Packaging and Disseminating the JOIN for ME Program in Low-Income Settings

NCT: 5U18DP006429-02

Informed Consent Form, v. 04/02/2021

Research Consent Form and Authorization Form

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

Name of Study Participant: _____

Principal Investigator: Elissa Jelalian, Ph.D.

Title of Research Study: Packaging and Disseminating the JOIN for ME Program

Study Key Information

You and your child 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 participating in this study is the best decision for you and your child. Taking part in this study is completely voluntary. Even if you decide to allow your child to take part in the study, you and your child are free to leave at any time if you change your minds. The researcher will explain the study to you and your child and answer any questions you may have. We encourage you to discuss this study with others (your family, friends or other doctors) before you agree to have your child participate in the research.

If you decide to allow your child to be in the study, you will be asked to sign this consent which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. If your child is 8 years or older, the "assent" (agreement) of your child will be obtained by the researcher before your child may participate in this study. Your child must sign the assent form. You will be given a copy of the signed consent form to keep.

A. What is the purpose of the research?

JOIN for ME is a family-based weight management program for children. The purpose of the program is to help children improve their eating and physical activity habits and achieve healthier weights. In this study, the JOIN for ME program will be offered to families in two community settings, primary care and public housing. The purpose of the study is to figure out how the program can best be delivered to families within these settings. We will also assess whether program results, such as change in child weight, differ between the two settings and, if so, why.

B. What is experimental/new in this study?

Other research studies have found that programs like JOIN for ME can help children achieve healthier weights, but this research was mostly conducted in university or medical offices. This study is unique because JOIN for ME will be delivered in a community setting, primary care or public housing, by community health workers.

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

You and your child will participate in the JOIN for ME program, a 10-month family-based pediatric weight management program. You and your child will attend 24 group sessions. The visits will be weekly for 4 months, every other week for 2 months, and then monthly for 4 months. The sessions will either take place in person, via Zoom (virtually), or a combination of in-person and Zoom, depending on what is safest for participants and our staff based on the COVID-19 pandemic.

Some families will start the program immediately. Other families will wait four months before starting the program. This will allow us to determine how well the program works because we will be able to compare families who have started the program with families who have not started it yet. In either case, the JOIN for ME program will be completed in 10 months. However, the total length of study participation for participants in the delayed start condition will be 14 months due to the 4-month delayed start.

The research team will not personally choose who is in what group; participants will be assigned to each group based on a set of study rules related to how participants are recruited for this study. For example, families enrolled on certain days of the week will be assigned to the immediate start group, while those enrolled on other days of the week will be assigned to the delayed start group. To ensure fair assignment to groups, the researchers who are reviewing this consent form with you are not told these rules.

Since this is a research study, you and your child will complete questionnaires at baseline (before the study begins), after completion of the weekly sessions (the four-month mark), and post-intervention (after 10 months). The questionnaires will ask about your child's health, health behaviors, and your families' access to food and economic resources. Each assessment visit will take approximately 90 minutes to complete.

The visits will be held in person at a location in your community, virtually via Zoom, or a combination of the two. Our team follows the most current CDC, state, and hospital guidelines for in person contact. If the visit is conducted virtually, we will ask you to provide height and weight measurements for you and your child using a scale and height measurement tool provided in advance by the study team. If the visits are a combination of

in person and virtual procedures, height and weight will be taken in person by study staff and all other procedures will be conducted virtually. If the assessment visit is done in-person, we will also measure waist circumference for you and your child (the distance around your waist).

You will be compensated with a $40 gift card for completion of each visit.

D. What could go wrong?

The risks associated with participation in the study are minimal. It may be uncomfortable for some children to fill out questionnaires about their weight or talk about progress toward their weight goals. There is also minor risk of minor physical strains and sprains associated with increasing physical activity in children who have not previously been involved with physical activity. It may also be uncomfortable for parents to complete questionnaires related to their child's weight and health or to their families' access to food and economic resources. In addition, if you are in the delayed start group, it may be hard to wait to receive this program.

