

Danya International, Inc.
Consent for Teachers to Participate in Evaluation
Brain Power! Challenge

You have been asked to participate in an activity by Henry Wong, Ph.D., Director of Research, Public Health Research Group at Danya International, Inc. (Danya), a research firm in Silver Spring, Maryland. Your participation is entirely voluntary. Please read the information below before deciding whether or not to participate. Please contact us at the phone number below if you have any questions.

PURPOSE OF THE EVALUATION

Researchers at Danya, with funding from the National Institute on Drug Abuse (NIDA), are developing science education materials for students in grades 6-8 on the brain and the effects of drugs on the brain. The curriculum is titled *Brain Power! Challenge* and includes a CD-ROM, written materials for students, a parent newsletter, and a teacher's guide for each module. We are asking you to use the materials in your classroom and provide us with feedback on the program.

PROCEDURES

Classrooms will be randomly assigned to either of the two following groups: Experimental Classrooms, which will use the *Brain Power! Challenge* curriculum materials in their classrooms, or Control Classrooms, which will not use any *Brain Power! Challenge* curriculum materials during the evaluation period. All *Brain Power! Challenge* curriculum and evaluation materials will be provided, as well as a comprehensive training to answer all questions and address concerns before the evaluation begins. Participation will last approximately 1 hour, 1 day a week, for 8 weeks.

ANTICIPATED BENEFITS

Based on our experience with similar projects, we believe that participation in this evaluation will help children learn about the brain and how drugs affect the brain. Your participation will also help us teach children about safety and health information regarding drug use. Some people may not receive any of these benefits from participating.

POTENTIAL RISKS

There are very few risks to participating in this evaluation. A remote possibility does exist that some children may become more curious about drugs and alcohol after participating in this evaluation. A remote possibility also exists that other participants in the group may share your personal information with someone outside of the project. The known and suspected risks are listed on the consent form. Danya does not have any program to provide compensation if you experience injury or other bad effects, which are not the fault of the investigators. In the unlikely event of physical or other injury resulting from this study, emergency medical treatment will be provided; however, financial compensation will not be available.

PAYMENT FOR PARTICIPATION

We will provide you with an incentive in appreciation for your time and effort.

PRIVACY AND CONFIDENTIALITY

Personal information about you will not be shared with anyone outside of this project. Danya will take every precaution to prevent the possibility of personal information collected in the research process being seen by someone outside of the evaluation, but Danya does not take any responsibility if any personal information about you is shared with anyone outside of this project. All data will be kept in locked files, and citation of this material will include a number or other nonpersonal identifier. Despite such precautionary measures, a small risk exists that information provided during the research will only be disclosed to others, if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

PARTICIPATION AND WITHDRAWAL

Your participation in this evaluation is completely voluntary. If at any time you decide to stop participation, there will be no penalty. You do not have to answer any questions that you do not want to answer or participate in any activities that you do not want to be involved in. The investigator reserves the right to terminate a subject’s participation at any time.

IDENTIFICATION OF INVESTIGATORS

If you have any questions about this project, you may call Henry Wong, Ph.D., Evaluation Director, at (240) 645-1760.

If you have any questions about your rights as a research participant, please call Dr. Dina Stolman, Chair of the Danya Institutional Review Board, at (410) 560-0482.

Please read and show that you understand what you have read by signing your consent below.

I have read this form and understand all of the information about my involvement in the program and agree to participate in this focus group.

Signature

Date

Signature of Representative (if necessary)

Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Signature of Investigator

Date

Danya International, Inc.
Parent's Permission for Students to Participate in Evaluation
Brain Power! Challenge

Your child has been asked to participate in an evaluation conducted by Henry Wong, Ph.D., Director of Research, Public Health Research Group at Danya International, Inc. (Danya), a research firm in Silver Spring, Maryland. Your child's participation is entirely voluntary. Please read the information below before deciding whether or not to agree to your child's participation. Please contact us at the phone number below if you have any questions.

