Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital, Newport Hospital, and Gateway HealthCare

Name of Study Participant(s): _____

Principal Investigator: Jennifer Warnick, PhD

Title of Research Study:

Type 1 Diabetes Adolescents for healthier Lifestyles Study (T1DAL Study) RCT

If you are a parent or legal guardian who is giving permission for a child (<18 years old) , please note that the word "you" in this document refers to your child.

Please check one of the following:

_____ You are the parent or guardian granting permission for a child in this study.

_____ You are the parent or guardian granting permission for yourself and your child to participle in this study.

_____ You are a young adult granting permission for yourself to participate in this study.

_____ You are the parent/caregiver of a young adult who is participating in this study and are granting permission for yourself to participate in this study.

Study Key Information

You are being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. In the sections that follow, the word "we" means the study doctor and other research staff. We will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or your other doctors) before you agree to participate in the research. If you agree that

you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

The purpose of this research study is to test a new, healthy lifestyles intervention for teens with type 1 diabetes compared to usual care. You are being asked to take part in this research study because you are between the ages of 13- and18-years old and you were diagnosed with type 1 diabetes mellitus more than 6 months ago.

In this research study we want to examine whether the T1DAL program helps to improve the health and wellbeing of teens with type 1 diabetes. Specifically, whether teens who participate in the T1DAL program have any changes to their percent time in target blood glucose range, body size, mood, eating and physical activity behaviors, and self-esteem compared to teens who do not participate in the T1DAL program.

B. What is experimental/new in this study

We have taken an effective, evidence-based healthy lifestyles behavior program for teenagers and adapted it to meet the needs of teens who have type 1 diabetes. All participants who join the program will have type 1 diabetes. We have worked for the past few years to make the program as fun and educational as it can be based upon feedback from real families living with type 1 diabetes. To the best of our knowledge, this type of program is not currently available as a resource for patients who may benefit from it. We already know that the T1DAL program is acceptable and feasible for families to attend. Next, we want to examine how helpful it is to improving teen's health.

C. What do I have to do in this research?

It will take you about 4-5 months to complete this study. During this time, we will ask you to complete 2 assessment appointments (~1 hour each), up to 12 group sessions (~1 hour each), and some individual check-ins (~10-20 minutes each). All sessions will occur virtually via our institutional HIPAA-compliant Zoom account.

If you decide to join this research study, the following things will happen:

- We will ask you complete some questionnaires
- We will measure your height, weight, and percent time in target blood glucose range
- If you are eligible to participate, we will randomly assign you either to the T1DAL program or to usual care
- If you are assigned to the T1DAL program, you will be asked to attend as many of the group sessions and individual check-ins as you can
- Parents/caregivers of teens randomized to the T1DAL program will be invited to attend 4 sessions

- We will ask you to wear a blinded Dexcom CGM if you do not already wear a Dexcom CGM or do not want to share your personal CGM data with the study

D. **What could go wrong?**

The risks of participating in this study are minimal. The most important potential risks to know about are that you may not be randomly assigned to the group you want. If you are assigned to the T1DAL program, it may not be helpful for improving your health, it is possible that you could experience more frequent episodes of hypo- or hyperglycemia as a result of changing your eating and exercise habits, and it is also possible that you could endure an injury from exercise during the program. In the event of a severe blood sugar low occurring during the T1DAL study sessions or should we be concerned about your diabetes health during the study, we will contact your physician to coordinate care.

E. What are the benefits?

You may or may not benefit from taking part in this study. Others may benefit in the future from the information that is learned in this study.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

G. **If I don't want to take part in this research what are my other choices?**

You do not have to be in this research study to change your lifestyle behaviors. Your healthcare provider can discuss with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical treatment options include meeting with a registered dietician, a certified diabetes educator, and/or a mental health provider. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

- **Please carefully read this form, additional detail about each item just described is found below.**
- **Please listen to the study team explain the study and this form to you.**
- **Please ask questions about anything that is not clear.**

1. Nature and Purpose of the Study

You are being asked to take part in a research project because you are a teenager with type 1 diabetes and are interested in living a healthier lifestyle and meeting other teens with diabetes. In this study we are trying to learn whether there are any differences in the health and wellbeing of teens who participate in the T1DAL program compared to teens who do not participate in the T1DAL program.

