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

December 18, 2017

Dear Naamit Gerber:

On 12/13/2017 10:12 AM EST, the IRB reviewed the submission below: All conditions for approval were met on 12/13/2017.

principal investigator	Naamit Gerber
email	Naamit.Gerber@nyumc.org
study number	i17-00993
study title	Breast cancer patients treated with chemotherapy, radiation therapy, and/or endocrine therapy: a retrospective analysis of clinical and pathologic characteristics, patterns of care, and outcomes.
performance period	12/13/2017
location(s)	Bellevue Hospital (Bellevue), Clinical Cancer Center (NYUMC Locations), Tisch Hospital (NYUMC Locations), Ambulatory Care Center (NYUMC Locations)
sponsor(s)	Name: Radiation Oncology;
review type	Initial Study [Exempt Categoryu 4]
board name	All Boards
materials approved for use	• S17-00993 Waiver Application.pdf, Category: Consent Form • S17-00993 Protocol Breast Cancer 12-11-2017 Clean.pdf, Category: IRB Protocol A request for waiver of Authorization to use identifiable health information for research has been approved in accordance with 45 CFR.164.512 (i)
#of subjects approved to consent	500
vulnerable populations approved for participation in this study	

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.

Helen Panageas December 18, 2017

RE: Study#i17-00993

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.