INFORMED CONSENT FORM

An Interactive Education Program to Reduce High Risk Behavior in Adolescents Phase I (1R42HD110333-01)

NCT05607784

08/26/2022

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: Christopher Houck, PhD; Wendy Hadley, PhD

Title of Research Study:

Interactive Emotion Regulation Skills Training to Improve Adolescent Health (Phase 1: Adolescent Advisory Board)

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 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 study is for you to work together with other people your age to provide opinions and feedback on prototypes of a web-based program. The program is designed to teach adolescents information and skills about emotions and sexual health.

B. What is experimental/new in this study

Your feedback will help researchers improve a new health program that promotes emotional and sexual health for students like you.

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

If you choose to participate in this study, we will ask you to be part of an Adolescent Advisory Board with a small group of other adolescents your age. The group will meet up to 6 times over 9 months. Each meeting will last about 90 minutes and be led by a trained research staff member. Topics you may discuss include how people can manage their emotions and how to teach emotion management and sexual health skills in fun, engaging ways. You will be able to see examples of the digital health program and provide feedback to researchers about whether you liked it and how it could be improved. All discussions will be audio-recorded and extensive notes will be taken. To protect your privacy, you can refuse to share your name, or provide a fake name, during group discussions.

D. What could go wrong?

The risks in this study are considered minimal. It may make you uncomfortable discussing topics about emotional and sexual health. You can always refuse to answer any such questions that make you uncomfortable. Participation in this study is completely voluntary and you can stop at any time.

E. What are the benefits?

You will not benefit directly. We hope your participation in this study could help improve the quality of this health program in the future.

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?

As this study does not provide treatment, if you choose not to participate in this project, there is no alternative to this study available.

- **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 this research study because you are a 7th grade student between the ages of 12-14 at a participating school.

The purpose of this study is for you to provide your opinions on prototypes of a web-based program designed to teach adolescents information and skills about managing emotions and about the connection between emotions and the way we act, especially when it comes to sexual health and relationships. We will ask you to provide feedback on the content of a new, web-based program and provide us with ideas about how to make the program more appealing to middle school students.

We expect to enroll about 16 adolescents for the preliminary Adolescent Advisory Boards. This study is funded by the National Institutes of Health (NIH).

2. Explanation of Procedures:

As part of this study, you will be asked to be a part of an Adolescent Advisory Board with other adolescents your age. This group will meet up to 6 times over about 9 months. You will meet for about 90 minutes each time and receive $50 per meeting for your feedback. The groups will be small, about 8 members, and will be separated by gender.

During these Board meetings, a facilitator will lead group discussions with you and other adolescents. You will be asked to provide feedback about paper and digital prototypes of our web-based program. The facilitator will ask both general and specific questions about how people best learn about managing emotions and sexual health. You will be asked to give feedback on the researchers' ideas for the program, including whether you understand the content, if you find it engaging, and how it might be best communicated to other people your age. The facilitator may also ask about how your personal experiences or identities impact how you interact with the content, structure, and procedures of the new prevention program.

Your feedback during the discussions may be used in decision-making as it relates to product or program development.

The groups' discussions will be recorded and transcribed for analysis**.** Notes will also be taken during the discussions. To protect your privacy, you do not have to reveal your name or where you live and can provide a fake name during the group if preferred. We may transcribe the recording, and if we do, we will remove names from this transcript. The recording will be securely stored and locked. Only study staff will have access to it. We will destroy the digital audio files at the end of the study. Focus group responses will not be shared with your parent(s)

or guardian(s). Responses may be aggregated and shared with schools, and in this case individual responses will be deidentified.

All testing sessions will take place at the Bradley/Hasbro Research Center, a Public Library, or at a school. However, if municipal, state or federal guidelines prohibit our research staff from interacting with your family face-to-face, in person meetings will be replaced with videochat meetings. Videochat meetings may also replace in person meetings if it is too hard to schedule focus group meetings at a shared physical location. If you require portable wireless or a Zoom-compliant device, we will work with you to ensure you have the necessary equipment to complete study procedures. When sessions are scheduled, we will notify you of the date, time, and location so that we can minimize schedule conflicts.

Your 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.

Text Messaging:
Text messaging is part of this research study. This may include you receiving text messages from research staff and/or you 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.

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 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

This research provides education but does not involve treatment. There are no costs to participate in this study.

Contact Information:

The principal investigator at Rhode Island Hospital (Lifespan) for this is Christopher Houck, Ph.D. His contact information is (401) 444-8539. His mailing address is Bradley/Hasbro Children's Research Center, One Hoppin Street, Suite 204, Providence, RI 02903.

3. Discomforts and Risks

The risks in this study are considered minimal, as participation only requires that you provide your opinions as part of an advisory board. Some adolescents may feel uncomfortable with topics about emotional and sexual health. However, these topics will be discussed sensitively and in a developmentally appropriate way, and you may refuse to answer any question that makes you uncomfortable. We will remind participants not to share comments or information from the advisory board outside the group. However, we cannot guarantee that what you share with the group will remain confidential.

4. Benefits

Although you may not directly benefit from your participation, the information we gain may be used to improve the effectiveness of emotion regulation and risk prevention interventions for other adolescents in the future.

5. Alternative Therapies

This is not a treatment study. If you choose not to participate in this study, information about emotion regulation and sexual health can be provided to you if requested.

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 National Institutes of Health may choose to end the study at any time, for reasons unrelated to health care.

7. Medical Treatment/Payment in Case of Injury

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

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 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 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;
- Klein Buendel, our business partner designing the health program.

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

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.

Signature Page for Child 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	

****

Consent for Audio-Recording: Signing below indicates agreement of the study volunteer or authorized representative to consent to audio-taping.

