



DATE:	November 27, 2024
TO:	Matthew Ramsey
FROM:	The University of Louisville Institutional Review Board 300 East Market Street, Suite 300, Louisville, KY 40202 P: 502.852.5188 E: hsppofc@louisville.edu
IRB NUMBER:	24.0794
STUDY TITLE:	Human dental plaque and saliva collection for microscopy and bacterial culturing
REFERENCE #:	794353
DATE OF REVIEW:	11/25/2024
CONTACT:	Steffany Gayton, 852-4535, slbarn01@louisville.edu

A chair of the Institutional Review Board (IRB) has reviewed this submission and determined the following changes are needed:

Application:

- 1) Section 4.3, Research team affiliation: Please change this to "UofL academic faculty/gratis faculty/staff/students submitting for UofL IRB review".
- 2) Section 10.2: Specimen collection should be selected.

Protocol:

- 1) Page 1: Please remove the grey-highlighted instructions at the top of the page.
- 2) Page 1 sample size section: sentence #3 needs a reference as it appears to be external data. Also, it appears that up to 50 individuals will be recruited for the plaque portion but as few as 16 are necessary for the saliva samples. Please clarify if these are 2 different groups, part(s) of the same group, or some other group. If some participants are going to be asked for 1 of the 2 samples, please make that clear in the application, protocol, and preamble.
- 3) Page 3 Saliva sample section line 15: It is stated "For plaque and saliva samples, subject names will be recorded in single written list" despite statements in the application (Sections 13.1, 13.6) and other sections of the protocol stating that unique study codes (no identifiers) will be used with samples. Please revise the application, protocol, and preamble so that all references to identifiers or unique study codes are consistent.

Preamble:

- 1) "What will happen" section line 2: "if you agree" suggests that participants may either donate saliva or plaque. If this is true, the protocol and the application need to be revised to reflect the option. If both samples are required for participation, please remove "if you agree."
- 2) "What will happen" section line 3: The protocol does not discuss multiple donations as referenced here. Please revise the protocol, application, and preamble to describe the conditions in which the

additional sample(s) may be donated, or remove this information. If you want to make it an option to donate more than once, the preamble must be presented and agreed each time.

Misc./General:

If students are to be invited (per the protocol: individuals in and around the UofL School of Dentistry), an opportunity to "opt in" is preferable to a face-to-face request to students to enroll in a study by a faculty member. We suggest posting flyers or using email/social media notices (all must be reviewed and approved by the IRB) containing contact information and the IRB#.

Instructions for responding to stipulations:

- You will need to [track your changes](#) in the documents in Microsoft Word. Update document version dates as well.
- You must attach both a "tracked" version and a "clean" version (with the tracked changes accepted) of any document revised.
- When ready to attach your updated documents, please use the document upload links provided in the stipulation. If a link is not provided, scroll down on the stipulation response form and click "add new component" and then click either "other study documents" or "informed consent" to upload your revised study documents.
- Once the documents are uploaded, click the box next to each one to add a check mark, and then click "attach" in the top right corner of the pop-up window.

For guidance on responding to stipulations and attaching revised documents, please follow the instructions at <https://louisville.edu/research/researchers/compliance/irb/answering-stipulations>.

Thank you,

A handwritten signature in black ink, reading "Paula Radmacher". The signature is fluid and cursive, with the first name "Paula" and last name "Radmacher" clearly distinguishable.

Paula Radmacher, Ph.D., Vice Chair, Biomedical Institutional Review Board