

<b>DATE:</b>	April 01, 2025
<b>TO:</b>	Matthew Ramsey
<b>FROM:</b>	The University of Louisville Institutional Review Board E. <a href="mailto:hsppofc@louisville.edu">hsppofc@louisville.edu</a> P: 502-852-5188
<b>IRB NUMBER:</b>	24.0794
<b>STUDY TITLE:</b>	<b>Human dental plaque and saliva collection for microscopy and bacterial culturing</b>
<b>REFERENCE #:</b>	794353
<b>CONTACT:</b>	Steffany Gayton 852-4535 <a href="mailto:slbarn01@louisville.edu">slbarn01@louisville.edu</a> Sent by Cathy J. Carter, <a href="mailto:cathy.carter@louisville.edu">cathy.carter@louisville.edu</a>

**This study now has final IRB approval from 04/01/2025 through 03/31/2028.**

Expedited Approval: Category 3: Prospective collection of biological specimens for research purposes by noninvasive means

- This study has been granted a waiver of written documentation of consent (waiver of signed consent).

Documents reviewed and approved:

Submit for Initial Review	Version 1.0		Approved
IRB Study Application	Version 1.1		Approved
Study Document Title	Version #	Version Date	Outcome
Clean protocol	Version 3.0	02/26/2025	
Updated clean consent form	Version 2.1	02/26/2025	Approved
Recruitment Flyer	Version 1.0	02/26/2025	Approved

## Downloading IRB Approved Documents From iRIS

IRB policy requires researchers to use the IRB approved version of all study documents. Additionally, the IRB places an electronic approval stamp in the top right corner of specific documents ([informed consent](#), [assents](#), [HIPAA documents](#), [recruitment materials](#)). Stamped documents are noted with “approved” in the table above. Instructions on locating and downloading the IRB approved documents in iRIS can be found on the [IRB website](#).

**PLEASE NOTE: IF UNABLE TO FIND YOUR STAMPED PREAMBLE CONSENT IN IRIS, PLEASE REACH OUT TO CATHY.**

## Continuation Requirements

- **Your study has been set with a three-year expiration date.** If you complete your study prior to the expiration date, you are required to submit a study closure amendment.
- You are responsible for submitting a continuation request approximately 30 days prior to the

expiration date of your research study. If a study lapse occurs, this is considered non-compliance and may prompt a HSPPO audit.

- Human Participants & HIPAA Research training are required for all study personnel. It is the responsibility of the investigator to ensure that all study personnel maintain current Human Participants & HIPAA Research training while the study is ongoing.

### **Study Site Approval**

Permission from the institution or organization where this research will be conducted **must** be obtained before the research can begin (e.g., UofL Health (research@uoflhealth.org), Norton Healthcare (RO@nortonhealthcare.org), Jefferson County Public Schools, etc.).

### **Amendments (Making Changes to the Study)**

Prior to making changes to the study, the investigator must submit an [amendment](#) to the IRB and receive approval. If the change is being made to ensure the immediate safety and welfare of the participants, refer to the amendments link above for more information.

### **Reportable Events**

The investigator is responsible for reporting certain study events to the IRB within 5 working days. Refer to the [reportable events page](#) on the HSPP Website.

In addition, you are required to follow all University of Louisville policies and procedures related to conducting human subjects research, including [protecting research data](#) and [providing payments to participants](#). For more information visit: [Human Subjects Protection Program Policies](#).

The committee will be advised of this action.

Thank you,



Paula Radmacher, Ph.D., Vice Chair, Biomedical IRB

We value your feedback; let us know how we are doing: <https://www.surveymonkey.com/r/CCLHXP>