TITLE: NOVEL MHEALTH PHYSICAL ACTIVITY INTERVENTION FOR YOUTH WITH TYPE 1 DIABETES MELLITUS
NCT NUMBER: NCT06018844
DOCUMENT DATE: 7/16/24

**CONSENT TO PARTICIPATE IN A
RESEARCH STUDY AT CHILDREN'S MERCY HOSPITAL**

NUDGE
Protocol ID: 14846

Hi. Welcome to Children's Mercy Hospital.
We would like to discuss an option to participate in research.

What is Research?

Research is a **set of steps or the use of a systematic process to gather data and analyze information** to increase our understanding of a topic or issue.

Research consists of three steps: Ask a question, collect data to answer the question, and review the data to answer the question.

Researchers perform research to increase our knowledge about disease processes or possible cures. Research can help us learn how to do things better, make better medicines or other treatments.

WHAT IS INFORMED CONSENT?

Informed consent is a learning process about a research study. We go through this process so you can learn about the study and ask questions.

We are asking you to be a part of this research study.

• Please read all of the information provided.
• Ask questions about anything that you do not understand before you make a choice to be in a research study.

SUMMARY (Details of this information are in the sections below)

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care. The purpose of this research study is to see if the NUDGE bot promotes physical activity (PA) in youth and young adults with type 1 diabetes (T1D).

The following things are part of this study:

- Wear 2 devices: a smartwatch (that tracks PA) and an accelerometer (a device that looks like a Fitbit and tracks PA and sleep).
- Receive a Network Underwritten Dynamic or NUDGE text message every day to set a daily PA goal, at a time of your choosing.
- Complete multiple surveys, including a baseline survey, a physical activity calendar, 4 questionnaires a day for 3 separate week-long time periods, and a follow-up survey at completion.

- Share your medical records with the study team to collect information.
- Periodically download your meter/pump data.

Being in this study will take approximately 4 ½ months with 3 weeks of active participation. Study visits can happen at the same time as your regular clinic visits. The biggest risks from being in this study are confidentiality, irritation to the skin, and discomfort due to survey questions. There may not be a direct benefit to being in this study. Instead of being in this study, you can continue to get regular medical care.

WHO IS DOING THIS STUDY?

A study team led by Dr. Mark Clements, is doing this study. Other healthcare professionals may help them.

WHY IS THIS STUDY BEING DONE?

This research study is being done to see if NUDGE text messages can help youth and young adults with type 1 diabetes become more physically active. By encouraging physical activity, we hope to see an improvement in HbA1c results as well.

WHO CAN BE IN THIS STUDY?

Each study has criteria for who can be involved. The study team will review these with you to see if this study is right for you.

Are you eligible?

- You are between the ages of 18.00-21.99
- You have a confirmed Type 1 Diabetes diagnosis
- You have you been diagnosed for at least 6 months
- You are on an intensive insulin regimen (pump or MDIs)
- You use a Continuous Glucose monitor
- You regularly have access to a smart device capable of Wi-Fi or data usage
- Your primary language is English

Up to 50 youth and young adults, ages 13 through 21.99, will be asked to be in this study at Children's Mercy Hospital. We are asking you to be a part of this research study because you meet the eligibility criteria.

WHAT WILL HAPPEN TO ME IN THIS STUDY? AND WHAT ARE THE RISKS?

While we take steps to reduce risks, there are certain risks (the possibility that something bad or unpleasant to happen) that could occur if you participate in this research. **Review carefully** the study procedures described below and their associated risks.

Questionnaire

Being in this study involves collecting information on multiple questionnaires. If you agree to be in this study, you will be asked to respond to the questionnaires at the start of the study, during the three weeks of active participation, and at the end of the study as well. The questionnaire will take about an hour to finish at the beginning and end of the study and approximately 20 minutes daily during the three active weeks of participation.

The questionnaires will ask about a wide range of things, including demographic information, eating habits, physical activity habits, how you feel, and more, and will include information that can identify you. However, the study team will keep a separate link to your name and your email address so we can link the questionnaires each week. This link will be destroyed upon completion of the study.

By signing this form, you are **authorizing the collection and use of the information you give in the questionnaires**.

