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PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 15-17

CONTACT INFORMATION

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Study Title: ABCs – Attention Bias in Cancer Survivors

You have the option to take part in a research study. The goal of this form is to give you information to decide whether to participate in the research. Feel free to take notes, write questions or highlight any part of this form. You can take as much time as you need to read the form. Please ask questions at any time. The word “we” used in this form means the research team and their staff.

If you are 17 years old or younger, your parent or legally authorized representative (LAR) would also need to give their permission and sign this form for you to join the study. An LAR is an individual (other than a parent) who is a legal decision maker for you.

If you are a parent or LAR, the goal of this form is to give you the information that you need to decide whether to allow your child to participate in the research.

Study Overview

You are being asked to take part in this study because you are a teen or young adult cancer survivor.

The goal of any research study is to answer questions and learn new things. The goals of this study are to:

- Learn more about attention bias, anxiety, mood, and quality of life in cancer survivors.

- Test an online program designed to reduce anxiety and stress, and improve mood in cancer survivors.

If you choose to take part in this study, your participation will take 4-8 weeks. You will be asked to complete an online brain training program, respond to text messages, and complete online surveys.

Overall, this study is minimal risk. One risk of this study are that some questions may be personal, sensitive, or stressful, or make you feel uncomfortable – but you can refuse to answer any questions you choose. There is also a risk that your confidentiality or privacy could be breached. This would mean that someone other the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

As part of this study, we may communicate via text message about your health. Texting is our recommended and preferred communication method. It's the best way to stay up-to-date about study activities. This may include protected health information (PHI) like your name and health condition. There is a risk that info you send or receive by text could be stolen. This is because texts are not encrypted, cannot be taken back, and can be intercepted on public Wi-Fi networks. You can reduce these risks by keeping your phone updated, saving this phone number as a contact, and avoiding public Wi-Fi networks. You don't have to send any info over text that you aren't comfortable with sending.

Participating in the study may help you feel better and improve your quality of life by reducing anxiety and increasing positive emotions. It may also feel satisfying to know you're contributing to knowledge that could benefit other teen and young adult cancer survivors.

You do not have to take part in this study if you do not want to. If you choose not to participate or choose to stop your participation at any time for any reason, it will not affect your care at Seattle Children's or any other hospital. If you choose not to participate or decide to stop participation, you will not lose benefits you are receiving outside of the study.

Please see below for additional information about the study.

How many people will take part in the study?

We think that up to 80 people will take part in this research study at Seattle Children's.

What will you be asked to do?

Our study has two main parts: one is doing an online brain training program and the other is completing online surveys.

In this study, you would be randomly assigned (like flipping a coin) to one of the two groups. You will have an equal chance of being given each treatment. Neither you nor the study doctor will choose what treatment you get.

- In either group, you will complete a 10-minute attention game on a computer or phone twice a week for 4 weeks, and take a few minutes to respond to brief daily texts about your mood.
    - The attention games and texts in one group are part of an anxiety brain training program that is being tested and could reduce anxiety.
    - The attention games and texts for the other group would not be designed to change anxiety but are essential to test if our program works. This is called a "control group".
- Your child/you won't be told which group you are in until after completing the study. If your child/you are assigned to the control group, you can use our anxiety brain training program after completing the study!

As for the online surveys, each one takes 20-30 minutes. You would complete 1 survey at the beginning of the study and 1 survey after completing the program. We would also ask you to complete a 10-minute computer reaction time test at the beginning of the study, before you start the 4-week program.

If you are assigned to use the anxiety brain training program, you could also participate in an optional 30-45-minute interview and survey to provide feedback on the program. This interview would be video and audio recorded. The recordings are for research purposes. You would not be named on the recording. We would label the recording with your study ID. We would store the recordings on secure, password and firewall-protected computers here at Seattle Children's. The recordings would be used to help us answer the research study questions. Only the research team would have access to the recordings, and they would be destroyed after study analysis is complete.

Identifiers will be removed from the identifiable private information collected (for example, your responses to the study surveys) and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the parent/LAR.

Future Research

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, the research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our

goal is to make more research possible. We plan to keep your data indefinitely, however, we will not keep any identifiers that could tie the data back to you.

Your data may be shared with other researchers. However, the decision to share your data is controlled. To get your data, future researchers must seek approval from the research team. Future researchers must agree not to try and identify you.

We would not be able to give you the results from research that is done using your data.

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

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

You will not receive any direct benefit from sharing your data. However, sharing your data may contribute to research that could help others in the future.

The use of your data may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if they have already been shared. If you do not want your data used for other projects, you should not participate in this study.

What about confidentiality and privacy?

If you join the study, we will do our best to make sure that information about you is kept confidential.

