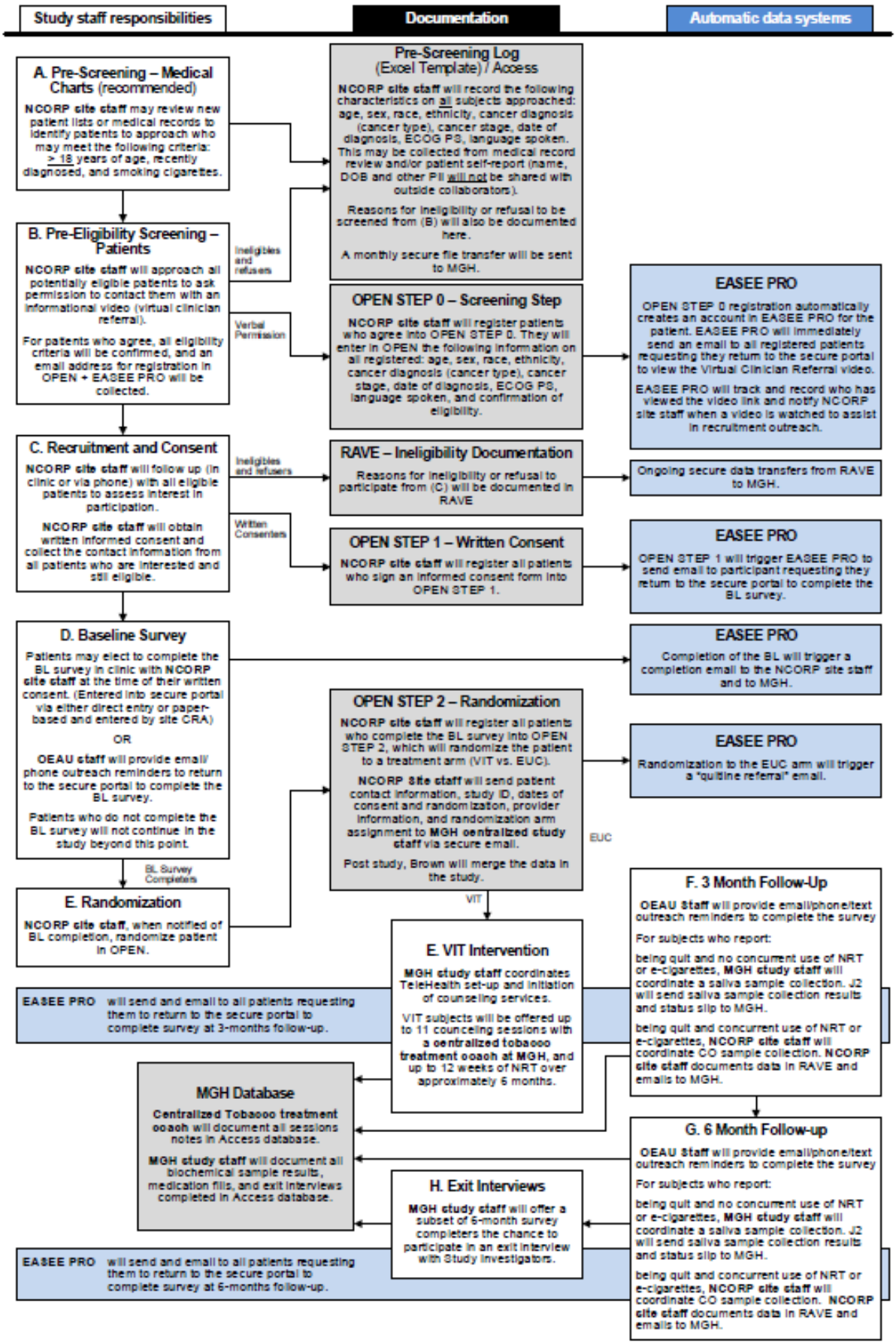
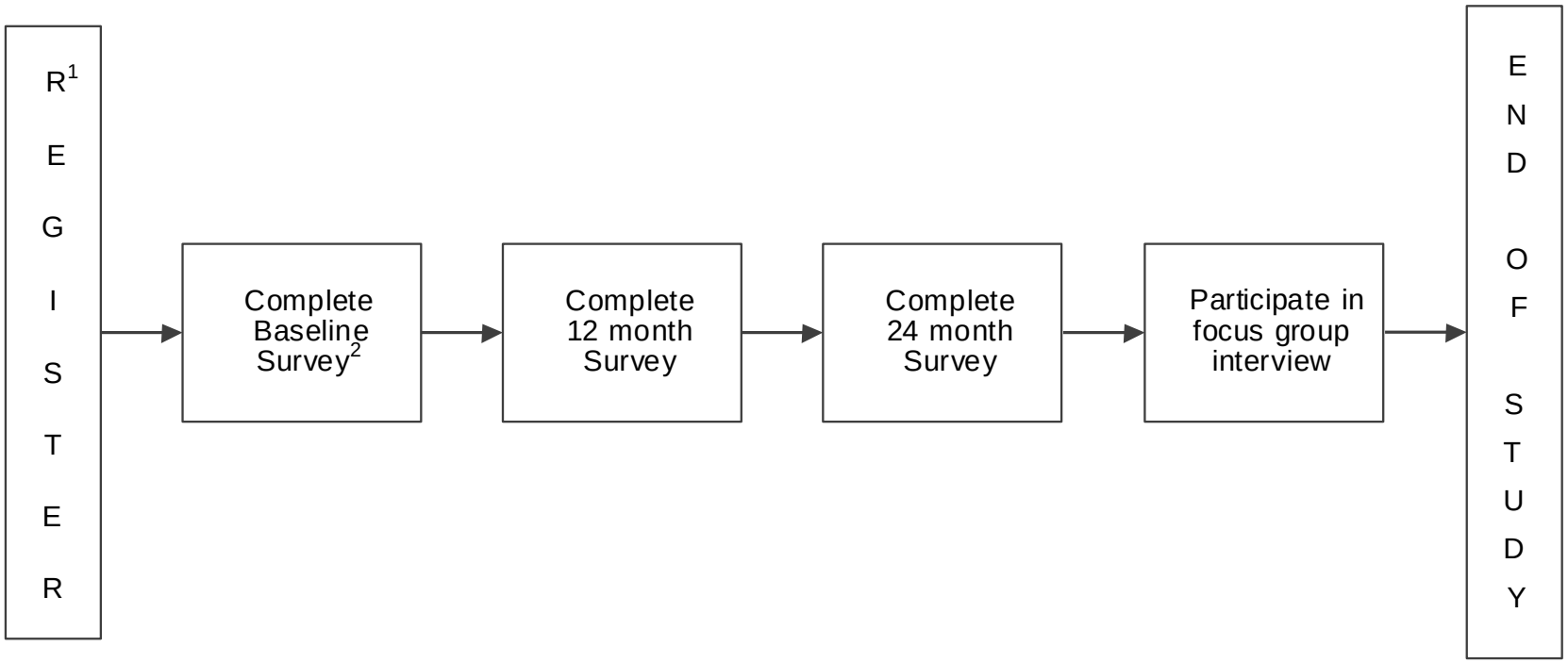
Cancer Research for the Ozarks