Questionnaire Risks

The questions asked may be uncomfortable or embarrassing. These risks are minimum and unlikely to occur. You do not have to give any information you do not want to give. Your confidentiality will be protected to the greatest extent possible.

By providing your email and/or phone number, the study team may communicate with you regarding setting up appointments, setting up device shipments, sending copies of permission/assent forms, and any other non-clinical study related communication.

The Children's Mercy Hospital standard is to send emails securely by encryption. If you reasonably request unencrypted email communication or respond without the use of encryption, please understand that unencrypted electronic communications, such as unencrypted email, may be intercepted or accessed by unauthorized people. Unencrypted information stored or viewed on your personal devices, like cell phones or computers, may be accessed or viewed by unauthorized people, especially if you share your device with other people. You acknowledge that you have been informed of the risk of unencrypted email.

We also offer the option of receiving study information and updates 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. 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.

Record Review

Your participation will involve collecting information from your medical record. Your information collected during normal clinical care will be collected and recorded for use by the research team.

The information collected will include the following:
device uploads, date of birth, age, gender, height, weight, race, ethnicity, address, phone number (parent, child, close friend), place of birth, primary language, parent age (mother & father), parent education (mother & father), parent occupation (mother & father), family income, parent marital status, medical history, (such as date of T1D diagnosis, T1D-related hospitalizations, treatment regimen, number of contacts and visits with clinic staff, insurance type, and blood glucose data, etc.).

The study team will get into your medical record from time to time to update the information collected. This will happen because researchers may need to know how your health has changed over time.

By signing this form you are authorizing the collection and use of this information for research purposes.

Confidentiality Risks for Record Review

One risk of taking part in a research is that more people will handle your information collected for this research. The research team will make every effort to protect the information and keep it confidential, but **it is possible that an unauthorized person might see it**.

Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect the ability to get insurance.

What if I am not ok with the risk to confidentiality?

This research requires the use of your information. If you choose not to let these groups collect, use and share the information as explained above, you will not be able to participate in this research.

If you choose not to allow us to use the information required, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related.

If suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect are witnessed within your home, CMH personnel, as mandatory reporters, are required to report it to the authorities.

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.

Future Research:

- This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to

this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data until all publication has been completed. There will be no direct benefits to you for the storage and future research use of the information. However, sharing your data may contribute to research that could help others in the future.

- Your name and identifying information will be removed from any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data.

WHAT ABOUT OTHER RISKS WE DON'T KNOW ABOUT?

There may be risks we don't know about right now.

We will tell you about any new information that might change your decision to stay in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

There may be no direct benefit to you from being in this research study. By being in this study, you may help researchers find better treatments for children and adults with type 1 diabetes in the future.

WHAT ABOUT EXTRA COSTS?

You **will not have to pay anything extra** if you are in this study.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?

You will receive each amount for completion:

Initial Study Visit	Wearing Actiwatch	Wearing Actiwatch 6/7 days	Completing Each EMA Survey	Completing EMA Survey 6/7 days	Timely Device Return	Completing Treatment Satisfaction Survey	Total Compensation Possible
$50	$5/day (x21)	$100	$2 ($168 possible)	$100	$75 ($25 each)	$50	$648

Maximum compensation for participating in the study is $648.

If you do not complete the study, you will be compensated for the activities that were completed. You will not be compensated for any uncompleted activities.

If the total value of payments to you from Children's Mercy Hospital totals more than $600 in any calendar year, the hospital must report this to the IRS on a Form 1099 with the recipient's social security number (SSN) or individual tax identification number (ITIN). You will receive a copy of this tax form. Accepting payment for taking part in the study may affect eligibility for Medicaid or other programs.

Children's Mercy Hospital can only make payments) if we have your SSN or ITIN Number, name, address, and phone number. If you do not provide this information, you can still participate in the research study; however, you will not receive payment. Your SSN or ITIN Number will be maintained in a secure manner.

WHAT ARE THE ALTERNATIVES TO BE BEING IN THIS STUDY?

Instead of being in this study, you may choose not to participate. If you choose not to enroll in this study, your routine care will remain unchanged.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to be in this study or withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled.

We will inform you of any new information that we find out during this study. This information may affect your decision to stay in the study. If you choose to withdraw from (quit) the study or if you are asked by your personal doctor to withdraw from the study, you must tell the study team as soon as possible.

