Parental Permission Form

Title of Study:	Building Adaptive School-based Interventions for Caries Study (BASICS) i24-01909
Principal Investigator:	Ryan Richard Ruff, PhD, MPH Department of Epidemiology & Health Promotion 212-998-9663

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “participants” or “research participants”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us using the contact information provided above. If you decide to take part in this study, you must sign this form.

Schoolyard Smiles has partnered with researchers at New York University to explore how the provided dental services can improve health.

The people who may be able to take part in this study may not be able to give consent because they are under 18 years of age (a minor). Instead, we will ask you—their parent(s) or legal guardian—to give consent. We will also ask the minor to agree (give their assent) to take part in the study. They will be given an Assent Form to sign. Throughout the consent form, “you” always refers to the “participant” or person who takes part in the study.

2. What is the purpose of this study?

Your child is attending a school participating in a dental cavity prevention program called Schoolyard Smiles. This program provides in-school dental cavity prevention and treatment once or twice per year, including dental sealants, fluoride varnish, atraumatic restorations, and silver diamine fluoride (SDF). All care will be provided by a dentist or dental hygienist. Receipt of silver diamine fluoride may create permanent stains on any decay on your child’s teeth, which means the treatment is working. These treatments can prevent up to 80% of cavities from occurring and stop up to 50% of existing cavities from getting worse.

The Schoolyard Smiles School-Based Cavity Prevention and Treatment Program will provide different medicines for cavities, including decay-stopping silver, dental sealants, cavity sealants, and fluoride varnish. If you also participate in this research study, your child may receive different combinations of these medicines to see which combination is the most effective. The purpose of the research study is to compare the different combinations to see which is the most effective at stopping and preventing dental decay. We are trying to enroll 1200 children for this study.

3. How long will I be in the study? How many other people will be in the study?

This study will last about 2.5 years and will involve about 6 visits. About 1200 children will be in the study.

4. What will I be asked to do in the study?

This study is a randomized study. This means, like flipping a coin, your child will be assigned to one of the treatment groups and receive either SDF or dental sealants as the first treatment. About a year later, we will then look at your child's teeth and decide whether additional care is needed. If so, your child may receive the same original treatment, the other treatment that was not initially provided, or a combination of both SDF and dental sealants. Your child also may receive an electronic toothbrush as a result of their participation. There are no special requirements or criteria to be in either group. You will have a 50% chance of receiving either SDF or dental sealants in the initial treatment and a 25% chance of any of the treatments at the next treatment. Dental sealants and SDF are both medical devices that protect teeth from getting cavities

5. What are the possible risks or discomforts?

Your child will be randomized as part of this study, as described above. The risk of randomization is that participants may not treated with the device their dentist may have otherwise use, based on clinical judgement. We will minimize this risk by follow up with patients and by using additional treatments based on clinical need.

There is also a small risk that people not connected with this study will learn your child's personal information. We will minimize this risk by limiting those who have access to any identifiable information related to your child.

There have been no reported cases of major health risks or severe reactions to SDF. SDF does contain silver, however, so it should not be used for people with allergies to silver.

_____ (initials) I confirm also that my child does not have a known allergy to silver, other heavy metals, colophony (kolophonium), rosin, or fluoride.

6. What if new information becomes available?

We don't anticipate learning any new information that could be important to you. However, if we do, we will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

We don't anticipate subjects will benefit from taking part in this study since they will still receive treatment provided by the school-based caries prevention program regardless of their participation.

8. What other choices do I have if I do not participate?

You do not have to participate in this study. This study is not designed to provide treatment and will have no impact on your ongoing medical care. You may discuss alternatives to participation with your personal doctor(s).

9. Will I be paid for being in this study?

You will not be paid for being in the study. However, depending on the study group to which your child is assigned, they may receive an electronic toothbrush worth about $25.

10. Will I have to pay for anything?

You and/or your health insurance will not be billed for the costs related to the dental products used in the study nor for the tests and procedures required solely for this study.

You and/or your health insurance company may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. There are no plans for the NYU Grossman School of Medicine or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

We are asking for your permission to use and share your information with others in connection with this study. The uses of this information include conducting and overseeing the study.

Your child's data will be shared with the researchers, consisting of the health status of their teeth and their sociodemographic information. Your child's name and birthdate will be used to create a unique code to identify them in the study. When data is received by the researchers, they will not have access to the identifying information, only the unique code will be visible. This de-identified data will kept confidential by being stored on secure computers, accessible only to the researchers. To do this, we will create a unique code for your child used to track them throughout the study. The link between the code and your child's identifiable information will not be known to researchers. This data will not be used or distributed for any future research purposes.

You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: Pulse Biosciences, Inc
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported, if applicable
- Other research doctors and medical centers participating in this study, if applicable
- Other study sites involved in the research.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYULH IRB Office number is (212) 263-4110. The NYULH IRB is made up of doctors, nurses, scientists, and people from the community.

16. Who can I call with questions, or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on the top of page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

NYU Langone Health is committed to providing a safe, productive, and welcoming environment for participants and researchers in all research studies and interactions. All participants will be treated with respect and consideration, and in turn, we ask that you please treat fellow participants and research staff with respect. Please refer to the NYU Langone Statement on the Conduct of Participants in Research Studies for further information.

17. Parent Signature

When you sign this form, you are agreeing to allow your child to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to allow your child to take part.

Signature of Parents/Guardians for Child
I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above. I confirm also that my child does not have a known allergy to silver, other heavy metals, colophony (kolophonium), rosin, or fluoride.

Name of Parent (Print)	Signature of Parent	Date
Name of Parent (Print)	Signature of Parent	Date

Name of Child (Print)

Person Obtaining Consent

Name of Witness (Print)	Signature of Witness	Date