PURPOSE OF THE EVALUTION

Researchers at Danya, with funding from the National Institute on Drug Abuse (NIDA), are developing science education materials for students in grades 6-8 on the brain and the effects of drugs on the brain. The curriculum is titled *Brain Power! Challenge* and includes a CD-ROM, written materials for students, a parent newsletter, and a teacher's guide for each module.

PROCEDURES

Your child will be randomly assigned to either of the two following groups: Experimental Classrooms, which will use the *Brain Power!* curriculum materials in their classrooms, or Control Classrooms, which will not use any *Brain Power!* curriculum materials during the evaluation period. Students will be interviewed or fill out questionnaires reporting on knowledge and attitudes toward drug use. Students will also be discussing these topics in the evaluation if they are assigned to the experimental group. Participation will last approximately 1 hour, 1 day a week, for 8 weeks.

ANTICIPATED BENEFITS

Based on our experience with similar projects, we believe participation in this evaluation will help your child learn about the brain and how drugs affect the brain. Your child's participation will also help us teach safety and health information to other children. Some people may not receive any of these benefits from participating.

POTENTIAL RISKS

There are few risks to children participating in this evaluation. The goal of this project is to introduce students to the brain, how the brain works, helpful medicines and harmful drugs, and how drugs affect the brain; to introduce them to science and research; to increase children's interest in science and research; and to instill positive attitudes toward science, scientists, and research. The program consists of science education materials and has not been designed as a prevention curriculum. The materials present facts about the damaging effects of drugs of abuse on the brain and body and offer students the knowledge and understanding of these dangerous substances. This gives the students the power to make the informed decision to stay away from drug use. However, as will all substance abuse programs, there is the possibility that some children may become more curious about drugs and alcohol after participating in this evaluation. In the unlikely event of physical or other injury resulting from the evaluation, emergency medical treatment will be provided; however, financial compensation will not be available. Danya does not have any program to provide compensation if your child experiences injury or other bad effects

that are not the fault of the investigators.

PAYMENT FOR PARTICIPATION

If you allow your child to participate, we will give him/her a small token of our appreciation for his/her time and effort.

PRIVACY AND CONFIDENTIALITY

Personal information about your child will not be shared with anyone outside of this project. Danya will take every precaution to prevent the possibility of personal information being seen by other participants in this study. Danya does not take any responsibility if personal information about your child is shared with anyone outside of this project. Please remind your children that all information in this evaluation is confidential and should not be shared with anyone outside of the group. All data will be kept in locked files, and citation of this material will include a number or other nonpersonal identifier. Despite such precautionary measures, a small risk exists that information provided during the research will only be disclosed to others if necessary to protect your child's rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity.

PARTICIPATION AND WITHDRAWAL

Your child's participation in this evaluation is completely voluntary. If at any time he/she decides to stop participation, there will be no penalty. Your child does not have to answer any questions that he/she does not want to answer or participate in any activities that he/she does not want to be involved in. The investigator reserves the right to terminate a subject's participation at any time.

IDENTIFICATION OF INVESTIGATORS

If you have any questions about this project, you may call Henry Wong, Ph.D., Evaluation Director, at (240) 645-1760.

If you have any questions about your child's rights as a research participant, please call Dr. Dina Stolman, Chair of the Danya Institutional Review Board, at (410) 560-0482.

NEXT STEP

Please sign and return one of the attached forms:

- *Consent Form* – The consent form gives permission for your child to participate in the study.
- *Refusal Form* – The refusal form will let us know that you do NOT want your child to participate.

Please read and show that you understand what you have read by signing your consent below. If you provide consent for your child to participate in this study, your child will be asked to sign his or her own assent for participation as well. You will receive a sample copy of the Assent Form your child will sign.