We will store all of your research records in a secure computer database only accessible to the study team, with extra security to protect identifiable information (like your name, MRN, or contact information) and prevent sharing outside of the study team.

These are some reasons that we may need to share the information you give us with others:

- If it is required by law, including suspected child abuse, elder abuse, intent to harm yourself or others and communicable diseases.
- If the author of the research plan (the research sponsor) or any persons or companies working for or with the research sponsor needs the information.
- Study records are sometimes reviewed to make sure studies are done correctly and safely. These reviews can be done by the research team, hospital staff, government staff or others with the responsibility to make sure studies are done correctly and safely for participants. If a review of this study is done, study records that include your information may be viewed. The reviewers will treat your information as confidential. The reviewers will not use your information for immigration reasons or to put you at legal risk.
- If results of this research are published, we will not use information that identifies you without your permission.

Permission for Use or Sharing of Specific Information

Individuals who are within the age ranges below will complete this section (age 13 or older). For minors under the age range(s) listed, the parent/LAR will complete this section. Mark your permission with your initials below if you agree to the creation, use, or sharing of the following information that will have the same privacy protections that are described above:

_____ Behavioral or mental health/illness (age 13 and older)
Initials

This study will also involve a type of information about you called Protected Health Information (PHI). PHI refers to information that is about your health and that could identify you. Researchers (such as doctors and their staff) taking part in this study here and at other centers will only create, use, and share your PHI for this research study with your permission.

PHI may include:

- Past or future medical records;
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history;
- Medical or laboratory records related to this study; or
- Information specific to you like your name, address, birthday or identifying numbers like your social security number.

PHI may be created, used, or shared to:

- Study the results of this research;
- Check if this study was done correctly and safely;
- Complete and publish the results of the study described in this form;
- Comply with non-research obligations (such as notifying others if we think you or someone else could be harmed); or
- Facilitate your health care.

PHI may be created by, used by, or shared with:

- The author of the research plan (the research sponsor) or any persons or companies working for or with the research sponsor;
- Review boards, data and safety monitoring boards, and others responsible for overseeing the conduct of research. Study records are sometimes reviewed to make sure studies are done correctly and safely. These reviews can be done by the research team, hospital staff, government staff or others with the responsibility to make sure studies are done correctly and safely for participants. If a review of this study is done, study records that include your PHI may be viewed. The reviewers will treat your PHI as confidential. The reviewers will not use your PHI for immigration reasons or to put you at legal risk;
- Other people or organizations involved with your health care;
- Public health authorities to whom we are required by law to report PHI for the prevention or control of disease, injury, or disability.

You have the right to look at or copy your PHI that may be created, used, or shared. However, for certain types of research studies, some of your PHI may not be available to you during the study. This does not affect your right to see what is in your medical records.

Your permission for the creation, use, or sharing of your PHI will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new PHI will be created or collected about you. However, PHI that has already been created or collected may still be used and shared with others. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your PHI will be stored as part of this study, it may be used in the future for other research. We will not ask for your permission prior to this future research.

We will follow privacy laws when creating, using, or sharing your PHI, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your PHI as part of this study may share it with others without your permission if doing so is permitted by law.

Permission for Creation, Use, or Sharing of PHI for Optional Procedure(s)

Participation in any research study is voluntary. If you agree to participate in this research study, there are some part(s) of the study you will be asked to do. There are other part(s) of this study that you can choose not to do and still participate in the rest of the study. These are called Optional Procedure(s). For this study, the Optional Procedure(s) are:

- Interview and survey after using program

If you decide to do these part(s) of the study, we need your additional permission to create, use, and share your PHI for these part(s) of the study. The same confidentiality rules and privacy rights discussed above apply here.

_____ I allow the creation, use, and sharing of my PHI for the Optional Procedure(s).

Initials

Remember that you can always change your mind about doing any part of the study. Your choice will not impact your medical care or benefits outside of the study. You can cancel your permission for these Optional Procedure(s) by telling us in writing. If you do this, you will still be in the overall research study unless you tell us to cancel your overall permission too.

Will it cost money to be in the study?

If you take part in this study, there will be no cost to you and no cost to your insurance company for the research procedures.

What if you are injured?

If you think you have been harmed from this study, please contact the Principal Researcher. Contact information is listed at the start of this form.

Will you be paid for this study?

To thank you for taking part in the study we will give you up to $100 dollars in Amazon gift cards; $50 for each of the two surveys. If you participate in the optional study interview, you will earn an additional $50 in Amazon gift cards. We will provide information on how to use and access the gift cards.

If your child/you complete all 8 computer-based attention tasks, they/you will be entered in a raffle to win a new pair of Apple AirPods Pro. There will be one winner in each of the two groups, randomly selected at the end of the study.

