

Life Justification

Regarding this study, one of the laboratories for the LIFE Study suggested minor change in the manner in which participants return saliva samples. Rather than shipping the saliva tube at room temperature, the lab is suggesting that participants freeze the sample in their home freezer before placing it in the envelope to ship.

While saliva samples are stable at room temperature for several days, any samples shipped on the weekend are at risk of bacterial contamination from being left at room temperature for too long. Apparently, this has led to invalid results in one of the assays (alpha-amylase) in another study on which they are working, which is why the lab called us to suggest the change.

As such, we are considering requesting permission to modify the saliva collection sheets slightly (see attached) to reflect this proposed change in instructions. Given that the change is minor and does not involve a change in participant burden, is this something that you can be done.

Thank you in advance for your guidance.