If you withdraw from the study early for any reason, the information that already has been collected will be de-identified and cannot be traced back to you. No further information will be collected for the study.

Dr. Mark Clements or the Institutional Review Board may stop the study at any time. The investigator(s) or your doctor, may remove you from the study at any time without your consent.

Authorization about Use and Disclosure of Health Information for Research Purposes

This research involves the use and sharing of your health information. Your health information is **protected by a federal privacy law called Health Insurance Portability and Accountability Act (HIPAA)**. HIPAA gives you the right to decide who can collect, use, or share your protected health information. HIPAA also requires this information to be kept secure and private. This form describes how the information collected about you for this research will be used and shared with others if you choose to participate in this research.

What Information is "Protected Health Information" (PHI)?
Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. Health information is considered "protected health information" (PHI) when it may be possible to figure out who the person is. For example, when a person's health information is combined with identifiers like name, address, phone number or social security, then the information is considered PHI.

What information about me will be accessed, collected and recorded in the research record?

The following information about your health will be used for this research:

- Your medical history
- Your laboratory results
- Your device data

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created and kept in the endocrine department research office. The research record may include documents that have your: name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, device uploads, gender, height, weight, race, ethnicity, place of birth, primary language, parent age (mother & father), parent education (mother & father), parent occupation (mother & father), family income, parent marital status, or medical history, (such as date of T1D diagnosis, T1D-related hospitalizations, treatment regimen, number of contacts and visits with clinic staff, and blood glucose data, etc.) list other unique personal identifier. All research records will be maintained in a confidential manner.

Who will be allowed to access and record my health information in the research record?

The following people and entities will have access to your health information and/or PHI for this research:

- The research team, which includes persons involved in this study at Children's Mercy Hospital, Nemours Children's Hospital, The University of Kansas, and The University of Kansas Medical Center;

- The Institutional Review Board at Children's Mercy Hospital; The University of Kansas Medical Center

- Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;

- 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, National Institutes of Health offices whose job it is to protect human subjects and oversee the conduct of research.

How is the information protected?

For this study we will:

- Store your data in a secured way using normal business practices (like using password protected computers, limiting the number of authorized personnel who can see your identifiers, using a code number instead of your name, or removing your identifiers when possible to do so);
- Share your health information only when we must;
- Share only the information that is needed to satisfy the request;
- Request anyone who receives the collected health information from us to protect your privacy; and
- Not use your name in any publication or presentation of the research results. You will be told of your study results when they are made public. Thus, you need to tell your doctor or clinic coordinator when your contact information changes.

Absolute confidentiality cannot be guaranteed because persons outside the research team may need to look at the research records that include your identifying information. Once your information is shared, we cannot promise that it will remain private. Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. They may pass information on to other groups or individuals not named here. If that happens, your information will no longer be protected by the HIPAA privacy laws.

What if I'm not ok with using my PHI?

Because we need your permission to use your health information, you cannot participate in this study unless you sign this form. If you choose not to allow us to use your protected health information, we will discuss any non-research alternatives available to you.

Refusing to sign won't affect your access to other medical care, your payments, eligibility for benefits, or ability to enroll in any health plans.

What happens if I change my mind later?

You may withdraw your permission for us to use your PHI for this research study by sending a written notice to Dr. Mark Clements at 2401 Gillham Road, Kansas City, Missouri 64108. You may also contact Children's Mercy Hospital Health Information Management (HIM) in writing. **If you cancel your permission to use and share your information, you may no longer participate in this research.**

We may still use and share information that was collected before receiving your cancellation. If we have sent your health information to a third party, such as the research sponsor, or we have removed your identifying information, it may not be possible to prevent its future use.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Your permission to use and share your health information will not expire unless you cancel it.

Can I ask to see the PHI that is collected about me for this research?

The federal HIPAA rules state you have the right to access your medical records. A copy of this research consent/HIPAA authorization form may be placed in your medical record. Additionally, information about

medications, tests and other procedures conducted as part of the research study may also be placed in your medical record if relevant to your clinical care, and may be viewed by individuals with access to your medical record (e.g. other health care providers).

