TITLE: Subject Registration		
POLICY #: REGIST-101	**Page:** 1 of 4	**Effective Date:** 1/31/2020

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.

2. BACKGROUND:

All cancer-related, hypothesis-driven clinical research studies conducted within the DF/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. Subinvestigator
3.3. Research Nurse
3.4. Study Coordinator
3.5. Enrollment Monitor
3.6. Research Manager
3.7. ODQ Director
3.8. ODQ Protocol Systems Coordinator

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.

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. Registration must occur before the protocol treatment/intervention begins, not including screening eligibility, and no greater than 30 days prior to the scheduled treatment start date.

5.2.1. For banking studies and Institutional Review Board (IRB) determined minimal risk protocols, retrospective registrations are allowed; however, registration must occur within 30 days of the date the subject provided informed consent.

5.3. For registration to industry-led or cooperative group protocols:

5.3.1. The PI or designated research team member registers the subject at the industry or cooperative group level first, and if applicable, obtains documentation of the dose level assigned by the sponsor.

5.3.2. If randomization is required prior to treatment, the subject will be randomized according to the guidelines specified in the protocol.

5.4. The investigator and research team are responsible for ensuring the protocol and all applicable DF/HCC and institutional policies are followed, and that each subject's registration status in OnCore is accurate and up to date.

5.5. **Centralized Registration** – Initial registration will be performed by ODQ for investigator-sponsored research randomized by ODQ, or when requested and approved by the ODQ Director. Following initial registration, appropriately trained and qualified research personnel are responsible for maintaining up-to-date subject status information in OnCore.

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

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

5.6.1. 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.

5.7. **Summary Accrual Reporting** – For certain non-interventional protocols (e.g., recruiting subjects that are not patients at DF/HCC member institutions, secondary use research, when mandatory OnCore data elements are not collected per protocol—initials, date of birth), registration in OnCore may be performed through submission of summary accrual data with the approval of the ODQ Director.

5.7.1. 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.

5.8. **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.

5.8.1. 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.

5.8.2. 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