We expect to enroll approximately 60 adolescents into this study. The study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

2. Explanation of Procedures:

If you agree to take part in this study, you will complete a few surveys to see if you are eligible to participate. Study staff will help you to measure your height and weight. If you do not meet all the study requirements and cannot be in the research study, the research investigator will discuss other options with you.

If you are eligible to participate in the study, you (the teen) will be asked to complete a few questionnaires about your medical history, eating behaviors, diabetes management, mood, and general demographics information. Your parent/caregiver will also be asked to complete a few questionnaires about their medical history, diabetes management engagement, and general demographics. This should take no more than 60 minutes total. You will be required to provide your continuous blood glucose (CGM) data for 10 days immediately following your first study appointment and for 10 days immediately following you last study appointment. If you currently wear a Dexcom CGM, you can provide your Clarity code to the study, and the study will collect your data from Dexcom's professional site. If you do not wear a Dexcom CGM or do not want to share your personal data, the study will provide you with a blinded Dexcom CGM to wear for both study assessment time points. You will be asked to return the CGM transmitter to the study after the 10-day data collection time, via a prepaid envelope. You (the teen) will also be asked to download the LifeData app, a free smartphone app for clinical research, on your phone. The app will prompt you a few times per day for 10 days immediately following your first study appointment and for 10-days immediately following your last study appointment. The app will ask you a few questions about your mood, day, and eating habits, and diabetes-management behaviors. For each prompt you answer, you will earn $0.50; and if you answer more than 85% of prompts total, you will earn an additional $25. The parent/caregiver will not be asked to complete any questions via the LifeData app. Please note that the answers to the LifeData questions will not be seen or evaluated in real-time.

For those who are eligible for the study, you and your parent/caregiver will be randomly assigned, "randomized", into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher can choose what group you will be in. You will have an equal chance of being placed either of the two groups. You and your parent/caregiver are randomized together, meaning that you will both be assigned to the same group.

T1DAL Program Group: If you are assigned to the T1DAL Program Group, you (the teen) will be asked to attend 12 group sessions over 16 weeks. These will occur virtually. Each session will last 60 minutes. The group will be composed of 1-2 trained facilitators and 4-8 teens with type 1 diabetes. Each group session will involve learning about how to live healthfully with type 1 diabetes. You will learn skills, have an opportunity to meet with and talk to other teens who may have similar interests to you, and play games to increase knowledge of the topics discussed. You (the teen) will also have an opportunity to meet one-on-one with a group leader every few weeks via Zoom or a phone call. These individual check-ins will offer you the chance to set and problem solve individual goals, discuss your specific health questions, and review your health behaviors over time. Teens in this group will have the opportunity to earn up to $50 for meeting individual goals and participating in group sessions. Parents/caregivers will be asked to attend 4 group sessions over the 16 weeks.

Usual Care Group: If you are randomly assigned to the Usual Care Group, you will continue your usual diabetes management clinical care. You will not be invited to the full T1DAL Program. Instead, you will receive monthly newsletters with free diabetes education and support. Once your participation in the study ends, you and your parent/caregiver will be offered a free, abbreviated T1DAL Program. Participating in this post-research study workshop(s) is completely optional.

After the 16-week program, we will ask you and your parent/caregiver to complete one final individual assessment via Zoom, where we will measure your (teen's) height and weight and ask you and your parent/caregiver to complete a few questionnaires. All teens will earn $25 for completing the first study appointment and $50 for completing the last study appointment. Caregivers will receive $15 for completing the first study appointment and $25 for completing the last study appointment. This means that teens will have the opportunity to earn up to $175 and caregivers can earn up to $40 for participating in this study.

Text messaging is part of this research study. This may include you receiving text messages from research staff and/or you are sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text

messages to the degree permitted by the technology being used. Depending on the nature of the study, some of the following steps may be taken encrypting the data during transmission, eliminating sensitive health care information from the texts, storing all data gathered on secure servers, providing you with a secure device when the circumstances warrant, and/or remote data deletion in the event of a lost or stolen device. The study will primarily use text messaging to remind participants of their scheduled appointments.

Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. These are “research only” services that will be paid for by the study and will not be billed to you or your health insurance company.