If you take part in this study, we will ask you to provide your name and mailing address so we can pay you. Information about you, including your name and mailing address, may be shared with an external vendor to facilitate payment.

The payments you receive for being in this study may be taxable. Seattle Children's is required to report to the IRS study payments totaling $600 or more made to anyone in any one year.

You can be in this study even if you do not give us your information, but you would not receive payment.

If you join the study, can you stop or be removed?

If you join the study, you can decide to stop **at any time for any reason.** If you don't complete your surveys, you may be removed from the study.

Who do you contact if you have problems, questions or want more information?

If you have general study questions, please contact a member of the research team (listed at the start of this form). You can also contact the research team if you have concerns or complaints related to the study.

This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is responsible for ensuring research is done in a way that meets legal and ethical standards, so that participants are protected. You can contact the IRB at (206) 987-7804 or at irb@seattlechildrens.org if you have questions about your rights as a participant in the study, if you have concerns or complaints about the study, or if you would like to contact someone outside the research team.

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

Study Participant Questions:

1. The best phone number to reach me at is: (_____) _____- _____
2. The best email address to reach me at is: _____
3. If assigned to use the anxiety brain training program, would you like to participate in the optional interview and survey about your experience with the ABCs program?

   _____ Yes, Please

   _____No, Thank You

4. Would you like to see a summary of study findings at the end of the study?

   _____ Yes, Please *(provide email info if Yes to either)*

   _____No, Thank You

5. May we contact you in the future to talk about additional opportunities to participate in this type of research? *(this only relates to future studies conducted by Dr. Nancy Lau and her research team, not other studies at Seattle Children's*)

   _____ Yes, Please *(provide email and phone email if Yes)*

_____No, Thank You

(Answers to be provided electronically below)

What does your signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You agree to take part in the research study.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- If the person reading this form is a parent/LAR, you agree to have your child take part in this research study.
- You permit the creation, use, and sharing of your and/or your child's health information for the purposes of this research study as described in the "**What about confidentiality and privacy?"** section above.
- *If using electronic documentation: You agree this form and any later updates to this form and notices provided in connection with this study may be provided to you in an electronic version. You agree that you are able to electronically receive, review, and save a printed or electronic copy of this form containing your signature. We and you agree to electronically sign this form. We and you agree that our actions to electronically sign this form document your informed consent. We and you agree that our electronic signatures have the same meaning and effect as handwritten signatures. You understand that you can request a paper form if you would prefer to use a paper consent form.*

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____

Printed Name of Child Participant

Child Assent

☐ *Check here to provide assent for the ABCs Study Team to communicate with you through text message. Enter phone number: ###*

_____
Signature of Child Participant Providing Assent for Self

_____ _____
Date *Time*

Parent/Legally Authorized Representative (LAR) Permission for Child: The individual signing this form must be a legal decision maker for the child participating in the study.

☐ *Check here to provide consent for the ABCs Study Team to communicate with **you** through text message, and permission for the ABCs study team to communicate with **your child** through text message. Enter your phone number: ###*

_____
Printed Name of Parent/LAR Providing Permission for Child

_____
Signature of Parent/LAR Providing Permission for Child

_____ _____
Date *Time*

Adult Participant Consent

☐ *Check here to provide consent for the ABCs Study Team to communicate with you through text message. Enter phone number: ###*

_____
Printed Name of Adult Participant Providing Consent for Self

_____
Signature of Adult Participant Providing Consent for Self

_____ _____
Date *Time*

For study team use only:

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient.
- ❑ Second parent is deceased, unknown, incompetent or not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child
- ❑ Permission has been obtained from an LAR who is not a parent

For study team use only (fill out for any enrolled minors and any enrolled adult participants incapable of providing consent):

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted, or a waiver of assent was approved by the IRB.

Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/LAR's questions and will answer any future questions to the best of my ability. I will tell the parent/LAR and/or participant of any changes in the procedures or in the possible harms/possible benefits of the study that may affect the participant's health or their willingness to stay in the study.

_____
Printed Name of Researcher Obtaining Parent/LAR Permission or Consent

_____
Signature of Researcher Obtaining Parent/LAR Permission or Consent

_____ _____
Date *Time*

Interpreter Information

The interpreter name is only recorded here if 1) the consent/assent or parent/LAR permission is documented with a corresponding translated form; or 2) the study meets the criteria for short form use and the consent/assent/parent/LAR permission is documented with a Short Form Consent in the appropriate language for those taking part. See the Investigator Manual (HRP-103, Appendix A-10) for more information and HRP-001 Definitions for more information.

_____
Printed Name of Interpreter during initial presentation of study *Date*

_____
Printed Name of Interpreter when translated form is presented (if applicable) *Date*

Original form to:
Research Team File

Copies to:
Participant