E. What are the benefits?

There are three potential benefits related to participation in this study. First, your child will be provided with a treatment for weight control. In addition, your child may learn more about eating and physical activity habits. However, it is possible that you and your child may not benefit in any way from this study. Nevertheless, your participation may provide information that can help researchers improve future programs designed to help children eat healthier and be more active.

F. Other things I should know about this research?

We will collect your child's weight in private before the start of each session and at each assessment visit. Children will be assigned calorie goals while in the program and will be asked to track what they eat throughout the 10-month intervention. They will also be asked to track their physical activity. They will track this information on a paper log provided by the research team. Alternatively, your child can choose to track this information via an app on an electronic device, but the study does not promote or provide technical support for the use of specific apps.

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

If your child does not want to participate in this study, we are happy to make a referral to a nutritionist in your area. You may choose this option at any time.

● 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**

The purpose of this study is to test JOIN for ME, a family-based pediatric weight control program, in two community settings, primary care and public housing. This study hopes to help families within these settings access the program more easily. You are being asked to participate because your family: 1) lives in Central Falls or Woonsocket and 2) either receives housing assistance or meets federal guidelines for a low-income household; 3) or because your child is a patient at the Providence Community Health Center.

In addition, you and your child are being asked to participate because your child is between the ages of 6-12 and you are interested in helping them improve their eating and activity habits. JOIN for ME is designed to help children improve their eating and physical habits, and to achieve healthier weights.

In past research studies, programs like JOIN for ME have been shown to help children achieve a healthier weight, but these studies were mostly conducted in university and medical offices. In this study, JOIN for ME will be delivered in two community settings, primary care and public housing. The purpose of the study is to figure out how the program can best be delivered to families within these settings. We will also assess whether program results, such as change in child weight, differ between the two settings and, if so, why.

This study is funded by the Centers for Disease Control and Prevention (CDC). We expect to enroll 128 parent-child pairs into this study over the course of 2 years.

2. **Explanation of Procedures:**

<u>What does participate in the JOIN for ME program involve?</u>

If you agree that your child can take part in this study, you and your child will participate in the JOIN for ME program, a 10-month family-based pediatric weight management program. You and your child will attend 24 group sessions. The sessions will be weekly for 4 months, every other week for 2 months, and then monthly for 4 months. The sessions will either take place in person, via Zoom (virtually), or a combination of both in-person and Zoom, depending on what is safest for participants and our staff based on the COVID-19 pandemic. Our team follows the most current CDC, state, and hospital guidelines for in person contact. In person meetings will be held at either a community organization in Woonsocket or Central Falls, or at the Providence Community Health Center.

The sessions will be conducted by a member of our research team, in Spanish and/or English. Approximately 6-8 other parent-child pairs from your community would also participate in the group sessions. Each session will be 60 minutes long and contain a combination of instruction, demonstrations, and activities designed to help your child improve their eating and physical activity habits. Prior to the start of each session, the group leader will conduct a private weigh in with your child, either in person or by Zoom. Weigh-ins will be done by Zoom if the group session is virtual. Our team follows the most current CDC, state, and hospital guidelines for in person contact.

Children will be assigned calorie goals while in the program and will be asked to track what they eat throughout the 10-month intervention. They will also be asked to track their physical activity. They will track this information on a paper log provided by the research team. Alternatively, your child can choose to track this information via an app on an electronic device, but the study does not promote or provide technical support for the use of specific apps.

At the end of each group session, we will ask you to complete a brief survey that asks how useful you found the content, and whether you used a Food Bank resource since the last session. You will be compensated with a $5 gift card to a local store (e.g. Wal-Mart) for completion of this survey. Since there are 24 group sessions, there are 24 surveys. If you complete them all, you will receive up to $120 in gift cards. The researchers will keep track of how many surveys you complete and then deliver the gift cards to you, without direct face-to-face interaction, every 8 weeks.

