Boston Children's Hospital

RESEARCH CONSENT FORM

This section only to be edited by IRB office.

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Improving Neurodevelopmental Outcomes in Children with Congenital Heart Disease: An Intervention Study

Principal Investigator: Jane Newburger, MD

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Participation in this research study is voluntary. You are free to say yes or no and your decision will not impact the care you receive at Boston Children's Hospital. You can withdraw from the study at any time. A description of the study and its risks, potential benefits and other important information are in this consent form. Please read this consent form carefully and take your time making a decision. The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

How are individuals selected for this research study?

You are being asked to participate in this research study because your child was born with a congenital heart disease and received care in the Cardiology Clinic at Boston Children's Hospital.

Why is this research study being conducted?

Children with a history of congenital heart disease sometimes experience cognitive and behavioral difficulties. One of the more frequent difficulties involves what are called executive functions. These refer to processes that guide, direct, and manage one's activities (e.g., the ability to initiate and control behavior, to select relevant task goals, to shift strategies flexibly as needed). Problems in these processes can make it harder for a child to learn in school or to maintain good relationships with others. In this research study we want to learn whether children with CHD can improve their executive functioning by using a computer program called the Cogmed Working Memory Program. Although this Program has helped other groups of children with executive function problems (e.g., children born prematurely or children with conditions such as Attention Deficit Hyperactivity Disorder), it is not known whether it can help children with CHD.

Who is conducting this research study, and where is it being conducted?

The study will be conducted only at Boston Children's Hospital by a team led by Dr. Jane Newburger, a pediatric cardiologist and Drs. David Bellinger and Johanna Calderon, research pediatric neuropsychologists. It is funded by a grant from the Department of Defense. Dr. Jane Newburger is the sponsor of this Non-Significant Risk investigational device study.

It is possible that Dr. Newburger is your child's cardiologist. Although she is an investigator in this study, your child's clinical welfare is her foremost concern. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this study. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate or not to allow your child to participate, your care at Boston Children's Hospital and/or with your health care provider will not be affected in any way at all.

How many people will participate in this research study?

Approximately 100 7 to 12 year old children and their families will take part in this study.

What do I have to do if I am in this research study?

The duration of your participation in this research study will be 4 to 5 months.

If you decide to join the research study, you will come to the Boston Children's Hospital three times in the next few months. At today's visit, your child will receive a neurodevelopmental assessment consisting of a global cognitive test, the WISC-V and a battery of cognition and executive function tasks from the National Institutes of Health (NIH) Toolbox Assessment of Neurological and Behavioral Function. These are game-like tasks and most are administered on a computer or tablet. This assessment will give us an idea of how your child is doing before receiving the Cogmed intervention and so make it easier to determine if the intervention helps. Also, you will be asked to complete 3 questionnaires that ask about your child's executive function behaviors. These are the Behavior Rating Inventory of Executive Function (BRIEF), the Connors' ADHD DSM-IV Scale (Connors), and the Social Responsiveness Scale. It will take about 45 minutes to complete these. In addition, we will ask you to give the BRIEF and the Connors' questionnaires to your child's teacher to complete. The total time of the visit will be about 2.5 hours.

Your child will then be randomly assigned to either the home-based intervention group, which will receive the Cogmed Working Memory Program, or to a control group. Randomization means that you are put into a group by chance. It is like flipping a coin. Your child will have an equal chance of being placed in the groups. Neither you nor the research investigators can choose what group you will be in. You and your child will know which group you were assigned to, though. Children in the control group will not receive the Cogmed intervention right away but will continue to receive the usual care for children with CHD, which involves surveillance for neurodevelopmental problems, and neurodevelopmental screening and counseling, as needed. When the research study is finished, you will be given the opportunity to have your child receive the same 5-week Cogmed Working Memory Training Program that children assigned to the intervention group received.

If your child is assigned to the intervention group, you will start the Cogmed intervention in the week following the first neurodevelopmental evaluation. A member of the study team will show you and your child how the Cogmed Working Memory Program works and will answer any questions you have on the first visit. Your child will be provided with an iPad on which the Program will be pre-loaded and a secured ID will be created for your child's personal use throughout the intervention. It is child-friendly and web-based. It presents different

game-like tasks for your child to play. The difficulty of the tasks changes to match your child's working memory capacity, so they become more difficult as your child's working memory improves. Your child will complete 25 sessions, each of which lasts 35-40 minutes. These will be spread out over 5 weeks, so that he or she will do one session a day for 5 days per week. The iPad will record your child's responses, and we will be able to securely retrieve these data remotely. We do ask that you supervise your child over this period so help make sure that he or she completes the sessions.

For children in the Cogmed group, Visit 2 (Post-Intervention) will be completed 1 to 2 weeks after completing the Program. For children in the control group, Visit 2 will be completed 6 to 7 weeks after Visit 1. At Visit 2, children in both groups will again be administered the NIH Toolbox tasks, and parents and teachers will complete the same questionnaires they completed at Visit 1. Visit 3 (Follow-Up) will be the final phase of the study. It will take place 4 to 5 months after Visit 1. The same assessments completed at Visit 2 will be done at Visit 3. The purpose of Visit 3 is to see if the beneficial effects of the intervention at Visit 2 (should there be any) are still present after several weeks. Visits 2 and 3 will each take 2 hours.