Any research information that is placed in your medical record will be kept there indefinitely.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Mark Clements is in charge of this research study. You may call Dr. Mark Clements at (816) 983-6982 with questions at any time during the study. You may also call Claire Petty, the study coordinator, at (816) 601-4546 with any questions you may have.

You should call Dr. Mark Clements if you believe that you have suffered injury of any kind as a result of being in this research project.

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 of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

CONSENT OF SUBJECT

Your signature means you agree to the following statements:
I have had a chance to discuss the study and ask questions. My questions have been answered.
I understand the purpose, the required procedures, risks and benefits involved if I participate in the research.
I understand that I do not have to be in this study.
I know I can decide to quit the study at any time.
I agree to be in the study.

_____ _____
Signature of Adult Date

STUDY PERSONNEL

Your signature means you have confirmed that legally effective consent has been obtained.
I have explained the purposes, procedures, and risks involved in this study in detail to the participant.
I have answered all questions.
I attest that, in my judgement, the participant possesses the legal capacity to give informed consent freely.
I have confirmed the agreement of the participant and obtained their signature documenting that agreement.

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Print Name of Person Obtaining Consent _____

PARENTAL PERMISSION AND CHILD ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT CHILDREN'S MERCY HOSPITAL

NUDGE
Protocol ID: 14846

Hi. Welcome to Children's Mercy Hospital.
We would like to discuss an option to participate in research.

What is Research?

Research is a set of steps or the use of a systematic process to gather data and analyze information to increase our understanding of a topic or issue.

Research consists of three steps: Ask a question, collect data to answer the question, and review the data to answer the question.

Researchers perform research to increase our knowledge about disease processes or possible cures. Research can help us learn how to do things better, make better medicines or other treatments.

WHAT IS INFORMED PERMISSION AND ASSENT?

Informed permission and assent is a learning process about a research study. We go through this process so you and your child can learn about the study and ask questions.

We are asking your child to be a part of this research study.

• Please read all of the information provided.
• Ask questions about anything that you do not understand before you make a choice for your child to be in a research study.

SUMMARY (Details of this information are in the sections below)

We are asking your child to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your child's regular medical care. The purpose of this research study is to see if the NUDGE bot promotes physical activity (PA) in youth and young adults with type 1 diabetes (T1D).

The following things are part of this study:

- Your child will wear 2 devices: a smartwatch (that tracks PA) and an accelerometer (a device that looks like a Fitbit and tracks PA and sleep).
- Your child will receive a Network Underwritten Dynamic or NUDGE text message every day to set a daily PA goal, at a time of your choosing.
- Your child will complete multiple surveys, including a baseline survey, a physical activity calendar, 4 questionnaires a day for 3 separate week-long time periods, and a follow-up survey at completion.
- Share your child's medical records with the study team to collect information.
- Periodically download your child's meter/pump data.

Being in this study will take approximately 4 ½ months with 3 weeks of active participation. Study visits can happen at the same time as your regular clinic visits. The biggest risks from being in this study are confidentiality, irritation to the skin, and discomfort due to survey questions. There may not be a direct benefit to being in this study. Instead of being in this study, your child can continue to get regular medical care.

WHO IS DOING THIS STUDY?

A study team led by Dr. Mark Clements, is doing this study. Other healthcare professionals may help them.

WHY IS THIS STUDY BEING DONE?

This research study is being done to see if NUDGE text messages can help youth and young adults with type 1 diabetes become more physically active. By encouraging physical activity, we hope to see an improvement in HbA1c results as well.

WHO CAN BE IN THIS STUDY?

Each study has criteria for who can be involved. The study team will review these with you to see if this study is right for your child.

Is your child eligible?

- Your child is between the ages of 13.00-17.99
- Your child has a confirmed Type 1 Diabetes diagnosis
- Your child been diagnosed for at least 6 months
- Your child on an intensive insulin regimen (pump or MDIs)
- Your child uses a Continuous Glucose monitor
- Your child regularly has access to a smart device capable of Wi-Fi or data usage
- You and your child's primary language is English

Up to 50 youth and young adults, ages 13 through 21.99, will be asked to be in this study at Children's Mercy Hospital. We are asking you and your child to be a part of this research study because they meet the eligibility criteria.

