NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Office of Science and Research
Institutional Review Board
1 Park Ave.| 6th Floor, | New York, NY 10016

Approval of Submission September 22, 2016

Dear Colin Phoon:

On 9/21/2016 6:14 PM EDT, the IRB reviewed the submission below: All conditions for approval were met on 9/21/2016.

principal investigator	Colin Phoon
email	phoonc01@nyumc.org
study number	i9478
study title	Estimation of Pressure Gradients by Physical Examination
performance period	9/21/2016 to 9/20/2017 inclusive. Before 9/20/2017 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. 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 9/20/2017, approval of this study expires on that date.
location(s)	Bellevue Hospital (Bellevue), NYU Faculty Group Practice (FGP) (NYUMC Locations), Rusk Rehabilitation (34th Street) (NYUMC Locations), Tisch Hospital (NYUMC Locations)
sponsor(s)	Name: New York University
review type	Continuing Review [Expedited 4]
board name	Reported to All Boards
materials approved for use	• Protocol 2010 02 02.pdf, Category: IRB Protocol Study is permanently closed to enrollment.

The current IRB Status of your study is: Approved. This study was reviewed by the NYU School of Medicine's Institutional Review Board (IRB). During the review of your study, the IRB specifically considered:

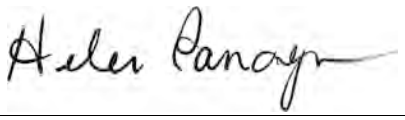
1. the risks and anticipated benefits (if any) to your subjects
2. the selection of subjects
3. the procedures for securing and documenting informed consent
4. the safety of your subjects
5. the privacy of your subjects and confidentiality of the data

Your study cannot commence until all ancillary review decisions are complete. In order to determine the state of all ancillary reviews please go the My Studies page of this study in Research Navigator. Ancillary review statuses will be found on the right side of the header section.

Please note; if your study includes a clinical trial agreement or budget you will need to ensure approval has been issued from My Agreements/CRMS and The Office of Clinical Trials before you proceed with any aspects of this study including the enrollment of human subjects.

Review Notes:

For NIH Grant funded research: the IRB has found the IRB approved protocol referenced above to be consistent with the NIH grant application.



September 22, 2016

RE: Study#i9478
Helen Panageas, Director, Institutional Review Board OHRP #FWA00004952

Notes

- You must submit all changes to this study (e.g., protocol, recruitment materials, consent forms, etc.) via eSubmission to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
- You must report all adverse and/or unanticipated event(s) that occur during the course of this study to IRB via eSubmission in accordance with IRB Policy.
- Use only IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Do not use expired consent forms.
- You must inform all research staff listed on this study of changes or adverse events that occur.
- IRB's approval is valid until the end date of the performance period indicated above. A reminder for renewal should be e-mailed to you from the IRB 90, 60 and 30 days before this study's approval is scheduled to expire. However, you are responsible for submitting all renewal materials at least eight weeks before expiration regardless of whether or not you receive a reminder notice.
- All IRB policy documents can be found on our website: http://irb.med.nyu.edu/library
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
    - ***Bellevue Hospital****: when Bellevue Hospital is listed as a site where your study can take place, please note that you may have to complete additional work in BHC's Reason system. Bellevue will be contacting you with any additional needed information. For questions on Bellevue Hospital research, please contact BellevueResearch@bellevue.nychhc.org*
    - CTSI - Clinical and Translational Science Institute, NYU School of Medicine [formerly General Clinical Research Center (GCRC)], ctsi@nyumc.org.
    - NYU Langone Medical Center (Tisch Hospital/Rusk Institute/Co-op Care/HJD/Perlmutter Cancer Center) site approval is handled for you automatically (as needed) by the Office of Clinical Trials
- The IRB may terminate studies that are not in compliance with NYU Langone Medical Center/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the Federal Government. Direct IRB questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, etc.) to 212-263-4110 or IRB-INFO@nyumc.org.
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative of the Office of Clinical Trials. You may contact the Office of Clinical Trials at 212.263.4210 or clinicaltrials@nyumc.org.

NYU SoM IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations. The NYU SoM IRB Federal Wide Assurance number is 00004952.

Notice of NYC Health + Hospitals Research Continued Approval

STAR@nychhc.org

Sent: Friday, October 28, 2016 2:31 PM
To: Phoon, Colin

125 Worth Street • Room 429 • New York, NY 10013 • 212-788-2181
Research Administration
Office of Healthcare Improvement

Study ID:	MODCR00000043
Principal Investigator:	Colin Phoon
Title:	Continued Approval and Modification #1 for Study StudyTX00001084
Facility:	Bellevue
IRB No.:	9478
Instructions:	The above referenced study has met the NYC Health + Hospitals criteria for having no substantial changes and has been renewed for continued implementation at Bellevue for no longer than 365 days beginning, 10/28/2016. No investigator may recruit any patients or continue protocol implementation unless the IRB and the NYC Health + Hospitals approvals are both documented as current. Prior to expiration, your study must be renewed following the guidelines listed in Operating Procedure No.: 180-9 HHC Human Subjects Research Protections Program Policies and Procedures, Part III, Section 12 on study renewals: - Research projects that are exempt from IRB review do not need to be renewed in STAR. - For non-exempt research projects, the PI must submit the IRB annual report and continuing approval letter to STAR prior to the IRB date of expiration listed in STAR. The Principal Investigator is the ultimate protector of the individuals who participate in research at NYC Health + Hospitals, and is expected to abide by the highest ethical standards; conducts research in accordance with the approved research protocol; and oversees all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. If you terminate or suspend this study without prior agreement of the sponsor, please inform the Office of Research Administration, sponsor and the IRB. If the IRB terminates or suspends approval of this study, you must promptly notify the sponsor, Christina Pili, Director of Research Administration, at christina.pili@nychhc.org and your Facility Research Coordinator. Facility Research Coordinators: First Name: Last Name: Phone: E-Mail: Anand Veeraraj 212-562-4176 anand.veeraraj@bellevue.nychhc.org Upon completion of this study, please notify the Office of Research Administration; your Facility Research Coordinator, the IRB with a summary of the study's outcome, and the sponsor with any reports required. Should you have any additional questions, please contact Christina Pili. Thank you.