



APPROVAL OF SUBMISSION

September 6, 2019

Joshua Miller
Stony Brook University
Tech Park 26 Research Way
East Setauket, NY 11733-8154

631/444-0580
Joshua.Miller@stonybrook.edu

Dear Joshua Miller:

On 9/6/2019, the Stony Brook University IRB reviewed the following submission:

Type of Review:	Modification and Continuing Review
Title of Study:	Effect of Glycemic Control on Colonic Adenoma-Carcinoma Progression in Patients with Diabetes Mellitus
Investigator:	Joshua Miller
IRB ID:	966231_MODCR002
Sponsor:	None
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none">• Inclusion/Exclusion Eligibility Form, Category: Other;• Miller_Adenoma & Diabetes_Consent_2019_final, Category: Consent Form;• Pre-procedure Data Questionnaire, Category: Other;• Miller_Adenoma & Diabetes_Consent Short Form_Spanish_2018_Clean.pdf, Category: Consent Form;• Miller_Adenoma & Diabetes_Protocol_2019_Clean.pdf, Category: IRB Protocol;

The IRB approved the study from 9/6/2019 to 9/5/2020 inclusive. Before 9/5/2020 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 9/5/2020, 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 Stony Brook University's Standard Operating Procedures (SOPs), which can be found by navigating to the Click IRB Library tab or to our website located at <http://research.stonybrook.edu/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 Mary O'Neill at Mary.oneill@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).
- Approval includes Amendment request to add Dr. Michael Clores and Sarah Malik to the study team. Removal of Chris Lascarides, Suman Grewal, Mohammad Khan, Ying Zhang, Wilson Sze, Brandon Lung, Breana Channer, and Joseph Mizrahi from the study.

You are reminded that you must apply for, undergo review, and be granted continued approval for this study before 9/5/2020 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 if you have questions or concerns.

