NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Institutional Review Board
Human Research Protection Program
1 Park Avenue | 6th Floor | New York, NY 10016
http://irb.med.nyu.edu

Application for Waiver of Authorization and/or Consent

Submission Instructions

Our website provides full instructions on submitting applications to the IRB: http://irb.med.nyu.edu/esubmission
Please contact the IRB office at 212 263-4110 with any questions.

Administrative Information

Study#	S17-00993	Date of this request	12/6/2017
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.		

Role	Name	Kerberos ID/Email**	Phone	Fax
Principal Investigator	Naamit Gerber	Gerben02/Naamit.Gerber@nyumc.org	212-731-5304	212-731-5512
Contact Person	Julie Xiao	yx236/Julie.xiao@nyumc.org	212-731-5883	212-731-5512

Request

In order to access or use an individual's Protected Health Information (PHI) in the conduct of research without the express authorization of the individual, you must request a waiver of authorization.

In order to conduct research without the express written consent of a human subject, you must request a waiver of informed consent.

You may also request an alteration in consent or authorization. In other words: you will be obtaining written consent but may require certain elements of the consent be altered and you will need to request an alteration in consent and authorization.

You may request a waiver of documentation of consent. There are required elements that must be met, but a waiver of documentation of consent means that you will obtain consent, but you do not use an informed consent document.

Indicate the nature of this request	☒ waiver of authorization (complete I and III) ☒ alteration or waiver of consent (complete II.A, II.B & III) ☐ waiver of documentation of consent (complete II.A, II.C & III)
Does this research present no more than Minimal Risk of harm to subjects	☒ Yes; Explain: Retrospective study of de-identified patient information ☐ No; **STOP:** This study is not eligible for an Alteration or Waiver of Authorization or Consent or a Waiver of Documentation of Consent

I. Authorization

Fill this out if you seek to obtain a waiver of authorization to use and disclosures protected health information.

A. Record/Specimen Use

Check the boxes of the items that will be used

Indicate your study's source(s) of health information	☒ physician/clinic records ☐ interviews/questionnaires ☐ mental health records ☐ billing records	☒ lab, pathology and/or radiology results ☐ biological samples obtained from the subjects ☒ hospital/medical records (in- and out-patient) ☐ data previously collected for research purposes ☐ other; specify:

B. Protected Health Information

Describe the PHI being used or disclosed in your study	☐ Patient/subject name ☐ Address street location ☐ Address town or city ☐ Address state ☐ Address zip code ☐ Elements of dates (except year) related to an individual. (ie. DOB, admission/discharge dates, date of death) ☐ Telephone number ☐ Fax number ☐ Electronic mail (email) address ☐ Social security number ☐ Medical record numbers ☐ Health plan beneficiary numbers ☐ Account numbers ☐ Certificate/license numbers ☐ Vehicle identification numbers and serial numbers including license plates ☐ Medical device identifiers and serial numbers ☐ Web URLs ☐ Internet protocol (IP) address ☐ Biometric identifiers (finger and voice prints) ☐ Full face photographic images ☐ Any unique identifying number, characteristic or code (a rare disease can be considered a unique id) ☐ Link to identifier (code)

C. Request for Waiver of Authorization

If any box in section I.B above is checked, list every investigator, research staff member or other staff member who will have access to this data	Naamit Gerber, Moses Tam, Carmen Perez, Nelly Huppert, Allison McCarthy, Chris Hitchen, Olivier Maisonet, Fauzia Shaikh, Juhi Purswani, Johanna Ghobrial, Indra Das, Peter Wu, Sherry Yan, Julie Xiao
Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy	Once the subjects have been identified, a de-identified study database will be created with elimination of any PHI. This will be kept using RedCap. Only authorized study staff will have access to this database. This will minimize the risk to patient privacy.
Describe investigator's plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time	All patient information will be de-identified and all data will be kept in a secure database (RedCap).
Explain why it is not possible to seek subjects' authorization for use or disclosure of the PHI	Retrospective study after patient's treatment completed.
Explain why it is not possible to conduct this research without use or disclosure of the PHI	No use of PHI.

II. Informed Consent

Complete II.A and II.B if you are seeking an alteration or complete waiver of your research subject's right to informed consent.

Complete II.A and II.C if you are seeking a waiver of documentation of informed consent.

A. Overview

Briefly explain the consent process for your study	There is no consent as this is a retrospective study for patients who have already undergone treatment.

B. Alteration or Waiver of Informed Consent

Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject	There is no harm as there is no intervention involved.
Explain why the waiver/alteration will not adversely affect the rights and welfare of the subjects	As long as there is no breach of confidentiality, the rights and welfare of the subjects will not be adversely affected.
Explain why it is impracticable to conduct this research if informed consent is required	We are studying questions that would be too expensive and impractical to study with prospective clinical trials. Alternatively, we are awaiting prospective trial results and are performing retrospective analyses in the interim to try to better understand a research question.
Explain, if appropriate, how the subjects will be provided with additional pertinent information after participation. If not appropriate, explain why	There is no formal participation as these are retrospective studies that may affect future clinical care but have no ability to affect care that already been delivered.

C. Waiver of Documentation of Informed Consent

For this subsection, complete either Subsection 1 or 2

Subsection 1

(a) The only record linking the subject to the research will be the consent document	☐ Yes; explain: * note you MUST have completed Section I.B (above) ☐ No; **not eligible for waiver under this section**
(b) Would the principal risk would be potential harm resulting from a breach in confidentiality	☐ Yes; explain: ☐ No
(c) Will subjects be provided with a written statement regarding the research*	☐ Yes; Attach document for IRB Review and Approval ☐ No explain:

**to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol.*

Subsection 2

(a) Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject	Harm if information is not de-identified but it will be de-identified.
(b) The research involves no procedures for which written consent is normally required outside the research context	☒ Yes; explain: Retrospective research with no patient identifiers. ☐ No; **not eligible for waiver under this section**
(c) Will subjects be provided with a written statement regarding the research*	☐ Yes; Attach document for IRB Review and Approval ☒ No explain: Retrospective research with no patient identifiers.

**to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol.*

III. Signatures

Principal Investigator's Signature

Date	12/6/2017
Print Name	Naamit Gerber
Signature	Naamit Gerber

I assure the IRB that the protected health information which I have detailed in this Waiver of Authorization and/or Consent application will not be reused (i.e.: used other than as described in this application) or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by the NYU SoM IRB.

I also assure the NYU SoM IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research project.