Signature of parent	Date	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.**

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: Christopher Houck, PhD; Wendy Hadley, PhD

Title of Research Study:

Interactive Emotion Regulation Skills Training to Improve Adolescent Health (Phase 1: Health and Education Professionals Panel)

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 study is to get feedback from you and other health and education professionals on the content of a web-based health program for middle school students. The program aims to convey information about managing emotions and sexual health.

B. What is experimental/new in this study

Your feedback will help researchers better design and develop a new health program that promotes emotional and sexual health for middle school students.

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

If you choose to participate in this study, we will ask you to be part of a Health and Education Professionals Panel with a small group of other health professionals. The group will meet up to 3 times over about 9 months. Each meeting will be led by a trained research staff member and will last about 90 minutes. In the meeting, you will be asked about your opinions on appropriate emotional and sexual health content for middle school students and how to teach health skills in fun, engaging ways. You will also be shown examples of the digital health program and will be asked to provide feedback to researchers. All discussions will be audio-recorded and extensive notes will be taken. To protect your privacy, you can refuse to share your name, or provide a fake name, during group discussions.

D. What could go wrong?

The risks in this study are considered minimal. It may make you uncomfortable discussing topics about emotional and sexual health. Participation in this study is completely voluntary and you can stop at any time.

E. What are the benefits?

You will not benefit directly. We hope your participation in this study could help improve the quality of this health program in the future.

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?

As this study does not provide treatment, if you choose not to participate in this project, there is no alternative to this study available.

- **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 health or education professional with knowledge about adolescent health.

The purpose of this project is for you to provide your opinions on prototypes of a web-based program designed to teach adolescents information and skills about the connection between emotions and sexual health-related behaviors. We will ask you to provide feedback on the content of a new, web-based program and provide us with ideas about how to make the program more appealing to middle school students.

We expect to enroll about 8 health professionals for the preliminary Health and Education Professionals Panel. This study is funded by the National Institutes of Health (NIH).

2. Explanation of Procedures:

As part of this study, you will be asked to be a part of a Health and Education Professionals Panel. This group will consist of about 8 members and will meet up to 3 times over 9 months. You will meet for about 90 minutes each time and receive $100 per meeting for your feedback.

During these Panel meetings, you will participate in moderated group discussions with other health and education professionals. You may be asked both general and specific questions about how adolescents manage emotions and how to present sexual health information in engaging, age-appropriate ways. You will be asked to give feedback on the researchers' ideas for the program, including whether you think the content is appropriate for middle schoolers and how to best communicate the emotional and sexual health information in the program. You will be asked to provide feedback about paper and digital prototypes of our web-based program. You may also be asked about your personal identities or experiences learning sexual health content, and about the program's accessibility for students from different experiences or backgrounds.

Your feedback during the discussions may be used in decision-making as it relates to product or program development.

The Panel's discussions will be recorded, transcribed, and coded for analysis. Notes will also be taken during the discussions. To protect your privacy, you do not have to reveal your name or where you live and can provide a fake name during the group if preferred. Names will be removed from the transcript of the recording. The recording will be securely stored and locked.

Only study staff will have access to it. We will destroy the digital audio files at the end of the study. Focus group responses may be aggregated and shared with schools, and in this case individual responses will be deidentified.

All Panel sessions will take place at the Bradley/Hasbro Research Center, a Public Library, or at a school. However, if municipal, state or federal guidelines prohibit our research staff from interacting with you, in person meetings will be replaced with videochat or phone meetings. Videochat meetings may also replace in person meetings if it is too hard to schedule in person meetings in the same shared physical location. If you require portable wireless or a Zoom-compliant device, we will work with you to ensure you have the necessary equipment to complete study procedures. When sessions are scheduled, we will notify you of the date, time, and location so that we can minimize schedule conflicts.

Text Messaging:
We will ask for your email address and phone number to communicate with you about the research study. We will ask if you would like us to communicate with you through text. If you approve study-related text communication, you will be responsible for any charges associated with receiving or sending text messages.

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.

All phone and text communication will be conducted on Lifespan-approved cell phones. Lifespan-approved cellphones are password-protected and handled by research staff only. All contacts saved to Lifespan cell phones are saved only on the individual device and will contain only your first name and the phone number(s) you give us.

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 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.
Your 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.

Costs for participating in this study
This research provides education but does not involve treatment. There are no costs to participate in this study.

Contact Information:
The principal investigator at Rhode Island Hospital (Lifespan) for this is Christopher Houck, Ph.D. His contact information is (401) 444-8539. His mailing address is Bradley/Hasbro Children's Research Center, One Hoppin Street, Suite 204, Providence, RI 02903.

3. Discomforts and Risks
The risks in this study are considered minimal, as participation only requires that you provide your opinions as part of an advisory board. Some people may feel uncomfortable with topics about emotional and sexual health. However, these topics will be discussed sensitively, and you may refuse to answer any question that makes you uncomfortable. We will remind participants not to share comments or information from the panel outside the group. However, we cannot guarantee that what you share with the group will remain confidential.

4. Benefits
Although you may not directly benefit from your participation, the information we gain may be used to improve the effectiveness of emotion regulation and risk prevention interventions for adolescents in the future.

5. Alternative Therapies

This is not a treatment study. If you choose not to participate in this study, information about emotion regulation and sexual health can be provided to you if requested.

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 National Institutes of Health may choose to end the study at any time, for reasons unrelated to health care.

7. Medical Treatment/Payment in Case of Injury

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

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 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 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;
- Klein Buendel, our business partner designing the health program.

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

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.

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

****

Consent for Audio-Recording: Signing below indicates agreement of the study volunteer or authorized representative to consent to audio-taping.

_____ _____ _____
Signature of Study Participant Date 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.