Some group sessions will be selected at random (completely by chance, like the flip of a coin) to be audio recorded via Zoom. These recordings will allow the research team to review a sample of treatment sessions and ensure the program is being delivered in a consistent manner. Due to a limitation in the Zoom software, both audio and video will be recorded during the call. However, upon download, the video files will be permanently deleted and only the audio files will be saved. The audio files will be stored on the secure Lifespan server and only accessible by study staff. They will be destroyed two years after completion of the study.

What additional resources will I have access to while in the program?

You and your child will have access to a website that will help you locate safe physical activity and low-cost food options in your community.

We will also help you access videos on nutrition from the RI Food Bank website. These videos are available to the public and we encourage you to watch them while you are a participant in the program because they focus on skills that support healthy eating, such as cooking on a budget.

Each parent-child pair will receive a tablet with internet access to use in the program. This tablet is Lifespan property and it must be returned to research staff at the end of the study. To participate in this study, you will be required to sign a form indicating you received a device,

that you agree to the rules for using it, and that it will be returned to researchers upon completion of the program.

When would my child and I start the JOIN for ME program?

Because this is a research study, we want to see if the results for children who are in the program are different for the results of children who are not in the program. Every parent-child pair who is eligible for the program will have the chance to participate in it. However, some families will start the program immediately, whereas others will be asked to wait four months ("delayed treatment"). In either case, the JOIN for ME program will be completed in 10 months. However, the total length of study participation for participants in the delayed start condition is 14 months due to the 4-month delayed start.

The research team will not personally choose who is in what group; participants will be assigned to each group based on a set of study rules related to how participants are recruited for this study. For example, families enrolled on certain days of the week will be assigned to the immediate start group, while those enrolled on other days of the week will be assigned to the delayed start group. To ensure fair assignment to groups, the researchers who are telephone screening and reviewing consent forms with participants are not told these rules.

If you are assigned to the delayed treatment group, we encourage you to watch the monthly nutrition videos on the Food Bank website as the content of these videos focus on building skills that may help you reach your goals when you start the JOIN for ME program. We also encourage participants who are actively participating in the JOIN for ME program to watch these videos throughout their participation.

How do I know if my child and I are eligible to participate?

If you decide to have your child join the research study, we will ask you and your child to complete a 90-minute baseline assessment to see if your child is eligible to participate. We will collect your child's age, height, and weight to determine if they meet criteria for having overweight / obesity (Body Mass Index (BMI) $\geq$ 85th percentile for age and sex). We will also ask you and your child to complete questionnaires about your child's health. The assessment will take place by Zoom or in person at a location within your community. We follow the most current CDC, state, and hospital guidelines for in person contact.

If the screening tests show that your child meets all study requirements, then the researcher will be able to enroll your child in the study. If the screening tests show that your child does not meet all the study requirements and cannot be in the research study, the research investigator will discuss other options with you. You will receive a $40 gift card to a local store (e.g. Wal-Mart) for your completion of the baseline assessment visit, regardless if you and your child are eligible to participate or not.

If you are enrolled in the study, we will also notify your child's pediatrician/health care provider of your child's participation in the JOIN for ME program. If your child does not have a

