APPROVAL OF SUBMISSION

October 7, 2020

Ellen Li
Stony Brook University
Health Sciences Center Room T17-060
Stony Brook, NY 11794-8173

631/444-2119
Ellen.Li@stonybrook.edu

Dear Ellen Li:

On 10/6/2020, the Stony Brook University IRB (FWA# 00000125) reviewed the following submission:

Type of Review:	Modification and Continuing Review
Title of Study:	Stony Brook Digestive Diseases Research Tissue Procurement Facility
Investigator:	Ellen Li
IRB ID:	163184_MODCR003
Sponsor:	Name: National Cancer Institute, Sponsor's Funding ID: P20 CA 192994
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	Protocol Amendment #10 Informed Consent form Spanish Informed Consent Letter of Attestation of Accuracy dated May 12, 2020

The IRB approved the study from 10/6/2020 to 10/5/2021 inclusive. Before 10/5/2021 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 10/5/2021, approval of this study expires on that date.

This study was approved under EXPEDITED REVIEW CATEGORY #9

All research must be conducted in accordance with this approved submission and you are required to follow the requirements listed in the Stony Brook University's SOPs, which can be found by navigating to our website located at: http://research.stonybrook.edu/orc/humans/CORIHS/index.shtml#human-subjects-standard-operating-procedures. Any modifications to the study as approved must be reviewed and approved by the IRB prior to initiation.

When you are ready to schedule and undergo the consent process with your first post-approval subject, please contact Aimee Minton at aimee.minton@stonybrook.edu to coordinate having her present to witness your consent process. This process is part of our ongoing effort to ensure maintained quality in our human research protection program.

If this activity has components that require approval from additional compliance committees (e.g., IACUC, collaborating IRB, IBC, SCRO, COI) it is your responsibility to not commence with the study until these approvals have been secured as well.

Please note:

- Consent forms signed by subjects in this study must be kept by the investigator for 6 (six) years from study termination, or indefinitely (if so indicated in the consent form).
- Inclusion of minors in this study is acceptable in accordance with 45 CFR 46.404 and 21 CFR 50.51
- Permission of one parent is acceptable. Parental permission and minor assent is obtained in accordance with 45 CFR 46.408. Minor assent is also obtained in accordance with SBU Assent Policy, Category 1.
- Approval includes Amendment dated 9/23/2020: addition of Dr. Olga Aroniadis, and Dr. Deborah Nagle to the study team; removal of Dr. Ramona Rajapakse, Dr. Yue Zhang, and Dimitri Joseph from the study.

You are reminded that you must apply for, undergo review, and be granted continued approval for this study before 10/5/2021 in order to be able to conduct your study in an uninterrupted manner. If you do not receive approval before this date, you must cease and desist all research involving human subjects, their tissue and their data until such time as approval is granted.

Where obtaining informed consent/permission/assent is required as a condition of approval, be sure to assess subject capacity in every case, and continue to monitor the subject's willingness to be in the study throughout his/her duration of participation. Only use current IRB forms in the consent process. Each subject must receive a copy of his/her signed consent/permission/assent document.

Unanticipated problems (including serious adverse events) must be reported to this office in accordance with SBU Policy at: http://research.stonybrook.edu/human-subjects-standard-operating-procedures/unanticipated-problems-involving-risks-subjects-or. Any complaints or issues of non-compliance must be immediately reported to this office.

If you have any questions or comments about this correspondence, please contact:

Office of Research Compliance
Division of Human Subject Protections
Stony Brook University
Stony Brook, NY 11794-3368
Phone: 631-632-9036
Fax: 631-632-9839

Please include your study title and IRB ID# in all correspondence with this office.

We are interested in receiving feedback regarding your experience with the Office of Research Compliance, SBU's IRB, or any other aspect of our Human Research Protection Program.

Please feel free to e-mail Rebecca Dahl, Assistant Vice President for Research Compliance, at rebecca.dahl@stonybrook.edu for questions or concerns.