WHAT WILL HAPPEN TO MY CHILD IN THIS STUDY? AND WHAT ARE THE RISKS?

While we take steps to reduce risks, there are certain risks (the possibility that something bad or unpleasant to happen) that could occur if your child participates in this research. Review carefully the study procedures described below and their associated risks.

When your child reaches adulthood (18 years of age), we will contact them to find out if they want to give consent for continued participation in this study and/or use of their 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 de-identified information will be kept on secure Children's Mercy servers.

Questionnaire

Being in this study involves collecting information on multiple questionnaires. If you agree for your child to be in this study you and/or your child will be asked to respond to the questionnaires at the start of the study, during the three weeks of active participation, and at the end of the study as well. The questionnaires will take about an hour to finish at the beginning and end of the study and approximately 20 minutes daily during the three active weeks of participation.

The questionnaires will ask about a wide range of things, including demographic information, eating habits, physical activity habits, how you feel, and more, and will include information that can identify you or your child. However, the study team will keep a separate link to your child's name and your email address, so we can link the questionnaires each week. This link will be destroyed upon completion of the study.

By signing this form, you are authorizing the collection and use of the information you and/or your child give in the questionnaires.

Questionnaire Risks

The questions asked may be uncomfortable or embarrassing. These risks are minimum and unlikely to occur. You or your child do not have to give any information you do not want to give. Your child's confidentiality will be protected to the greatest extent possible.

By providing your email and/or phone number, the study team may communicate with you regarding setting up appointments, setting up device shipments, sending copies of permission/assent forms, and any other non-clinical study related communication.

The Children's Mercy Hospital standard is to send emails securely by encryption. If you reasonably request unencrypted email communication or respond without the use of encryption, please understand that unencrypted electronic communications, such as unencrypted email, may be intercepted or accessed by unauthorized people. Unencrypted information stored or viewed on your personal devices, like cell phones or computers, may be accessed or viewed by unauthorized people, especially if you share your device with other people. You acknowledge that you have been informed of the risk of unencrypted email.

We also offer the option of receiving study information and updates 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. 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.

Record Review

Your participation will involve collecting information from your child's medical record. Your child's information collected during normal clinical care will be collected and recorded for use by the research team.

The information collected will include the following:
device uploads, date of birth, age, gender, height, weight, race, ethnicity, address, phone number (parent, child, close friend), place of birth, primary language, parent age (mother & father), parent education (mother & father), parent occupation (mother & father), family income, parent marital status, medical history, (such as date of T1D diagnosis, T1D-related hospitalizations, treatment regimen, number of contacts and visits with clinic staff, insurance type, and blood glucose data, etc.).

The study team will get into your child's medical record from time to time to update the information collected. This will happen because researchers may need to know how your child's health has changed over time.

By signing this form you are authorizing the collection and use of this information for research purposes.

Confidentiality Risks for Record Review

One risk of taking part in a research is that more people will handle your/your child's information collected for this research. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it.

Depending on the kind of information being collected, it might be used in a way that could embarrass you/your child or affect the ability to get insurance.

What if I am not ok with the risk to confidentiality?

This research requires the use of your child's information. If you choose not to let these groups collect, use and share the information as explained above, your child will not be able to participate in this research.

If you choose not to allow us to use the information required, we will discuss any non-research alternatives available to your child. Your decision will not affect your child's right to medical care that is not research-related.

If suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect are witnessed within your home, CMH personnel, as mandatory reporters, are required to report it to the authorities.

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.

Future Research:

- This study is collecting data from your child. We would like to make your child's data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your child's data until all publication has been completed. There will be no direct benefits to you or your child for the storage and future research use of the information . However, sharing your child's data may contribute to research that could help others in the future.

- Your child's name and identifying information will be removed from any data before they are shared with other researchers. Researchers cannot easily link your child's identifying information to the data.

WHAT ABOUT OTHER RISKS WE DON'T KNOW ABOUT?

There may be risks we don't know about right now.

We will tell you about any new information that might change your decision to keep your child in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

There may be no direct benefit to your child from being in this research study.
By being in this study, your child may help researchers find better treatments for children and adults with type 1 diabetes in the future.

WHAT ABOUT EXTRA COSTS?

You will not have to pay anything extra if your child is in this study.