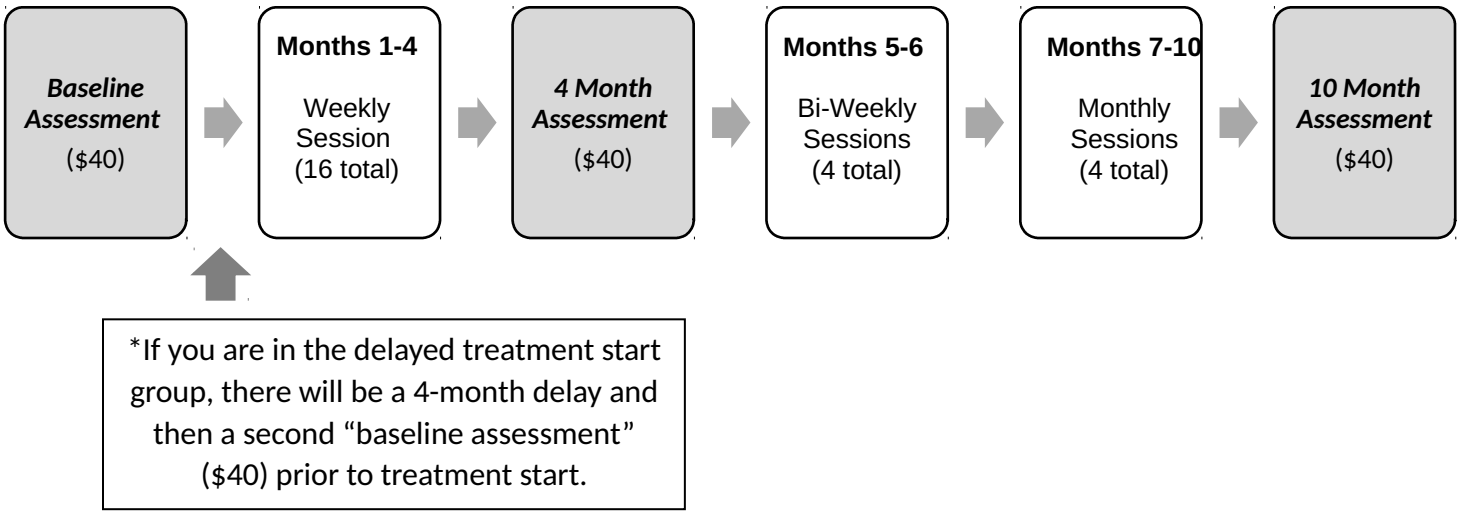
pediatrician, we will provide you with a referral. Upon completion of the study, you will have the option to send your child's pediatrician/health care provider a form that will provide them an update on your child's participation in the JOIN for ME program.

Will there be other assessments in addition to the baseline assessment?

If you and your child are enrolled in the study, you will complete 2-3 additional assessments during your participation in the study. Each assessment will take approximately 90 minutes. The visits will be held either in person (at location in your community) or virtually. We follow the most current CDC, state, and hospital guidelines for in person contact. We will collect your child's weight and ask them to complete a questionnaire. We will ask you to complete a set of questionnaires. These questionnaires are described in a later section of this form. The child portion of the assessment will take no longer than 30 minutes.

You will be compensated with a $40 gift card to a local store (e.g. Wal-Mart) for each assessment visit completed. If you are in the immediate start group, you will complete two assessments, at the 4-month mark and at the end of the program, and receive up to $80 in gift cards. If you are in the delayed treatment group, you will complete 3 assessments (a "second baseline visit' right before the program starts, at the 4-month mark, and at the end of the program) and can receive up to $120 in gift cards.

Figure 1: Study timeline – Group sessions and assessment visits



What will my child and I be asked about during the assessments?

We will measure height and weight for you and your child at each assessment visit. If the assessment visit is done in-person, we will also measure waist circumference for you and your child (the distance around your waist). Your child will be asked to complete a single questionnaire that asks how they think their physical size has affected their day to day activities.

We will ask you to complete a set of questionnaires related to your child's health, health behaviors, and your family's access to food and economic resources. Unless otherwise noted, the following questionnaires are given at each assessment visit, including the baseline visit:

1. Demographics. At the baseline assessment only, you will be asked some basic information about your family, such as age, gender, ethnicity and level of education.

2. Access to Technology: At the baseline assessment only, we will ask you to complete a questionnaire that asks about your access to technology and internet.

3. Feedback on the screening process for the study: At the baseline assessment only, we will ask you to complete a short interview with a research staff member to hear your feedback on the process of contacting us about the study and completing the telephone screen.

4. Health-related quality of life: We will ask you to complete a questionnaire about how you think your child's physical size has impacted their day to day activities.

5. Weight-related behaviors. We will ask you to complete questions related to weight-related behaviors in children such as diet and sleep.

6. Changes in Health: We will ask you if whether you have joined any other weight loss or physical activity programs. We will also ask about any changes in you and your child's physical and mental health.

