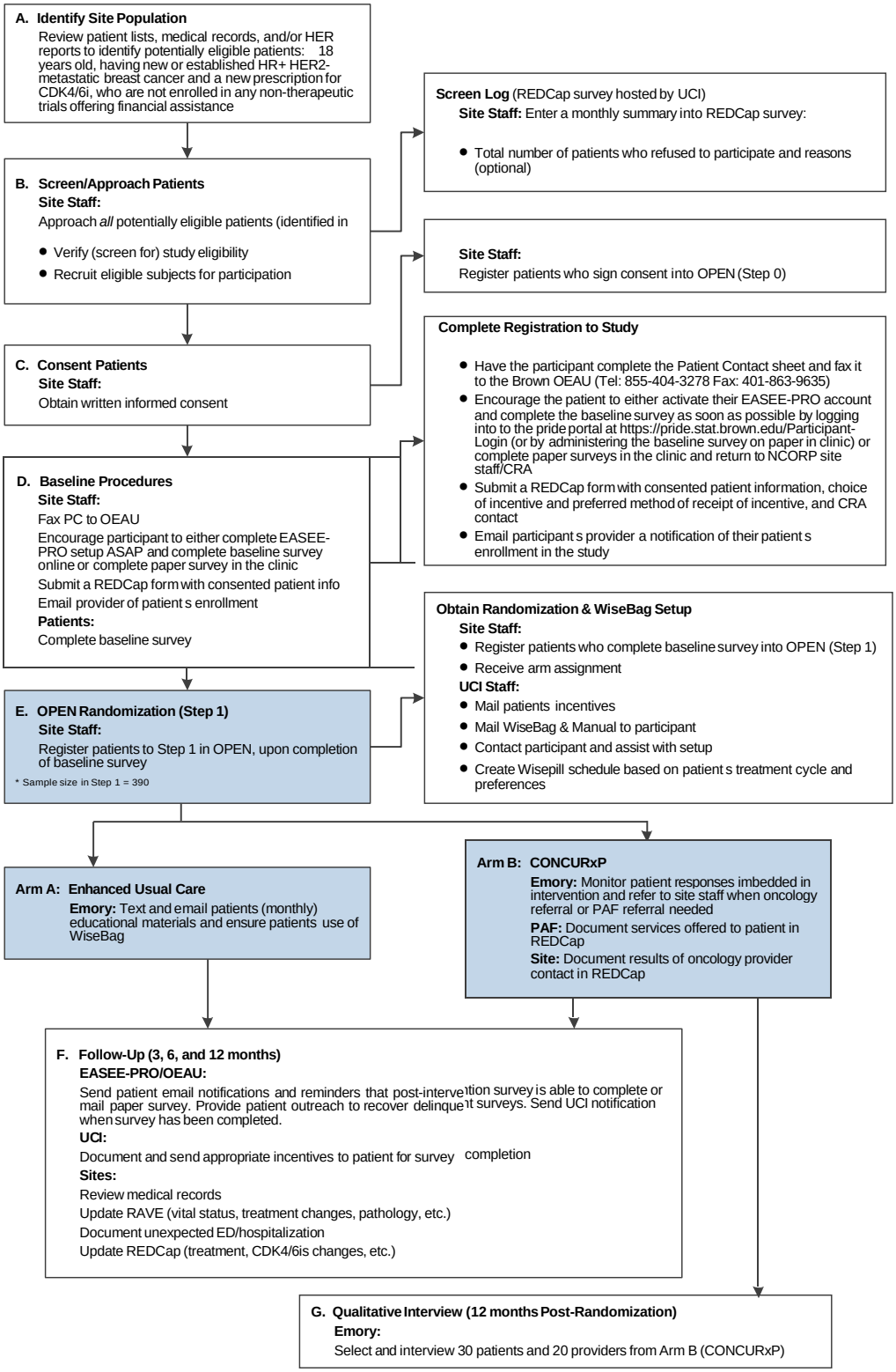
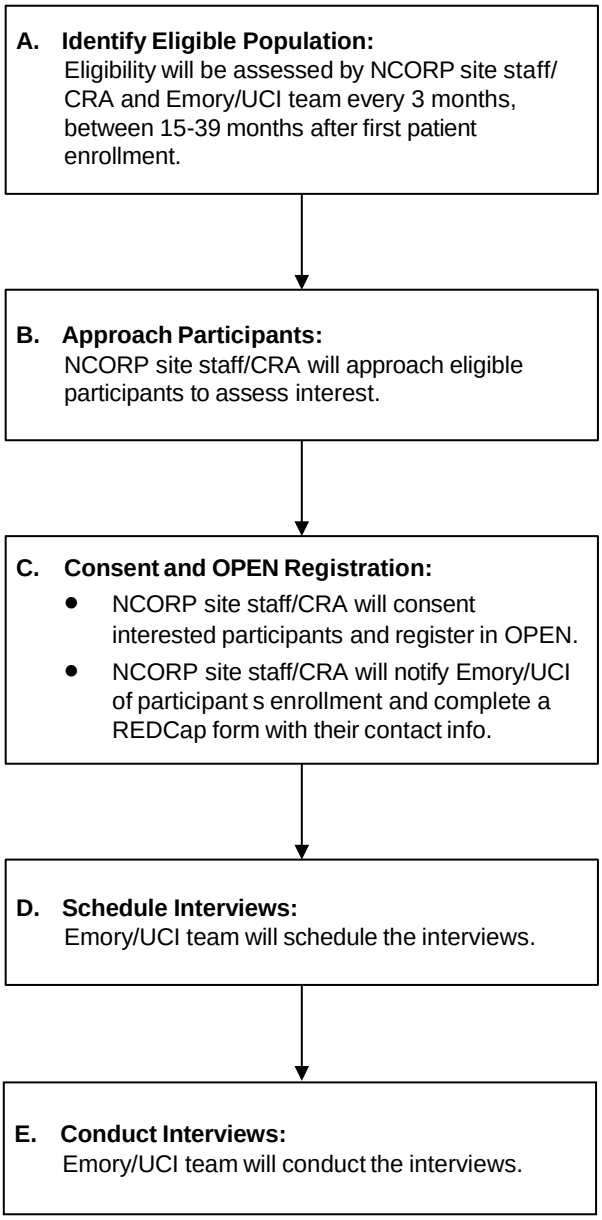
Patient Schema