EAQ171CD
Patient Schema



NCORP Site Staff Schema



1. For each NCORP site, the CCDR lead will identify 8-10 multidisciplinary staff members to participate in this study.
2. Site staff must complete baseline survey prior to first patient enrollment.

3. Participant Selection

3.1 Selection of NCORP Site Staff Participants

In order to achieve Aim 3, we will enroll a subset of staff (n=approximately 110) from a minimum of 11 participating NCORP sites. We are seeking to elicit implementation process perspectives from key stakeholders (clinicians and research administration staff) who would most likely be instrumental in making tobacco use assessment and treatment routine part of cancer care. Guided by his/her knowledge of key stakeholders' roles and responsibilities, the Cancer Care Delivery Research (CCDR) Leader and site PI from each participating site will be responsible for identifying approximately 10 multidisciplinary staff members to complete brief (approximately 15 minute) surveys and participate in focus group interviews (approximately 45-60 minutes). Although specific site staff participant composition will vary somewhat by site, we envision participation of the CCDR Leader, the Site PI, 2-3 oncology nurses, 2-3 additional medical oncologists and 2-3 additional staff members.

In terms of eligibility criteria, eligible NCORP site staff participants will be English-speaking, employed at the NCORP site for at least three months, and able to provide informed consent to participate in this study (see Informed Consent for NCORP Staff). Given the minimal risk, minimal burden and broad relevance of this research to CCDR priorities for enhancing high quality cancer care, we do not anticipate any difficulty recruiting staff participants. In the event that there is staff turnover, the CCDR Leader will be responsible for identifying one or more replacement staff participants who will provide 12 and 24-month follow-up surveys and participate in the focus group interview. Given our assumption that the selected staff represent key site stakeholders and that the quantitative (baseline, 12 and 24-month follow-up surveys) and qualitative data (focus group interview) will be analyzed at the level of the site, some variation in pre- and post-trial participants will is allowable and will not diminish the accomplishment of Aim 3.

3.1.1 Staff Eligibility Criteria

_____ 3.1.1.1 Must be English speaking

_____ 3.1.1.2 Must be employed at NCORP site for at least three months

3.2 Selection of Patients

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: NCI 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. 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 Step 0

3.2.1.1 Inclusion

_____3.2.1.2 Age ≥ 18 years.

_____3.2.1.3 Patient presenting with any type of cancer with a date of diagnosis within the past 4 months.

Recurrence, diagnosed within the last 4 months, of tumors in patients with past cancer diagnoses will be considered eligible. Patients with a new primary cancer, diagnosed within the last 4 months, who have been treated previously for other types of cancer will also be considered eligible. “In situ” cancers, diagnosed within the past 4 months, will also be considered eligible.

_____3.2.1.4 Patient must be a current smoker. Current smoker is defined as any cigarette smoking (even a puff) in the past 30 days.

_____3.2.1.5 Patient must be fluent in both, written and spoken, English or both, written and spoken, Spanish.

_____ 3.2.1.6 Patient must have telephone, web and e-mail access.

NOTE: The restriction to those with web and e-mail access is based on the primary intention of the study; to assess the implementation of the virtual intervention in the NCORP network.

3.2.2 Exclusion (Subject must not meet any of the criteria listed here)

_____3.2.2.1 Patient has an ECOG performance status of 3 or above, or is deemed medically unable to participate by study investigators or oncology clinician (i.e., referral to hospice).

_____3.2.2.2 Patient has no intention to receive their cancer care or monitoring at an NCORP community cancer site.

3.2.3 Eligibility Criteria Step 1

3.2.3.1 Patient must still meet all criteria outlined in Step 0

3.2.4 Eligibility Step 2 (Randomization)

3.2.4.1 Patient must have completed Baseline Survey in EASEE-PRO within 1 month (30 days) of the date of Informed Consent (Step 1).

_____ _____

Physician Signature Date

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