7. Access to Resources: We will ask you to complete questionnaires about your family's access to social and economic resources such as housing, food, and insurance. We will also ask whether COVID-19 has affected your family's access to these resources.

8. Treatment Satisfaction: At the end of the study, we will ask you to complete a questionnaire about your overall satisfaction with the JOIN for ME program.

Your child's identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Results of the study will be available upon written request to the researcher in charge of the study, Dr. Elissa Jelalian, Ph.D., once all 128 participants have completed the study protocol. The results will contain a summary of how well the program worked and how well it was received by families. The results will be a summary based on the group of individuals who participated in the study; the results will not identify specific participants or their results.

What is the total amount of compensation I will receive for participation in the study?

If you complete the survey at the end of each treatment session, you will receive up to $120 in gift cards ($5 per survey x 24 surveys).

You will also be compensated for each assessment visit you and your child complete. If you complete the baseline visit, you will receive a $40 gift card. If you are in the immediate start group and complete the two follow-up assessments (at 4-month and at the end of the program), you will receive $80 in gift cards. If you are in the delayed start group and complete the three follow-up assessments (before the program starts, at the 4-month and at the end of the program), you will receive $120 in gift cards.

Thus, parents in the immediate start can receive up to $240 and parents in the delayed start can receive up to $280 in gift cards. The $40 difference is due to the additional assessment completed by the delayed start group. No additional compensation is provided to the child.

Figure 2. Amount of Compensation for Completing Study Procedures

	Immediate Start Group	**Delayed Start Group**
Study Procedure		
End of Group Session Survey ($5 a survey x 24 sessions)	$120	$120
Baseline Assessment Visit	$40	$40
2nd Baseline Assessment Visit	N/A	$40
4-Month Assessment Visit	$40	$40
10-Month Assessment Visit	$40	$40
Total Amount of Compensation (if all End of Group Session Surveys and all assessment visits are completed)	$240	$280

Text Messaging:

Text messaging is part of this research study. We will not send text messages to your child, but we will send you text messages. 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.

In this study, research staff will text you to schedule appointments, send appointment reminders, and check in if you miss an appointment. No sensitive information, such as information about your child's health, will be included in the text messages. Likewise, our

responses should not include sensitive information. If you have sensitive information to share with the study, please call a study staff member. Contact information will be provided to you upon study enrollment.

However, 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. 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 the 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. In addition, please note that message and data rates may apply and these costs would not be paid for by Lifespan or the study.

Costs for participating in this study

Some of the services your child will receive are being performed only because your child is participating in this research study. These 'research only' services include participation in the behavioral weight control intervention, JOIN for ME. These services will be paid for by the study and will not be billed to you/your child or your health insurance company.

However, as described above, text messaging is a part of this study. Depending on the service plan for your mobile phone, text message and data rates may apply and these costs would not be paid for by Lifespan or the study.

Contact Information:

If at any point during this study, you or your child experiences any discomfort or has any concerns about being part of the study, please contact the researcher in charge of the study, Elissa Jelalian, Ph.D. at 793-9716.

3. **Discomforts and Risks**

The risks associated with participation in the study are minimal. I

If you are in the delayed start group, it may be hard to wait to receive this program.

In addition, it may be uncomfortable for some children to talk about their weight and adherence to weight goals, or to answer questions about these topics during the assessment visits. They may decline answering any questions they feel are uncomfortable. They are free to stop participating at any time during the study.

There is also minor risk of minor physical strains and sprains associated with increasing physical activity in children who have not previously been involved with physical activity. To minimize potential for injury, please follow all study instructions carefully and notify the study staff and your child's pediatrician of any changes in your child's health.

As a parent, you will be asked to complete questionnaires. These questionnaires are commonly used in research and clinical practice. However, it may be uncomfortable to answer questionnaires related to your child's weight, or to your family's access to social and economic resources. You may decline answering questions if you are uncomfortable. All information will be kept confidential.

There may be risks associated with study participation that unknown at this time and that could not be predicated in advance. If any risk information changes during the course of your participation in the study, the investigator and/or her designee will inform you as soon as possible.

