

Dear Parent,

We are inviting your child/children to participate in a research study (project) called *XXXX* (“you” refers to you or your child/children throughout this consent form)*.* The *xxxx* research studyis designed to xxxx (goals/objectives/benefits, etc.). Your child/children was/were selected to participate in this study because xxxx (i.e., a school wide intervention, a specific classroom intervention, etc.).

This research is being conducted by xxxx (name of investigator(s) and is funded by xxxx (sponsor).

**WHAT YOU WILL BE ASKED TO DO**

If you agree to participate in this research study here is what you can expect:

* List out procedures/steps

Add this section if filming students:

If you agree to allow your child to participate in the filming of *xxxx* we will ask your child/children to be video taped while participating in xxxx lessons, school events, or performances. We will use the videos to study how the xxxx works and to show others about the program. Your child’s/children’s name will not be in the videos.

**HOW LONG THE STUDY WILL LAST**

The study will last \*about # of days, weeks, months, etc. and involve up to \*# visits (to include how long each visit will last such as a classroom period, all day, etc.)

**THE RISKS OF PARTICIPATING, AND WHAT WE DO TO MAKE THOSE RISKS AS SMALL AS POSSIBLE**

There is a very small risk that confidential data will be compromised. We will minimize this risk by ensuring that only study staff and xxxx (list others) involved in the study have access to the study data/files. (modify as appropriate) Identifying information is removed from the data in a timely manner; that electronic data storage methods utilize encryption as well as password protection; and that hard copies of documents and videos are kept in locked, secure offices. The information that we gather will be used only for scientific or educational purposes to improve xxxx for students.

Are there any other potential participant risks? If so, describe them. If not, state that there are no risks greater than those involved in normal daily routines. If other risks are present, what are the procedures for reducing them?

**KEEPING YOUR INFORMATION CONFIDENTIAL**

Xxxx will follow all applicable federal and state laws that protect student personal and health related information (e.g., HIPAA and FERPA), including maintaining appropriate physical, electronic, and procedural safeguards. Student information is confidential and will not be shared or discussed with anyone outside of the approved study researchers and data collectors. All collected data for this project will be securely stored in lockable locations, secure computer files, or on computer servers accessible only to the approved and trained researchers and authorized staff.

How long will data be kept?

What about if a threat of violence is made (i.e., via a survey comment or a verbal statement)? Do you need a statement indicating that in such circumstances, information may be shared with others as appropriate?

Explain how participant data will be used/reported, i.e., in subsequent written reports, or journal articles, or presentations, etc.

Will all data be aggregated overall or by subgroups, so that individuals cannot be identified in subsequent reporting?

The Institutional Review Board (IRB), Southern California Brainspotting Institute, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, absolute confidentiality cannot be guaranteed.

**PAYMENT FOR BEING IN THE STUDY**

Describe the prorated amount (amount of payment per visit, per procedure, etc.) and the total amount of payment for completing the study. Include any additional payments that may be offered. You may use a table format for clarity. Payment cannot be contingent upon successful completion of the study, as this would be coercive per 21 CFR 50.20, 50.25(a)(6), and ICH Guideline 3.1.8.

You may receive up to \*$0.00 for being in the study. You will be paid per completed *\*(visit, procedure, etc.)* as follows:

|  |  |
| --- | --- |
| **Visit** **(LIST OUT EACH VISIT)** | **Compensation (amount)** |
|  | $.00 |
|  | $.00 |
|  | $.00 |
|  | $.00 |

If you choose to leave or are withdrawn from the study for any reason before finishing all \**(visits, procedures, etc.)* you will be paid for each completed *\*(visit, procedure, etc.)*. You will receive payment within \*(*number of days, weeks, etc.)* after your last study visit, or if you choose to leave or are withdrawn from the study for any reason, you will receive payment within \*(*number of days, weeks, etc.*) [**If the compensation time frames listed above are the same, combine the two statements.**]

**OR**

You will not be paid for being in this study.

**LEGAL RIGHTS**

You will not lose any of your legal rights by signing this consent form.

**ALTERNATIVES TO PARTICIPATING IN THE STUDY**

Since this study is for research only, the only other choice would be not to be in the study.

If a parent does not want his/her child to participate in something, it may be that an alternate activity might be needed; i.e., a different lesson or assignment to keep the child occupied while participating students complete some other research activity.

**BENEFITS**

There are several potential benefits to participating in the project, which we believe far outweigh the risks. Your child/children may find participating in the xxxx research study fun and interesting. Your child/children may learn valuable skills and receive helpful instructional support from the program that may improve other school-based skills. Information you provide may help your child’s/children’s school develop resources for students and teachers to continue to xxxx. Additionally, your child’s participation will potentially benefit many other students and schools across the country and around the world, by helping us learn more about xxxx.

**YOUR RIGHT TO WITHDRAW FROM THE PROJECT**

Your child’s/children’s participation in the *xxxx* research study is entirely voluntary and your decision about whether or not to allow your child to participate will involve no penalty or loss of benefits your child might otherwise receive. It will not affect your child’s grades, relationship with teachers or with the school administration. If you do decide to allow your child to participate, your child can stop participating at any time without penalty. You have the right to refuse your child’s participation in the *xxxx* research study.

**CONTACT INFORMATION**

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please contact xxxx (name and phone number/email)

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact Southern California Brainspotting Institute. Southern California Brainspotting Institute’s policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to [IRB@SocalBrainspotting.org](mailto:IRB@SocalBrainspotting.org)

Southern California Brainspotting Institute has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean Southern California Brainspotting Institute has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study. Your child will also receive assent information either as documented or verbally.

**AGREEMENT TO BE IN THE STUDY**

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

\_\_\_\_\_ I have read and understand this consent information, and I agree to participate in the xxxx research study

OR

\_\_\_\_\_ I have read this and understand this consent information, but I do not agree to participate in the xxxx research study

Print name:

Signature:

Print student name:

School:

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please sign and return in the survey envelope (modify as appropriate).

You will receive a signed copy of this consent form to keep.

We appreciate you taking the time to consider being a part of the *xxxx* project.

Printed Name of Person Explaining Consent Form:

Signature of Person Explaining Consent Form:

Signature of Investigator:

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_