONFIDENTIALITY?

You and your child have rights regarding the privacy and confidentiality of your health information. Federal laws require that your/ your child's information be kept secure, private, and under your control. We strive to keep your/ your child's information confidential. Agreeing to be in this study allows the

research team to access your child's medical record and use your/ your child's private information for the research purposes described in this letter. Agreement also allows the following people access to your/ your child's information (if necessary):

- The research team, which includes persons involved in this study at Children's Mercy Hospital
- The Institutional Review Board at Children's Mercy Hospital
- People from organizations that provide independent accreditation and oversight of hospitals and research
- Government/regulatory agencies (both US and international), such as the Office for Human Research Protections, the Food and Drug Administration, and/or National Institutes of Health offices who protect human subjects and oversee research

Some people or groups who get your/ your child's identifiable health information might not have to follow the same privacy rules that we follow. We will share necessary health information only when we must and will ask anyone who receives it from us to protect your/ your child's privacy. However, once information is shared outside of CMH, we cannot promise that it will remain private.

There will be a separate database, in which all study information is collected. This database will be used to analyze the study information and find out the study results.

You may cancel the use and sharing of your/ your child's information at any time. If you want us to stop using and sharing your information, contact the study worker listed under "Problems or Questions?"

Results of this study may be made public. If made public, you and your child will not be identified in any publications or presentations.

HOW WILL THIS STUDY BE SHARED?

In addition to the use of data described above, a description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you/ your child chooses to stop the study, the link between your/ your child's identifiable information and the collected information will be destroyed (de-identified). No identifiable information will be saved. The anonymous account and de-identified information collected will remain with the study team and will be kept in the study database.

CAN I STOP THE USE OF MY INFORMATION?

You/ your child may stop us from using and sharing your information at any time by contacting the people in "Problems or Questions?". Information that has already been collected for the study may still be used. But no new information will be collected except information related to any safety issues.

If you and your child do not cancel your permission, your information may be kept until the entire study is finished. This may take years. Any study information recorded in your child's medical record will be kept forever. Unless stated elsewhere in this form, you/ your child may not have access to your research record or research test results.

WHAT IDENTIFIABLE INFORMATION WIL BE USED FOR THE STUDY?

- **Youth data:** Name, assigned study ID number, home street address, telephone number, medical record number, date of birth, social security number, dates of service, email address, and CGM device number (for downloading T1D information).
- **Parent data:** Name, home street address, telephone number, and email address.

HOW WILL OUR INFORMATION BE USED IN THE FUTURE?

Your/your child's information, even if de-identified, will not be used for future research.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

You may choose not to be in this study and continue with your child's normal clinical treatment for T1D. You or your child may change your mind at any time. Your decision will not impact your child's standard care at Children's Mercy.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY? Your child will get to keep the Garmin watch for being in this study. Your child will be paid $15 every time you and your child complete the study surveys for a study visit:

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

WHAT SHOULD I DO IF THE DEVICE IS BROKEN OR LOST?

- Contact the study team (information is below) if your watch is broken/ lost to talk about possible options (including fixing/ replacing the watch).

PROBLEMS OR QUESTIONS? Please contact either Dr. Mark Clements 816-983-6982 maclements@cmh.edu or Priscilla Connell 816-601-4543 pcconnell@cmh.edu if you or your child have any questions about this study.

You may also call the Children's Mercy Hospital' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee that ensures that a research study is ethical and that the rights of study participants are protected.

Marking "I agree" on the REDCap study form means that you agree to be in this study.

WHAT DO WE DO AFTER READING THIS LETTER?

If you agree to be in this study, you and your child will:

- Mark "I agree" on the REDCap survey containing this letter
- The study team will confirm you are eligible, then mail your child the Garmin watch and send you and your child the baseline surveys in your personal email via REDCap
- When you get the Garmin Device, you will set up the Garmin Connect app to connect the Garmin watch to the data storehouse. The research team will provide an anonymous email to you so that you do not need to use your private email
- Once the Garmin watch is set up, complete the REDCap surveys
- The study team will send you the Visit 5 surveys when 180 days have passed

STUDY CALENDAR:

	Visit 1 Day 1 appx.	Visit 2[a] Day 14 appx. (if needed)	Visit 3[b] Day 28 appx. (if needed)	Visit 4[c] Day 56 appx. (if needed)	Visit 5 Day 180 appx.	Visit 6 Day 365 appx.
Consent	X					
Demographics	X					
Medical history[b]	X					X
Send Garmin tracker	X					
Surveys[c]	X				X	X
Mid- Study Check In Survey					X	
Device Fixing Visits (if needed)		X	X	X		

a. *Additional online or in person visits may be scheduled as Visit 2, 3, or 4 as needed for any issues with the Garmin watch*
b. *A1c information will be collected from regular clinic visits, extra labs will not be needed*

c. *This includes the International Physical Activity Questionnaire (for>15 YO) (IPAQ) and Hypoglycemic Fear Survey (HFS) for children, parents, or adults*