*Site staff refers to NCORP site staff/CRA

Non-Patient Participant Intervention Schema



3. Selection of Participants

3.1 Non-Patient Participants

To achieve Aim 3, we will enroll a subset of oncology healthcare providers (n=approximately 20) from a minimum of 10 participating NCORP sub-affiliates. We are seeking to elicit implementation process perspectives from key stakeholders who would be most likely to be instrumental in making the CONCURxP intervention a routine part of cancer care.

3.1.1 Non-Patient Participant Eligibility Criteria

3.1.1.1 Participants must be an oncology healthcare provider (i.e., oncologist, advanced practice provider, or oncology nurse).

3.1.1.2 Participants must have taken care of at least one patient randomized to Arm B (CONCURxP) who had less than 85% adherence rate at 12 months as measured by the WiseBag.

3.1.1.3 Participant must speak English.

3.1.1.4 Participant must be employed at an NCORP site for at least 6 months.

3.1.1.5 Participant must be able to provide informed consent to participate in this study.

The criteria may be adjusted based on the pool of providers available for the interview.

3.2 Patient Eligibility Criteria

Each of the criteria in the checklist that follows must be met in order for a patient to be considered eligible for this study. Use the checklist to confirm a patient's eligibility. For each patient, this checklist must be photocopied, completed and maintained in the patient's chart.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday four weeks later would be considered Day 28.

ECOG-ACRIN Patient No. _____

Patient's Initials (L, F, M) _

Physician Signature and Date _____

NOTE: CTEP Policy does not allow for the issuance of waivers to any protocol specified criteria (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm). Therefore, all eligibility criteria listed in Section 3 must be met, without exception. The registration of individuals who do not meet all criteria listed in Section 3 can result in the participant being censored from the analysis of the study, and the citation of a major protocol violation during an audit, and require reporting to the IRB of record as non-compliance.

All questions regarding clarification of eligibility criteria must be directed to the Group's Executive Officer (EA.ExecOfficer@jimmy.harvard.edu) or the Group's Regulatory Officer (EA.RegOfficer@jimmy.harvard.edu).

NOTE: Institutions may use the eligibility checklist as source documentation if it has been reviewed, signed, and dated prior to registration/randomization by the treating physician.

3.2.1 Patient Eligibility Criteria for Step 0 (OPEN Screening Registration)

_____3.2.1.1 Patient must be ≥ 18 years of age.

_____3.2.1.2 Patient must be fluent in written and spoken English

OR

Patient must be fluent in written and spoken Spanish

_____ 3.2.1.3 Patient must present with new or established pathologically proven HR+ HER2- metastatic breast cancer at the time of Step 0.

_____ 3.2.1.4 Patient must have initiated any of the CKD4/6 inhibitors (Palbociclib or Ibrance, Ribociclib or Kisqali, Abemaciclib or Verzenio) within 30 days prior to consenting to Step 0 or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent.

NOTE: Patients who have been treated previously with anticancer treatments other than CDK4/6 inhibitors are eligible.

NOTE: CDK4/6 inhibitors must be provided/supplied as a single agent blister pack. If the medication is supplied as capsules in a pill bottle (e.g., Ibrance capsules), patient is not eligible.

NOTE: Ribociclib (Kisgali) and Abemaciclib (Verzenio) are only available in blister packs. Palbociclib (Ibrance) is the only CDK4/6 inhibitor that might be available in a capsule formulation. However, this is an outdated formulation and is rarely prescribed as a new start. The format of ordered Palbociclib can be determined based on the prescription order.

——— 3.2.1.5 Patients must not have been previously treated with any of the following CDK4/6 inhibitors: Palbociclib or Ibrance, Ribociclib or Kisqali, and Abemaciclib or Verzenio.

_____3.2.1.6 Patients must not already be enrolled in a therapeutic clinical trial that monitors CDK4/6 inhibitors.

_____3.2.1.7 Patient must confirm that they intend to receive their care or monitoring at an NCORP site.

_____3.2.1.8 Patient must have a personal mobile phone in which they are able and willing to send and receive text messages.

NOTE: The restriction to those with mobile phone access with text messaging is based on the primary intention of the study which involves the use of text messaging to improve adherence.

_____ 3.2.1.9 Patient must have an email address.

NOTE: The restriction to those with an email address is based on the primary intention of the study which involves patients responding to questions regarding their reasons for non-adherence after every missed dose to improve adherence.

_____ 3.2.1.10 Patient must have the ability to understand and the willingness to sign a written informed consent document.

NOTE: Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available are not eligible.

_____ 3.2.1.11 Patient must not have an ECOG Performance Status ≥ 3.

OR

Patient must not be deemed medically unable to participate in the study by the study investigators or an oncology clinician (i.e., referral to hospice).

_____ 3.2.1.12 Patient must not be enrolled in other trials offering financial assistance.

NOTE: Gift cards for survey completion, parking passes, or free medication provided as part of therapeutic trials are not considered financial assistance.

3.2.2 Patient Eligibility Criteria for Step 1 (OPEN Randomization)

_____ 3.2.2.1 Patient must meet all the eligibility criteria for Step 0 outlined in Section 3.2.1.

_____ 3.2.2.2 Patient must have signed a written informed consent form.

_____ 3.2.2.3 Patient must have completed Baseline Survey within 30 days of the date of Step 0 Registration.

_____ 3.2.2.4 Patients must have initiated their CDK 4/6 inhibitors within 30 days of the date of Step 0 Registration.

_____ _____

Physician Signature Date

OPTIONAL: This signature line is provided for use by institutions wishing to use the eligibility checklist as source documentation.