Study Visit Timeline	Visit 1 Baseline	Visit 2 Post-intervention (6-7 weeks after baseline)	Visit 3 Follow-up (4-5 months after baseline)
Consent /Assent	X		
WISC-V	X		
NIH Toolbox	X	X	X
Behavior Rating Inventory of Executive Function	X	X	X
Connors' ADHD/DSM-IV Scale	X	X	X
Social Responsiveness Scale-2	X	X	X

What are the risks of this research study? What could go wrong?

Some procedures used in this research may present risks that are not well-known or understood. Therefore, there may be unforeseeable risks associated with participating in this research.

There are no invasive procedures involved in participating. Children in the intervention group might find it tiring to complete 5 35-40 minutes sessions per week. You may be asked questions in an interview or on a questionnaire that make you uncomfortable or cause you to remember situations that were upsetting to you. You may become frustrated if you are asked questions that you do not know how to answer. You may not be able to answer all the questions, and you do not need to answer any questions that you do not wish to answer. If

you or your child becomes upset at any time, you can stop the interview or stop completing an evaluation or a questionnaire. If you wish to speak to someone about how you are feeling, we can help you arrange this.

What are the benefits of this research?

If the Cogmed Working Memory Training Program is effective, children might benefit from improved executive function abilities. All children who enroll in the study will have the opportunity to do the Program, though there will be a delay of a few months before the children randomized to the control group will be able to do so.

If any of the information collected suggests that your child might benefit from additional neuropsychological evaluation, we will tell you and discuss options for following-up.

Are there costs associated with this research? Will I receive any payments?

There are no costs to you to participate in this study.

Families in both the intervention and control groups will need to return the iPad to us after the Cogmed Working Memory Training Program is completed.

Regardless of whether group your child is assigned to, the intervention or standard of care group, you will be paid $100 after Visit 2 is completed, and your child will be given a $25 gift card. If you and your child complete Visit 3, you will receive an additional $100 and your child another $25 gift card. This will add up to a total payment of $200 to you and a total of $50 in gift cards to your child. Parking costs will also be paid for you for all visits. In addition, if you travel from far away for the study visits, transportation costs will be covered with airfare/train for the study participant and one parent or legal guardian, vouchers for taxi transportation, parking and/or mileage reimbursement. If needed, hotel costs for 1 night will also be covered.

This research study will use a service called ClinCard® by the company Greenphire, www.greenphire.com, to manage all payments associated with your participation in study visits, your time and travel related to participation in the study. ClinCard/Greenphire will provide documentation for filing your taxes (1099 form), to the hospital, and may ask for your name and social security number using a secure website to meet that federal requirement. Boston Children's Hospital or the sponsor has contracted with ClinCard/Greenphire to provide this service but Boston Children's Hospital and ClinCard/Greenphire are separate entities and have no other relationship. ClinCard/Greenphire is solely responsible for the security of any information you provide to them.

You will be issued a ClinCard, which is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. When a study visit is completed, funds will be loaded onto your card. The funds will be available within 1 day and can be used as you wish.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by

signing this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research, tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed in this consent form.

If I do not want to take part in this research, what are the other choices?

If you do not join this research study, your doctor can discuss other healthcare choices with you. It would be possible for your child to participate in the Cogmed Working Memory Training Program, or some other executive function training, without participating in a research study such as this one.

Are there other things I should know about?

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

Why would I be taken off the study early?

The research investigator may take you out of this study at any time. This would happen if:

- The research is stopped.
- You are not able to attend the research visits required.
- If your child is not able to complete the Cogmed training sessions as needed.
- The research investigator feels it is in your child's best interest to be taken out of this research.

If this happens, the research investigator will tell you.

Other information that may help you:

Boston Children's Hospital has developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

Who may see, use or share your health information?

A copy of this consent form will be placed in your medical record. The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary

of the results. You can search this web site at any time. The US Food and Drug Administration has the right to inspect this study at any time.

Contact for Future Studies: Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

Please check and initial one of the options below regarding future contact about other research that we do.

_____ ☐ Yes, I may be contacted about participating in other research projects studying congenital heart disease or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children's Hospital.

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

What should you know about HIPAA and confidentiality?

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research;
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;

- And/or your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling. Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigator:	Phone: 617-554-424	▪ General questions about the research

Jane Newburger	Pager:	▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Research Contact: David C. Bellinger	Phone: 617-355-6565 Pager:	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Institutional Review Board	Phone: 617-355-7052	▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/research contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

Child Assent

■ If child/adolescent's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Research Investigator /or Associate's Statement & Signature

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

■ _____ _____

Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness

Or

☐ The individual is not English or Spanish speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness