Research Consent Form and Authorization Form
Parent Pedi Consent

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

Name of Study Participant: _____

Principal Investigator: Deidre Donaldson, Ph.D.

Title of Research Study:
Project HOME: **H**ome-Based Treatment **O**ptions and **M**echanisms for **E**ating Disorders

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 participate and 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 participate and to have your child participate in the research.

Due to COVID-19, you might be reading this form in your home, on a research website called "REDCap", or in-person at our research center. If you decide to participate and 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 participate and 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?

We are interested in understanding how effective and feasible two types of in-home therapies are: Family-Based Treatment (FBT, a multi-phase standard approach to parental refeeding of a child with an eating disorder) and integrative family therapy (IFT, which combines family and individual therapy, and focuses more on thoughts and feeling) in adolescents with restrictive-type eating disorders. In particular, we want to examine outcomes of these two types of treatment when given in the home setting.

B. What is experimental/new in this study?

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Home-based FBT has not yet been tested against home-based IFT for adolescent eating disorders. There also is not a lot of information about alternative treatments to FBT. This study has the potential to help inform scientific and clinical understanding of providing treatment in the home, and whether home-based options improve accessibility to treatment and treatment outcomes.

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

You will be asked to complete assessments at 4 time points: pre-treatment, week 6 of treatment, week 12 of treatment, and week 24 of treatment (or 24 weeks after the pre-treatment assessment). These assessments will include a battery of questionnaires for both you and your child. Your child will also be asked to complete an interview on their eating and general psychological functioning, as well as give height/weight measurements. A small subset of families will also be asked to complete an additional post-treatment interview.

D. What could go wrong?

Risks in the study are no greater than risks already associated with eating disorders; however, your child will be receiving treatment for their eating disorder. We anticipate that the study procedures will pose non-significant risks. The in-home treatment they receive will either be FBT or IFT. There is a chance that your child will not respond well to treatment. You and your therapist will determine whether treatment should be continued, or whether an alternative might be better suited for your family.

E. What are the benefits?

We hope the information from this study will help us learn better how eating disorder treatments and adaptations work when given in the home setting.

F. Other things I should know about this research?

Your child can still receive treatment regardless of study participation. Your participation in this study (or decision not to) will not affect your child's treatment at Gateway Healthcare or The Providence Center.

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

Participation is 100% voluntary, and you are not required to complete any study activities that you do not want to. You can still receive in-home or outpatient treatment through Gateway Healthcare, The Providence Center, or another agency of your choosing. Alternate eating disorder treatment options include FBT through private practice, outpatient therapy, cognitive-behavioral therapy, or any of the programs/services offered by the Hasbro Hospital eating disorder clinic.

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• 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 and your child are being asked to take part in a research project because you are receiving home-based treatment from Gateway Healthcare or The Providence Center for an adolescent eating disorder. Currently, there is no standard of care for in-home eating disorder treatment. We want to better understand the feasibility and effectiveness of two home-based treatment options, Family Based Treatment (FBT) and Integrative Family Therapy (IFT). FBT is widely used in outpatient settings but has not yet been standardized for home-based services. FBT includes a multi-phase approach, each phase giving increasing control to the recovering adolescent. The first phase is marked by parental control over the adolescent's eating during the refeeding process. The second phase is indicated by a stable weight and a transition of eating control back to the adolescent. The third phase includes maintaining a healthy weight, establishing a healthy relationship between the adolescent and parents, and preparing the adolescent for full control over their eating. IFT is widely used in home-based settings but has not yet been tested against other in-home treatments. IFT consists of a home-based integrated approach to family therapy, including education about eating disorders, combined with supportive family therapy, individual therapy with the adolescent, and elements of cognitive-behavioral therapy (e.g., improving thoughts and behaviors related to eating/weight) and dialectical behavior therapy (e.g., working on tolerating stress). This study is a clinical trial, which means that families will be randomized to treatment rather than choosing which one they want. We hope our findings provide clarity around the use of these treatments in a novel setting and expand treatment options outside of office- and hospital-based services.

We expect to enroll 70 families into this study. The study is sponsored by the National Institute of Mental Health.

2. Explanation of Procedures

If you agree to participate and to have your child take part in this study, you and your child will be asked to …….

1. Complete a **pre-treatment assessment visit**, either in your home or online/virtually via REDCap and Zoom. At this visit, you and your child will be asked to complete questionnaires on their eating behaviors, thoughts around weight and shape, psychosocial behavior, and attitudes towards treatment. These questionnaires will be available on REDCap, a secure and confidential website used for research, should

you choose to complete them electronically. We will take your child's height and weight if completing this visit in-person or obtain their height/weight data from your therapist. A calibrated scale and portable stadiometer will be provided by the research team for these measurements. Your child will also be asked to complete an interview with the researcher on their eating and general mood/behavior. This interview will either be conducted in person, or via Zoom. We would like to audio-record the interview portion of the visit for training purposes; however, you can decline recording.

During this study, Dr. Donaldson and her research team will collect information about you and your child for the purposes of this research. This includes your name, your address, phone number, e-mail address, gender, and your child's age and date of birth. We will also measure and record height and weight of your child, and collect information about his or her psychological functioning, such as eating and psychosocial behavior. This information will be used to determine study eligibility, and to understand more about their eating behaviors and attitudes towards treatment. The pre-treatment assessment will take about an hour to complete.

2. **Engage in either home-based Family Based Treatment (FBT) or home-based Integrative Family Therapy (IFT)**. If you agree to participate in this study, your family will be randomized to receive either FBT or IFT. The type of treatment you receive will be decided by 50/50 chance. You will be assigned a therapist based on which treatment you are randomized to. Both types of treatment will take about 10 – 24 weeks to complete, with therapy sessions occurring 1 – 2 times a week. It is possible that family members, including siblings, will be asked by your therapist to attend therapy sessions. You, your adolescent, and your therapist will decide which family members should attend and when. One parent/guardian must engage in treatment with your adolescent; however, no other family members are required to. It is up to your family whether or not you want other family members to be engaged in treatment and/or the study. No other family members will be approached by the research team until you, your child, and your therapist have decided it is okay for them to participate in treatment and/or the study. Should your family and therapist decide to engage a sibling in treatment and/or the study, you (or the sibling's legal parent/guardian) will need to sign an additional parent consent for that child.

3. You will then be asked to attend **follow-up visits at 6-, 12-, and 24-weeks** after the pre-treatment assessment. Each follow-up visit should take 30 – 60 minutes. These follow-up visits will occur either in your home or online/virtually. At these visits, you and your child will be asked to complete the same questionnaires as the first visit, and your child will be asked to complete the interview on their eating and general

mood/behavior again. Your child's height and weight will be taken if in-person or obtained from their therapist.

4. A few families will be asked to complete a **post-treatment interview** with the research team to give their feedback on treatment and the study in general. This post-treatment interview will either be conducted in your home or virtually via Zoom. Families will be randomly selected. The interview will last about an hour and will involve all family members who were involved in treatment and want to participate in the interview.

   We think you and your child will be in the study for a little over 24 weeks, starting from the time of the phone screen, until you finish the 24-week follow-up. It is possible that you will continue treatment beyond the 24-week follow-up; however, no study procedures will continue after that. If you complete treatment before the 24-week follow-up, you will still be asked to complete the visit.

   The baseline visit will take about 1 hour, and all follow up visits will take about 30 – 60 minutes. We would like to your permission to stay in touch with you after the 24 weeks of follow-up, in case we have additional studies that would allow us to assess you beyond the timeline of the current study. At the present time there is no plan to administer any assessments beyond the 24-week follow-up; we just want to contact you to make sure we have accurate contact information and keep you posted on the study's progress.

I AGREE TO BE CONTACTED AFTER I COMPLETE THE 24-WEEK FOLLOW-UP

☐ YES ☐ NO

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

Your child will be given $50 for the pre-treatment visit, $50 for the 6-week follow-up, $75 for the 12-week follow-up, and $100 for the 24-week follow-up visit. If selected for the post-treatment interview, your family will be given $75 for completing it. You, the parent/guardian, will be responsible for determining how this $75 is distributed to the family members present.

You and 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.

If you agree to be in the study and agree to have your child participate, we would like your therapist to audio- or video-record the treatment sessions to help us with our research. These tapes will be reviewed only by two members of the research team to see how therapy is being given. Therapists will need to transport recording devices to and from treatment and supervision sessions, which may present a small risk of loss of confidentiality in the case that the recording devices are lost or stolen; however, recordings will be uploaded within 24-hours of the session and promptly erased from the recording devices. Recordings will be stored on a secure, password-protected folder through Microsoft OneDrive. Only members of the research team and therapists consented into this study will have access to this folder. Recordings will be permanently erased about 5 years after the end of the study. All information on the tapes will be kept strictly confidential to the extent allowed by law. All family members who attend audio- or video-recorded sessions will be asked to sign a consent form. Any family members who do not wish to be recorded will not be present during recorded therapy sessions. You can still participate in the study if you decide you don't want therapy sessions to be audio- or video-recorded. If you agree to audio- or video-recording now, you can change your mind at any time. Just tell your therapist that you do not want the session to be recorded. You can also ask your therapist to halt or terminate recording at any time, or to immediately erase recordings of sessions in which you perceive the content to be unfavorable.

I GIVE THE RESEARCHERS PERMISSION TO AUDIO-RECORD THE THERAPY SESSIONS WITH MY FAMILY

☐ YES ☐ NO

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

I GIVE THE RESEARCHERS PERMISSION TO VIDEO-RECORD THE THERAPY SESSIONS WITH MY FAMILY

☐ YES ☐ NO

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

I GIVE THE RESEARCHERS PERMISSION TO AUDIO-RECORD THE PRE-TREATMENT INTERVIEW WITH MY CHILD

☐ YES ☐ NO

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

☐ YES ☐ NO

_____ _____ _____

Signature of parent/guardian* Date and Time when signed

Costs for participating in this study

Services your child will receive during this research study (i.e., treatment) are considered "routine clinical services" that your child would have received even if they were not in the research study, with the exception of the assessment visits and possible post-treatment interview. If selected for a post-treatment interview, the costs of the interview session will be covered by the research study and will not be billed to your insurance. Assessment visits will also not be billed to your insurance. Examples of routine clinical care *not* covered by this study include monitoring by a physician to ensure that your child is medically stable for outpatient treatment and any appropriate medication or alternative treatments are being prescribed. The home-based FBT or IFT treatment sessions also fall under this category. The specific therapy your family receives will be determined by research randomization; however, both therapies are billed to insurance as standard in-home care. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. Insurance costs for in-home treatment do not differ between study participants and non-study patients. If you do not have health insurance, you will be responsible for those costs.