4. **Benefits**

There are several potential benefits related to participation in this study. First, your child will be provided with a treatment for weight control. In addition, your child may learn more about eating and physical activity habits. However, it is possible that you and your child may not benefit in any way from this study. Nevertheless, your participation may provide information that can help researchers improve future programs designed to help children eat healthier and be more active.

5. **Alternative Therapies**

If your child does not want to participate in this study, we are happy to make a referral to a nutritionist in your area. You may choose this option at any time.

6. **Refusal/Withdrawal**

It is up to you whether you want your child to be in the study. You are not required to enroll your child or have them participate. If you decide you want your child to participate, you can always change your mind and remove them from the study at any time. If you decide not to have your child be in the study, or if you remove them later, your child will still be able to get the health care services they would normally get. If you enroll your child but later the researcher or your child's doctor feels being in the study is no longer good for your child, they may choose to

take your child out of the study before it is over. If new information becomes available that might change your mind about whether you want your child to stay in the study the researcher will share this information with you as soon as possible. In addition, the study sponsor, the Centers for Disease Control and Prevention (CDC) may choose to end the study at any time, for reasons unrelated to health care.

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

- The researcher believes that it is not in your child's best interest to stay in the study.
- Your child become ineligible to participate.
- Your child's condition changes and your child needs treatment that is not allowed while your child is taking part in the study.
- Your child does not follow instructions from the researchers.
- The study is suspended or canceled.

Follow-up after Withdrawal of Consent

If you remove your child from the study, it would still be useful for us to know how your child does over the next 10 months. We would appreciate if you would permit us to get follow-up information about your child's health from their doctor and/or their medical record.

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

_____ I do not give my permission for you to continue to collect information about my child if I withdraw my child from the study.

_____ _____

Signature of study parent or guardian Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to have your child quit the study, please tell the head researcher, Elissa Jelalian, PhD at 793-9716.

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 your child is injured by a medical treatment or procedure they would have received even if they 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 your child does

experience a research injury, Lifespan or the study doctor can arrange medical treatment for them. Such treatment will be paid for as described below.

If you have insurance and your child has a research injury that is not covered by the study, it is possible that some or all the cost of treating your child 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 or your child 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 Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246.

9. **Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.**

Your child's 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 child's information to someone outside of Lifespan) their health information for research purposes. If you sign this form you agree to have your child be in this research study and you permit the use and disclosure of your child's 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 your child 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, your child will stop taking part in the study and no new information will be collected about them. However, if you cancel your permission, it will not apply to actions already taken or information already collected about your child 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 released 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, the Centers for Disease Control and Prevention (CDC)
- Other researchers we are working with (collaborators) as part of this project; these researchers are from Brown University and the University of North Carolina-Chapel Hill

- Doctors, nurses, laboratories and others who provide services to your child 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 child's 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 child's 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 child's information.

You have the right to refuse to sign this form and not allow your child to 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, your child will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to have your child quit the study after signing this form (as described in Section 6), no new information will be collected about your child unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you removed your child from the study to complete analysis and reports of this research.

You will not be allowed to see or copy the information about your child's participation described in this form if the research study is open. You may see and copy the information when the study is completed.

Clinical Trials: 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 your child. At most, the Website will include a summary of the results. You can search this Website at any time and locate this trial. Search by either the title of the study (Packaging and Disseminating the JOIN for ME Program) and/or the name of the Principal Investigator (Elissa Jelalian) to find the trial.

Contact for Future Studies:
Your child's participation in **any research** is completely voluntary and you/ your child should feel no pressure to have them participate in another research study.

Please INITIAL and CHECK 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 my child participating in other research projects studying eating, physical activity, and weight in children. I give permission for my contact information to be given to other researchers working with the study investigator.

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

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT MY CHILD 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. I understand that I have the option to sign a paper consent or electronically sign the consent form via a website called REDCap, and that if I chose to sign electronically, the research staff will show me how to do so. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

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

The Researcher is required to provide a copy of this consent to you.

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

Print name of Child participant

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.**