WHAT WILL MY CHILD RECEIVE FOR BEING IN THIS STUDY?

Your child will receive each amount for completion:

Initial Study Visit	Wearing Actiwatch	Wearing Actiwatch 6/7 days	Completing Each EMA Survey	Completing EMA Survey 6/7 days	Timely Device Return	Completing Treatment Satisfaction Survey	Total Compensation Possible
$50	$5/day (x21)	$100	$2 ($168 possible)	$100	$75 ($25 each)	$50	$648

Maximum compensation for participating in the study is $648.

If your child does not complete the study, your child will be compensated for the activities that were completed. Your child will not be compensated for any uncompleted activities.

If the total value of payments to your child from Children's Mercy Hospital totals more than $600 in any calendar year, the hospital must report this to the IRS on a Form 1099 with the recipient's social security number (SSN) or individual tax identification number (ITIN). You will receive a copy of this tax form. Accepting payment for taking part in the study may affect eligibility for Medicaid or other programs.

Children's Mercy Hospital can only make payments if we have your child's SSN or ITIN Number, name, address, and phone number. If you do not provide this information, your child can still participate in the research study; however, your child will not receive payment. Your child's SSN or ITIN Number will be maintained in a secure manner.

WHAT ARE THE ALTERNATIVES TO BE BEING IN THIS STUDY?

Instead of being in this study, you and your child may choose for your child not to participate. If you and your child choose not to enroll in this study, your child's routine care will remain unchanged.

WHAT ARE MY CHILD'S RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. Your child does not have to be in this study to receive medical care. If you choose for your child not to be in this study or withdraw you child from this study, there will be no penalty or loss of benefits to which your child is otherwise entitled.

We will inform you of any new information that we find out during this study. This information may affect your decision to keep your child in the study. If you choose to withdraw your child from (quit) the study or if you are asked by your child's personal doctor to withdraw your child from the study, you must tell the study team as soon as possible.

If you withdraw your child from the study early for any reason, the information that already has been collected will be de-identified and cannot be traced back to your child. No further information will be collected for the study.

Dr. Mark Clements or the Institutional Review Board may stop the study at any time. The investigator(s) or your child's doctor, may remove you from the study at any time without your consent.

Authorization about Use and Disclosure of Health Information for Research Purposes

This research involves the use and sharing of your child's health information. Your child's health information is **protected by a federal privacy law called Health Insurance Portability and Accountability Act (HIPAA).** HIPAA gives you the right to decide who can collect, use, or share your child's protected health information. HIPAA also requires this information to be kept secure and private. This form describes how the information collected about your child for this research will be used and shared with others if you and your child choose to participate in this research.

What Information is "Protected Health Information" (PHI)?
Protected health information is information that personally identifies you/your child and relates to you/your child's past, present, or future physical or mental health condition or care. Health information is considered "protected health information" (PHI) when it may be possible to figure out who the person is. For example, when a person's health information is combined with identifiers like name, address, phone number or social security, then the information is considered PHI.

What information about my child will be accessed, collected and recorded in the research record?

The following information about your child and your child's health will be used for this research:

- Your child's medical history
- Your child's laboratory results
- Your child's device data

The research record is separate from your child's medical record. Information about your child that is obtained during this study will be recorded in a research record and may also be recorded in your child's medical record. A research record will be created and kept in the endocrine department research office. The research record may include documents that have your child's: name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, device uploads, gender, height, weight, race, ethnicity, place of birth, primary language, parent age (mother & father), parent education (mother & father), parent occupation (mother & father), family income, parent marital status, or medical history, (such as date of T1D diagnosis, T1D-related hospitalizations, treatment regimen, number of contacts and visits with clinic staff, and blood glucose data, etc.) list other unique personal identifier. All research records will be maintained in a confidential manner.

Who will be allowed to access and record my child's health information in the research record?

The following people and entities will have access to your child's health information and/or PHI for this research:

- The research team, which includes persons involved in this study at Children's Mercy Hospital, Nemours Children's Hospital, The University of Kansas, and The University of Kansas Medical Center;

- The Institutional Review Board at Children's Mercy Hospital; The University of Kansas Medical Center
- Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
- 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, National Institutes of Health offices whose job it is to protect human subjects and oversee the conduct of research.

