This template is based on the NIH instructions here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1

For Human Subjects Research Claiming Exemptions: Justify why the research meets the criteria for the exemption(s). This justification should explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves. For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.

See this link from the University of Utah IRB Investigator Guidance Series for the Federal Exemption Categories criteria starting on page 4.
https://irb.utah.edu/_resources/documents/pdf/IGS%20-%20Exempt%20Research%20version%20012119.pdf

When document is complete, delete this box and save as PI LAST NAME_3.1 Protection of Human Subjects_DDMONYEAR (example-01JAN2022)

NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype, 11 pt or larger, margins .05 or larger
https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

For more information:
Refer to the NIH's Human Subjects Research website.

3.1 PROTECTION OF HUMAN SUBJECTS

Sample Language

Our project was considered Exempt Research based on Category 2 criteria. The primary reasons that this project was considered Exempt Research are that it involves interview procedures where the information obtained will be recorded by us in a way that the identity of participants cannot be readily ascertained, directly or through identifiers linked to the participants.

The identity of participants and their privacy will be protected during and following their participation using several steps. Discussions about the study with participants will occur in a private place and the interview itself will be conducted by telephone as an individual interview. The collection of information about the participants is limited to only the amount necessary to accomplish the research aims, and no unneeded information will be collected. We will deidentify all audio recordings and transcripts of the interview. In addition, research data will be stored on password protected computers and kept in locked cabinets in locked offices. Participant identifiers will be stored separately from the coded, participant data. The transcript data and coded data will be completely de-identified and we will destroy all recordings at that end of the study. The Principal Investigator will monitor the study data, documentation, and deidentification of data throughout the study.

This research is exempt under Category 4 of federal exemption regulations. Through a University of Utah IRB approved protocol, specimens for the University of Utah GI Tissue Bank have all been collected from participants who have given informed consent for storage of their

biospecimens for research purposes. This study proposes accessing specimens from the University of Utah GI Tissue bank through a separate IRB-approved protocol that allows the investigator's use of identifiable health information for research purposes only as regulated under 45 CFR 160 and 164. The investigator will not contact subjects.