



Option 1 (most preferred)

- Obtain written informed consent from the patient.

Option 2

- Use a LAR/Authorized Representative to sign the informed consent document if the patient is not able to provide consent because of an impairment or being unable to communicate (i.e., on a ventilator and sedated).

Option 3 (use only when option 1 or option 2 are NOT feasible)

- We understand that it may be too difficult or challenging to obtain written informed consent in person, especially if the patient is critically ill and not able to provide consent. If the consenter is unable to be physically in the room with the patient at the time of written informed consent, they or their designee trained to get informed consent can speak with the patient via a telemedicine or telephone device, and ask the patient to sign the consent form. The patient or his/her family member or health care worker can photograph the consent form and email it with signature to the physician/PI.

A component of this amendment is to assess ‘social variables’ at outlined below. Please comment on how that will be done. Questionnaire? What?

- 1. To determine the effect of nonbiologic (social) variables of neighborhood disadvantage on response to neoadjuvant chemotherapy for AA and EA women with triple-negative breast cancer.*
- 2. To evaluate the effect of biologic (molecular) variables of neighborhood disadvantage on response to neoadjuvant chemotherapy for AA and EA patients with triple-negative or HER2-positive breast cancer.*