

**HARVARD CANCER CONSORTIUM
POLICIES FOR HUMAN SUBJECT RESEARCH**

TITLE: Subject Registration		
POLICY #: REGIST-101	Page: 1 of 4	Effective Date: 3/26/26

1. POLICY STATEMENT:

For all trials where the NCI mandates accrual reporting under the Cancer Center Support Grant (CCSG), subjects are required to be registered in the OnCore Clinical Trials Management System (CTMS). Registration must occur before the protocol treatment/intervention begins, except as indicated below. The Office of Data Quality (ODQ) must perform centralized randomization for all investigator-sponsored, treatment research protocols, except as indicated below.

2. BACKGROUND:

All cancer-related, hypothesis-driven clinical research studies conducted within the HCC are reported under the CCSG, including interventional, observational, ancillary and correlative research. For CCSG reporting purposes, clinical research includes patient-oriented research, epidemiological and behavioral studies, and health services research. Accrued subjects to CCSG-applicable trials must be registered in OnCore.

3. RESPONSIBLE PERSONNEL:

- 3.1. Principal Investigator (PI)
- 3.2. Sub Investigator
- 3.3. Research Nurse
- 3.4. Study Coordinator
- 3.5. Enrollment Monitor
- 3.6. Research Manager
- 3.7. ODQ staff

4. DEFINITIONS:

- 4.1. **Enrollment Monitor (EM)** – Staff responsible for reviewing the eligibility checklist for completeness and accuracy based on any source data or source documentation used to establish subject eligibility.
- 4.2. **Centralized Randomization** – Refers to the performance of randomization procedures within ODQ as opposed to randomization being performed by the study team or an external collaborator.

Version: 17
Effective Date: 3/26/26
Last Reviewed Date: 3/12/26

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POLICIES FOR HUMAN SUBJECT RESEARCH**

TITLE: Subject Registration		
POLICY #: REGIST-101	Page: 2 of 4	Effective Date: 3/26/26

5. POLICY:

- 5.1. Prior to registration, the PI, or an appropriately delegated research team member, must obtain informed consent from the subject (when required) in accordance with CON-100.
- 5.2. For banking studies, Institutional Review Board (IRB) determined minimal risk protocols, and protocols approved for Summary Accrual reporting (see below), retrospective registrations are allowed; however, registration must occur within 30 days of the date the subject began participating in the research.
- 5.3. Prospective registration in OnCore is required for all other applicable studies (see section 2).
 - 5.3.1. For subjects at HCC institutions using Epic, once informed consent is obtained, a registration record must be created in OnCore with a consented status the same business day.
 - 5.3.2. All subjects must be registered to an on-study status in OnCore once it is determined they are eligible and will participate, and before the protocol treatment/intervention begins.
- 5.4. For registration to external sponsor protocols:
 - 5.4.1. The PI or designated research team member registers the subject with the external sponsor as required, and (if applicable) obtains documentation of the arm/dose level assigned by the sponsor. Sponsor registration must be confirmed prior to moving a subject to on study status in OnCore.
 - 5.4.2. If randomization is required prior to treatment, the subject will be randomized according to the protocol.
- 5.5. The investigator and research team are responsible for ensuring the protocol and all applicable HCC and institutional policies are followed, and that each subject's registration status in OnCore is accurate and up to date.

Version: 17
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**HARVARD CANCER CONSORTIUM
POLICIES FOR HUMAN SUBJECT RESEARCH**

TITLE: Subject Registration		
POLICY #: REGIST-101	Page: 3 of 4	Effective Date: 3/26/26

5.6. **Centralized Randomization** – ODQ must perform centralized randomization for investigator-sponsored, treatment research protocols.

5.6.1. Exception requests:

5.6.1.1. Exceptions allowing randomization to be performed outside of ODQ (e.g., by an external collaborator) for investigator-sponsored treatment protocols must be approved by the ODQ Director in consultation with HCC clinical trials leadership.

5.6.1.2. For other protocol types (e.g., non-treatment) requiring randomization, ODQ may perform centralized randomization procedures, however this must be requested and approved by the ODQ Director.

5.6.2. For subjects enrolled at HCC institutions using Epic, the research team must create the registration in OnCore per 5.3.1. The study team will then notify ODQ when randomization is required per protocol.

5.6.3. Randomization cannot occur outside of normal ODQ business hours (8:30am-5pm EDT).

5.6.4. Following randomization, the research team is responsible for maintaining up-to-date subject status information in OnCore.

5.7. **De-centralized Registration** – Appropriately trained and qualified research personnel will directly register subjects and maintain up-to-date subject status information in OnCore.

5.7.1. When applicable, the designated research team member is responsible for supplying ODQ with copies of source documentation needed for quality control of subject enrollment data in OnCore. ODQ will determine which subjects require quality control review.

5.8. **Summary Accrual Reporting** – For certain non-interventional or pragmatically-designed interventional protocols (e.g., studies that do not recruit individual participants, studies that recruit a large number of participants without collection

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**HARVARD CANCER CONSORTIUM
POLICIES FOR HUMAN SUBJECT RESEARCH**

TITLE: Subject Registration		
POLICY #: REGIST-101	Page: 4 of 4	Effective Date: 3/26/26

of individual identifiers), registration in OnCore may be performed through submission of summary accrual data with the approval of the ODQ Director.

5.8.1. The research team must enter summary accrual data into OnCore at least monthly while the protocol is open to accrual, regardless of the number of accruals each month.

5.9. After Hours Registration – In accordance with institutional policies, the study team registering the subject must identify staff to be available to complete all registration steps outside of business hours, when necessary.

5.9.1. Eligibility determination by the screening staff must occur prior to registration. For after hours registrations only, Enrollment Monitor review must be completed no later than the next business day.

5.9.2. After Hours Registration should occur only when protocol treatment is required after hours on the same day, or next day over a weekend or holiday.

APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 - Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects

6. RELATED REFERENCES:

International Conference on Harmonisation – E6

7. RELATED FORMS & TOOLS:

REGIST-OP-1: Subject Registration Procedures

Version: 17
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