Consent Form

I have read this form and understand all of the information about my child's involvement in the study and give my permission for my child,
_____, **to participate in this evaluation.**

(Child's Name)

Child's Age _____ Child's Grade _____ Child's Gender _____

Signature of Parent or Guardian

Date

Signature of Representative (if necessary)

Date

If you do NOT want your child to participate in this evaluation, please fill out this form so we do not contact you again. Thank you.

Refusal Form

After reading the information about this evaluation, I do NOT give my permission for my child, _____, to participate.
(Child's Name)

Child's Age _____ Child's Grade _____ Child's Gender _____

Signature of Parent or Guardian

Date

ASSENT TO PARTICIPATE IN A RESEARCH STUDY
Agreement for Participation in an Evaluation

Title of Study: *Brain Power! Challenge*
Evaluation Director: Henry Wong, Ph.D.
Phone Number: (240) 645-1760
Co-Investigator: Greta Tessman

Researchers at a company called Danya International are making a program with information about the brain and how drugs affect the brain.

The **purpose** of this study is to help kids learn how drugs affect the brain.

The people **in charge** of this study are Henry Wong and Greta Tessman.

This study will take place in your classroom, and the information will be taught by your teacher. The study will last for about an hour over the course of 8 weeks.

During this study, this is **what will happen:** You will participate in a program taught by your teacher. Your teacher may teach about the brain and the effects of drugs, or maybe something different. At the beginning, and again at the end of the program, we will ask you some questions about science and research. You may also answer some other questions that will be asked by your teacher, such as *what do you think drugs do to the brain?*

You do not have to be in this study if you don't want to. If you don't want to, you may participate in other activities. **You may stop being in the study at any time.** If you decide to stop, no one will be mad or upset with you. You only have to answer the questions you would like to answer.

Only the people doing this study will know what you say. Your parents and teachers will not be told your answers. We won't even write down your name.

What you think about this project will help us to make this information more interesting and fun for children to learn.

If you have **any questions** about this study, you may ask the person teaching the program.

If you would like to be in this study, please sign your name on the line below.

(1) _____
Signature of Research Subject Date

(2) _____
Signature of Person Obtaining Assent Date

Danya International, Inc.
Consent for Parents
Brain Power! Challenge

You have indicated your interest in participating in an evaluation conducted by Henry Wong, Ph.D., Director of Research, Public Health Research Group, at Danya International, Inc. (Danya), a research firm in Silver Spring, Maryland. Your participation is entirely voluntary. Please read the information below before deciding whether or not to agree to your participation. Please contact us at the phone number below if you have any questions.

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PROCEDURES

Your child has been participating in the evaluation of *Brain Power! Challenge*. Parental reaction and opinion is an important part of this evaluation. You have filled out a postcard indicating your interest in participating in the evaluation. Your participation in this study will be in the form of a phone interview by one of the researchers conducting the study. You will be asked questions about your reaction to the materials and the degree to which you find the curriculum informative and appropriate. Your feedback will be helpful to ensure the materials are engaging, age appropriate, and informational to the students. The phone interview will take about 15 minutes.

ANTICIPATED BENEFITS

Based on our experience with similar projects, we believe your participation in this evaluation will help us teach children about the brain and how drugs affect the brain. Your participation will also help us teach safety and health information to other children. Some people may not receive any of these benefits from participating.

POTENTIAL RISKS

There are few risks to you from participation in this evaluation. A remote possibility exists that other participants in the group may share your personal information with someone outside of the project. The known and suspected risks are listed on the consent form. Danya does not have any program to provide compensation if you experience injury or other bad effects, which are not the fault of the investigators. In the unlikely event of physical or other injury resulting from the evaluation, emergency medical treatment will be provided; however, financial compensation will not be available.

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Please read and show that you understand what you have read by signing your consent below.

I have read this form and understand all of the information about my involvement in the program. By signing below, I agree to participate.

Signature of Parent

Date

Signature of Representative (if necessary)

Date