You *will not* be charged for the study Dexcom CGM if you receive one. It will be provided by the study sponsor

There are other services you will receive which are considered "routine clinical services." These are services you would receive even if you were not in the research study (standard of care). These non-research services will be billed to your health insurance company, and you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Taking part in this research study may lead to added costs to you or your insurance company if, for example, you need to schedule additional medical appointments to adjust insulin dosing. Ask your study doctor or nurse for help finding the right person to talk to if you are unsure

which costs will be billed to you or your insurance provider. If you have questions about your insurance coverage, or the items you might be required to pay for, please call your insurance company for this information.

Contact Information: You can call us with any concerns or questions about the research. Please call Dr. Jennifer Warnick at (401) 793-8757 if you have any questions about the study and its procedures. Dr. Warnick can be contacted Monday through Friday between the hours of 8:30am and 5:30pm. If you need to contact her in writing, please send mail to 196 Richmond Street, Providence, RI 02903.

3. Discomforts and Risks

The risks of participating in this study are minimal. You may not be randomly assigned to the group you want. The T1DAL Program may not be effective in helping you to live a healthier lifestyle. It is possible that you could experience more frequent episodes of hypo- or hyperglycemia if you adjust your diet and exercise behaviors. As a result, you may need to contact your personal physician for insulin dosing adjustments. Inserting the CGM sensor has the risk of momentary discomfort and bruising. CGMs might also become uncomfortable, for example, the CGM sensor might cause minor skin irritation. You can stop wearing the device at any time. If you experience a severe low during the study sessions or if the study team is concerned about your health during the study, we will be contacting your physician to coordinate your care.

4. Benefits

You may not receive any benefits to participating in this study. Participants randomized to the T1DAL Program Group will receive well-studied information about healthy eating, physical activity, and diabetes management specific to persons with type 1 diabetes mellitus. Participation in this program may help you to eat a more balanced diet, become more active, manage your weight, and/or develop more stable blood glucose levels. However, there is absolutely no guarantee that you will change your health.

5. Alternative Therapies

There are currently no alternative programs available, to the best of our knowledge, that promote healthy lifestyle change specific to youth with type 1 diabetes. There are registered dieticians, certified diabetes educators, and mental health providers available within some healthcare clinics who can discuss health behavior change with you.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in

the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible. In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- You say or do anything that is deemed unsafe or threatening to yourself or another participant.
- The study is suspended or canceled.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 5 months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or medical record.

_____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the head researcher: Dr. Jennifer Warnick at 401-793-8757.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure, you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director, Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. (HIPAA)

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and release for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, NIDDK
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;

- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving, and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed.

10. Additional Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

NIH Certificate of Confidentiality

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report

child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Contact for Future Studies:

Your participation in **any research** is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.
Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying type 1 diabetes or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies

Signature Page for Adult Participants

Adult Participant

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below, I give my permission to participate in this research study and for the use of associated protected health information as described above (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp.

DO NOT sign this document after this expiration date.

_____
Print name of Study Participant

_____
Signature of Adult Study Participant Date (MM/DD/YEAR) Time when signed

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

_____
Signature of researcher or designate Date (MM/DD/YEAR) Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**

Signature Page for Teen Participants

Parent/Guardian Signature(s)

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below, I give my permission for my child to participate in this research study and for the described uses and releases of information (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

Print name of child participant		
Signature of Parent/Guardian	Date (MM/DD/YEAR)	Time when signed
Print name of Parent/Guardian	Relationship to child	

Child/Adolescent Assent

Signature of **Child/Adolescent Subject**	Date (MM/DD/YEAR)	Time when signed
Child/Adolescent Age		

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**

Signature Page for Teen and Adult (Parent) Participants

Consent for Participation

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below**, I give permission for myself and my child to participate in this research study** and for the described uses and releases of information (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

Print name of child participant		
Signature of Parent/Guardian	Date (MM/DD/YEAR)	Time when signed
Print name of Parent/Guardian	Relationship to child	

Child/Adolescent Assent

Signature of **Child/Adolescent Subject**	Date (MM/DD/YEAR)	Time when signed
Child/Adolescent Age		

Research Investigator /or Associate's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**