Contact Information:

For questions about the study or concerns, please contact the researcher (Deidre Donaldson, Ph.D.) at (401) 724-8400 or DDonaldson2@lifespan.org.

3. Discomforts and Risks

There are risks, discomforts, and inconveniences associated with any research study. Possible risks to participating in this study may include feelings of discomfort sharing thoughts and feeling. Similarly, some of the questions from the questionnaires may be upsetting to you or your child. Risks associated with treatment include discomfort sharing thoughts and feelings during family sessions, difficulty adhering to treatment, and emotional or physical discomfort for your child during the refeeding/weight restoration process. Families assigned to receive FBT might experience additional stress, as it takes a collaborative approach and additional involvement in treatment might be required for family members. There is a chance that your child will not respond well to the treatment you are assigned to. You and your therapist will determine whether treatment should be continued, or whether an alternative might be better suited for your family.

Due to the nature of eating disorders and common comorbid disorders, there is a small chance that your child could be hospitalized during the course of the study. If your child enters full or partial-hospitalization while enrolled in the study, all study activities will cease until your family is back under the care of your therapist. If you do not return to your therapist for home-based treatment upon discharge, you will be removed from the study.

Other possible risks for participating in the study include the possibility that the information would be released outside of the research setting, which could be upsetting for you; however, strong measures are taken to ensure that all information remains confidential. Specifically, all participants will be identified only by code number which will appear on documents used for evaluation for statistical analyses. All recordings will be uploaded in a timely manner and erased from the recording devices. These recordings will be saved on a secure, password-protected server and will contain no identifying information. All records and information will be kept locked in the clinical research facilities. Recordings will be permanently erased about 5 years after the end of the study. Publications of this research will not identify individual participants.

If any mental health related problem is detected, such as suicidality, intent to harm others, or drug abuse, or if previously unreported abuse is discovered, you and/or your child will be further evaluated and steps will be taken to ensure their safety (e.g., creating a safety plan, providing referrals). Reports of physical or sexual abuse will be reported to state authorities as mandated by law.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

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4. Benefits

Although you will not receive any direct benefits from participating in this research study beyond the treatment your child is receiving at Gateway or The Providence Center, we hope the information learned from this study will benefit future patients, researchers, interventionists, and health care planners by providing valuable information about ways to improve outcomes and access to care in adolescents with eating disorders.

5. Alternative Therapies

This study examines two therapeutic approaches: family-based treatment and integrative family therapy. Your family will be randomized to receive one of the two; however, you or your therapist might decide a different treatment approach is better suited for your family's needs. In that case, you will not be asked to complete the treatment you are assigned to and will not be asked to continue study procedures. You are not required to complete the treatment you are assigned to; however, you and your child will be unenrolled from the study should you decide to explore other treatment options. Other treatment options include office-based FBT, outpatient therapy, the partial-hospitalization eating disorder program at Hasbro Hospital, or in-home services through Gateway Healthcare or The Providence Center not associated with this research study. The research team and/or your therapist can provide more information on alternative treatments, should you choose to explore other options.

6. Refusal/Withdrawal

It is up to you whether you want to participate and 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 you and your child to participate, you can always change your mind and leave 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 therapist/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.

7. Medical Treatment/Payment in Case of Injury

A research related injury/illness is unlikely to occur, as your family will receive one of the two most common & well-validated treatments for adolescent eating disorders. Your child will receive ongoing medical monitoring in addition to therapy and must be medically cleared for outpatient services at all times during the study. If your child is found to be medically unstable or temporarily transferred to a higher level of care, all study procedures will be halted until they are medically cleared again.

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 the Lifespan Director of Research Protection 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: National Institutes of Health;
- 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.

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.

National Institutes of Health - 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 your child. The researchers may not disclose information that may identify your child, even under a court order or subpoena, unless you give your permission to release this information about your child. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about your child 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 child's 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 child's medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented your child to in this informed consent document. The Certificate does not stop you or your child from voluntarily releasing information about themselves or your child's involvement in this research. If others

obtain your written consent to receive research information about your child, then the researchers may not use the Certificate to withhold that information.

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 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 my child participating in other research projects studying eating behaviors and/or psychosocial factors contributing to weight status. 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 my child participating in other research projects. **Do not** give my contact information to the staff of any other research studies.

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SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO PARTICIPATE AND TO HAVE MY CHILD TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I agree to participate and to give my permission for my child to participate in this research study and for the described uses and releases of information. *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
Signature of researcher or designate	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.**