HIPAA Research Authorization

IRB# 24-41686 UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF HEALTH) PERMISSION TO USE PERSONAL HEALTH INFORMATION FOR RESEARCH STUDY TITLE: Validating Artificial Intelligence (AI)-Generated Dental Caries Detection and Treatment Plan Recommendations
PRINCIPAL INVESTIGATOR NAME: Dr. Stuart Gansky, Dr. Lisa Berens, Dr. Enihomo Obadan-Udoh
SPONSOR / FUNDING AGENCY: US National Institutes of Health/ NIDCR

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that UCSF Health can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UCSF Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing UCSF Health to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

- ☐ Entire Medical Record
- ☐ Ambulatory Clinic Records
- ☐ Progress Notes
- ☐ Other Test Reports
- ☐ Other (describe)
- ☐ Lab & Pathology Reports
- ☐ Dental Records
- ☐ Operative Reports
- ☐ Discharge Summary
- ☐ Consultation
- ☐ Emergency Dept. Records
- ☐ Financial Records
- ☐ Imaging Reports
- ☐ History & Physical Exams
- ☐ Psychological Tests

Please specify other source(s) of Personal Health Information:

_____

C. Do I have to give my permission for certain specific uses?

Yes.
Check this box if any of the following 4 categories of sensitive information will be collected.
Then, check the box only for each specific type of information that will be collected for this study.

☐ The research team will also be collecting information from your medical record that is marked by the check box. The following information will only be released if you give your specific permission by putting your initials on the line(s).

1. Drugs and Alcohol

☐ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

Initial to confirm that you agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.	_____
2. HIV/AIDS	☐ I agree to the release of HIV/AIDS testing information.
Initial to confirm that you agree to the release of HIV/AIDS testing information.	_____
3. Genetics	☐ I agree to the release of genetic testing information.
Initial to confirm that you agree to the release of genetic testing information.	_____
4. Mental Health	☐ I agree to the release of information pertaining to mental health diagnosis or treatment

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes: To the research team for the research described in the attached Consent Form; To others at UC with authority to oversee the research To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives including but not limited to the contract research organization (CRO), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways: To perform the research Share it with researchers in the U.S. or other countries; Use it to improve the design of future studies; Share it with business partners of the sponsor; or File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

	◯ There are no optional research activities. ◯ The research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.
	☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.
Initial to confirm additional optional research activity:	_____

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Participant If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

Participant's Name:

_____
(Participant's Name)

Date:

_____

Electronic Signature:

_____
(Participant's Electronic Signature)

Witness If this form is being read to the Participant because s/he cannot read the form, a witness must be present and is required to pring his/her name and sign. You will be given a signed copy of this form.

Witness's Name:

_____
(Witness's Name)

Date

_____

Electronic Signature:

_____
(Witness's Electronic Signature)

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