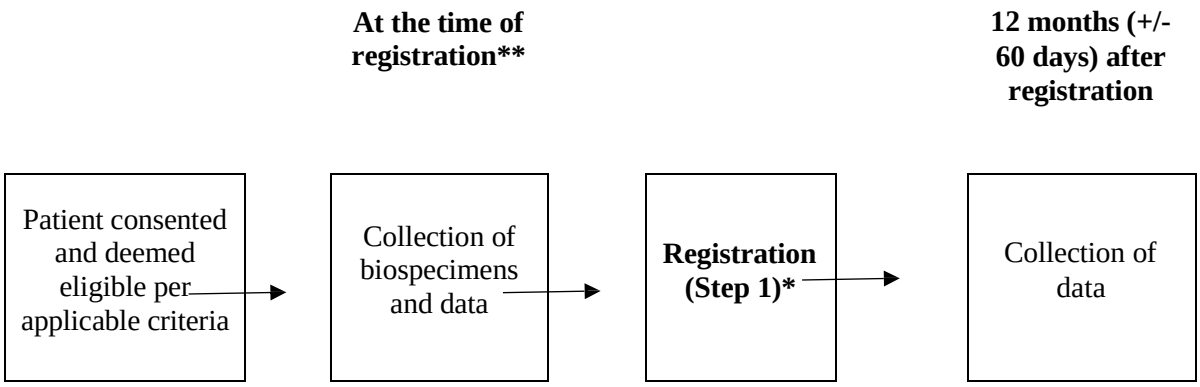
Schema



* Slot reservation required (see Section 4.3).

** For patients with a cancer diagnosis, biospecimens and data should be collected prior to any definitive therapy for the cancer.

3.1 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.2 On-Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient.

Physicians should consider whether any of the following may render the patient inappropriate for this protocol:

- Psychiatric illness which would prevent the patient from giving informed consent. In

addition:

Women and men of reproductive potential should agree to use an appropriate method of birth control throughout their participation in this study as fetal DNA may lead to false positive test results. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives or double barrier method (diaphragm plus condom).

3.3 Eligibility Criteria for Participants with a Cancer Diagnosis

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following page(s).

When calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test were done on a Monday, the Monday one week later would be considered Day 7.

A female of childbearing potential is a sexually mature female who: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 12 consecutive months (i.e., has had menses at any time in the preceding 12 consecutive months).

___ **3.2.1 Documentation of Disease:**

Histologic Documentation: Histologically confirmed diagnosis of invasive cancer

Stage: Stage I-IV per AJCC 7th edition, with the exception of patients with leukemia, lymphoma, and multiple myeloma.

For leukemia: Type (CLL, CML, ALL, AML)

For lymphoma: Stage I-IV based on Ann Arbor staging

For multiple myeloma: Stage I, II, III based on Revised International Staging System (RISS)

___ **One of the following tumor types:**

a) Colorectal
b) Bladder
c) Head and Neck
d) Hepatobiliary
e) Lung
f) Lymphoma
g) Leukemia
h) Ovary*
i) Pancreas*
j) Multiple Myeloma
k) Gastric, esophageal or gastroesophageal
l) Breast
m) Thyroid
n) Kidney*
o) Endometrium
p) Prostate
q) Melanoma*
r) Sarcoma

*For these specific cancer types only, patients may be enrolled prior to histologic confirmation of malignancy. Sites are required to contact the Study Chairs to review appropriateness for enrollment. See Section 4.3.2. Eligibility criteria for these patients are listed in Section 3.4.

___ **3.2.2** No prior definitive systemic or local anti-cancer intervention.

___ **3.2.3** Age ≥ 40 and ≤ 75

___ **3.2.4** No known current pregnancy by self-report

___ **3.2.5** No known or prior history of in situ or invasive malignancy (excluding *in situ* non-melanoma skin cancers) other than the current cancer diagnosis.

___ **3.2.6** Willingness to provide blood samples for research use.

___ **3.2.7** Absence of medical contraindications to a research blood draw volume of 60mL

____ **3.2.8** No history of organ transplantation

____ **3.2.9** Ability to read and comprehend English or Spanish

Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.

3.4 Eligibility Criteria for Participants <u>without a Cancer Diagnosis and without Suspicion of Cancer</u>

____ **3.3.1** Age ≥ 40 and ≤ 75

____ **3.3.2** No known current pregnancy by self-report

____ **3.3.3** No known or prior history of in situ or invasive malignancy (excluding *in situ* non-melanoma skin cancers)

____ **3.3.4** Willingness to provide blood samples for research use

____ **3.3.5** Absence of medical contraindications to a research blood draw volume of 60mL

____ **3.3.6** No history of organ transplantation

____ **3.3.7** Ability to read and comprehend English or Spanish

Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.

3.5 Eligibility Criteria for Participants <u>with a High Suspicion of Cancer</u>

____ **3.4.1** High suspicion of ovarian cancer, pancreatic cancer, kidney cancer, or melanoma by clinical and/or radiological assessment, with plans for histologic or cytologic confirmation within 28 days after study blood draw.

Examples of highly suspicious cases include: elevated CA125 and abnormal transvaginal ultrasound, suspicious renal or pancreatic mass on imaging, suspicious cutaneous lesion concerning for melanoma.

____ **3.4.2** Central review of radiology reports and/or clinical documentation conducted by Study Chairs (see Section 4.3.2).

____ **3.4.3** Age ≥ 40 and ≤ 75

____ **3.4.4** No known current pregnancy by self-report

____ **3.4.5** No known or prior history of in situ or invasive malignancy (excluding *in situ* non-melanoma skin cancers)

____ **3.4.6** Willingness to provide blood samples for research use

____ **3.4.7** Absence of medical contraindications to a research blood draw volume of 60mL

____ **3.4.10** No history of organ transplantation

____ **3.4.11** Ability to read and comprehend English or Spanish

Eligibility is restricted to individuals who can comprehend and read English or Spanish given that participation in the study will require the ability to read and complete questionnaires that are available only in those two languages.