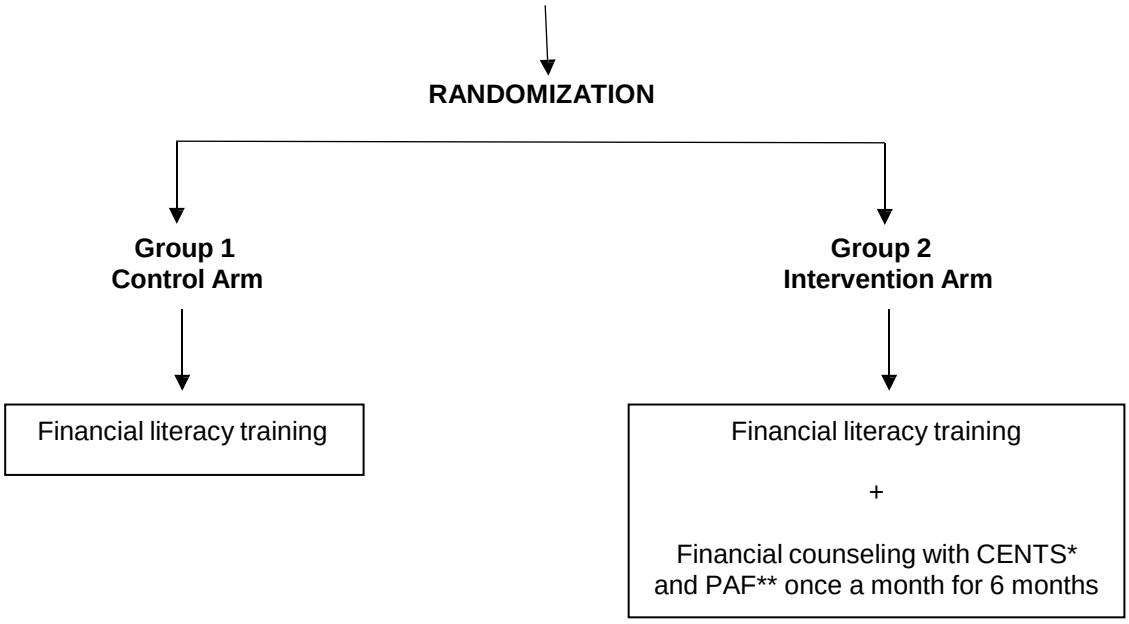
SCHEMA

Patient and spouse caregiver

Completion of baseline forms



In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in Section 13.4.
* Consumer Education and Training Services (CENTS)
** Patient Advocate Foundation (PAF)

5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration in OPEN. Section 5 may be printed and used to by the site, but is not to be uploaded in RAVE (unless specially stated).For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see Section 14.0). Any potential eligibility issues should be addressed to the SWOG SDMC in Seattle at 206/652-2267 or cancercontrolquestion@crab.org prior to registration. **NCI policy does not allow for waiver of any eligibility criterion** (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, as an example, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 28 falls on a weekend or holiday, the limit may be extended to the next working day.**

5.1 Disease Related Criteria - Patient

a. Patients must have a diagnosis of a metastatic solid tumor or a hematologic malignancy and must receive anti-cancer treatment per the timing described in Section 5.2a (i.e. chemotherapy, hormonal therapy, targeted therapy, biologic therapy, immune therapy, bone marrow transplant). Registration must occur within 120 days after diagnosis. Patients with indolent hematologic diseases undergoing observation alone are not eligible.

b. Patients with recurrent solid tumors will be allowed as long as 1) this is the first presentation of metastatic disease and 2) the diagnosis of the metastasis is at least 180 days (6 months) after the diagnosis date of the previous earlier stage cancer.

c. Patients with a history of secondary malignancy are allowed as long as they were not diagnosed within the previous 24 months, are not on active therapy, and are disease-free. Patients with adequately treated basal cell or squamous cell skin cancer, and *in situ* cervical cancer at any point prior to enrollment are eligible.

5.2 Prior/Concurrent Therapy Criteria – Patient

a. Patients who have started anti-cancer treatment for the current diagnosis must have started within 60 days prior to registration.

b. Patients who are planning to start anti-cancer treatment for the current diagnosis must start within (≤) 30 days after registration.

c. Patients are allowed to be co-enrolled on other clinical trials (including non-treatment studies and studies that may or may not include investigational drugs).

d. Patients may not be enrolled in hospice care at the time of registration.

5.3 Clinical/Laboratory Criteria - Patient

a. Patients must be at least 18 years of age.

b. Patients must have a Zubrod performance status of 0-2.

c. Patients must complete the baseline PRO questionnaires prior to registration and must be able to complete questionnaires in English or Spanish.

d. Patients must provide their full name, primary address in the U.S., birth date and social security number at registration for the purposes of accessing credit report data. (This may be obtained directly from the patient, study questionnaires, or the medical record.)

e. Patients must provide email and telephone number for the purposes of being contacted by financial navigators.

5.4 Spouse Caregiver Criteria

a. Spouse caregiver must be willing to participate in the trial.

b. Spouse caregiver must be legally married, or file their tax returns as married filing jointly.*

c. Spouse caregiver must be living in the same household with the eligible patient enrolling in this trial.

d. Spouse caregivers must be at least 18 years of age.

e. Spouse caregivers must provide their full name, primary address in the U.S., birth date and social security number at registration for the purposes of accessing credit report data.

f. Spouse caregivers must provide email and telephone number for the purposes of being contacted by the financial navigators.

g. Spouse caregivers must be able to complete questionnaires in English or Spanish and must complete the baseline questionnaires prior to patient registration.

*The study team acknowledges that other types of caregivers may also face financial hardship following a patient's cancer diagnosis and may similarly benefit from financial education and navigation. The decision to focus solely on *spouse* caregivers was scientific, to facilitate analysis of primary endpoint (household financial hardship).

5.5 Regulatory Criteria

a. Participants (patients and spouse caregivers) must sign and give written informed consent in accordance with institutional and federal guidelines. Use of legally-authorized representative is not permissible for this study. Documentation of informed consent via remote consent is permissible, as indicated in Section 18.2.

NOTE:As a part of the OPEN registration process (see Section 13.5 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.