How is the information protected?

For this study we will:

- Store your child's data in a secured way using normal business practices (like using password protected computers, limiting the number of authorized personnel who can see your child's identifiers, using a code number instead of your child's name, or removing your child's identifiers when possible to do so);
- Share your child's health information only when we must;
- Share only the information that is needed to satisfy the request;
- Request anyone who receives the collected health information from us to protect your child's privacy; and
- Not use your child's name in any publication or presentation of the research results. You will be told of your child's study results when they are made public. Thus, you need to tell your child's doctor or clinic coordinator when your child's contact information changes.

Absolute confidentiality cannot be guaranteed because persons outside the research team may need to look at the research records that include your child's identifying information. Once your child's information is shared, we cannot promise that it will remain private. Some people or groups who get your child's identifiable health information might not have to follow the same privacy rules that we follow. They may pass information on to other groups or individuals not named here. If that happens, your child's information will no longer be protected by the HIPAA privacy laws.

What if I'm not ok with using my child's PHI?

Because we need your permission to use your child's health information, your child cannot participate in this study unless you sign this form. If you choose not to allow us to use your child's protected health information, we will discuss any non-research alternatives available to your child.

Refusing to sign won't affect your or your child's access to other medical care, your payments, eligibility for benefits, or ability to enroll in any health plans.

What happens if I change my mind later?

You may withdraw your permission for us to use your child's PHI for this research study by sending a written notice to Dr. Mark Clements at 2401 Gillham Road, Kansas City, Missouri 64108. You may also contact Children's Mercy Hospital Health Information Management (HIM) in writing**. If you cancel your permission to use and share your child's information, your child may no longer participate in this research.**

We may still use and share information that was collected before receiving your cancellation. If we have sent your child's health information to a third party, such as the research sponsor, or we have removed you or your child's identifying information, it may not be possible to prevent its future use.

If you do not cancel your permission, your child's PHI may continue to be recorded until the entire study is finished. This may take years. Your permission to use and share your child's health information will not expire unless you cancel it.

Can I ask to see the PHI that is collected about my child for this research?

The federal HIPAA rules state you have the right to access your child's medical records. A copy of this research permission/assent/HIPAA authorization form may be placed in your child's medical record. Additionally, information about medications, tests and other procedures conducted as part of the research study may also be placed in your child's medical record if relevant to your child's clinical care, and may be viewed by individuals with access to your child's medical record (e.g. other health care providers).

Any research information that is placed in your child's medical record will be kept there indefinitely.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Mark Clements is in charge of this research study. You may call Dr. Mark Clements at (816) 983-6982 with questions at any time during the study. You may also call Claire Petty, the study coordinator, at (816) 601-4546 with any questions you may have.

You should call Dr. Mark Clements if you believe that you have suffered injury of any kind as a result of being in this research project.

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 of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

PERMISSION OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE

Your signature means you agree to the following statements:
I have had a chance to discuss the study and ask questions. My questions have been answered.
I understand the purpose, the required procedures, risks and benefits involved if my child participates in the research.
I understand that my child does not have to be in this study.
I know my child and I can decide to quit the study at any time.
I agree for my child to be in the study.

Signature of Parent/Legally Authorized Representative Date Relationship to Participant

Print name of Parent/Legally Authorized Representative

ASSENT OF MINOR

Your signature means you agree to the following statements:
I have been told that I don't have to be in this research study.
I can quit the study at any time and no one will be mad at me.
I agree to be in the study.

Signature of Minor Date

STUDY PERSONNEL

Your signature means you have confirmed that legally effective permission of the parent and assent of the child (when required) has been obtained.
I have explained the purposes, procedures, and risks involved in this study in detail to the participant and parent/LAR.
I have answered all questions.
I attest that, in my judgement, the participant possesses the legal capacity to give informed permission freely.
I have confirmed the agreement of the participant and obtained their signature documenting that agreement.

Indicate if assent is not obtained:
___ The child IS in my opinion capable of assenting to participating in this study.
___ The child IS NOT capable of assenting because
__ Age (child is less than 7 years old)
__ Limitation in understanding based on child's condition
__ Other, please explain

Signature of Person Obtaining Permission/Assent Date Time

Print Name of Person Obtaining Permission/Assent