TITLE: ~~Decentralized~~ Subject Registration		
POLICY #: REGIST-~~101B~~101	**Page:** 1 of 6	**Effective Date:** ~~2/28/17~~

1. POLICY STATEMENT~~:~~:

For all trials where the NCI mandates accrual reporting under the Cancer Center Support Grant (CCSG),
~~The decentralized subject registration process allows study teams to directly register~~ 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 ~~outlined~~indicated below.

Commented [FNR1]: Combined REGIST-101A and 101B. Moved process steps to Operation. Added language to allow summary accrual reporting in limited situations, as well as language stating the study team's responsibility for updating subject information in OnCore for randomized trials where the initial registration/randomization is performed centrally by ODQ.

2. BACKGROUND:

~~Study staff must consult with their Research Managers for any clarification on the appropriate subject registration process to be followed for a given study.~~

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. Overall Principal Investigator (PI)
3.2. Site Responsible Investigator
3.3. Sub Investigator
3.4. Research Nurse
3.5. Study Coordinator
3.6. Enrollment Monitor
3.7. Research Manager
3.8. Office of Data Quality (ODQ) Director
3.9. ODQ Clinical Research Systems Coordinator

4. DEFINITIONS:

4.1. **Enrollment Monitor (EM)** – Staff responsible for reviewing the eligibility checklist for completeness~~,~~ and accuracy ~~and verifying eligibility determination~~

~~using~~based on any source data or source documentation used to establish subject eligibility.

5. POLICY:

5.1. ~~The~~ Prior to registration, the Overall PI, or an appropriately ~~designated~~delegated research team member ~~obtains~~, must obtain informed consent from the subject~~,~~ (when required) in accordance with CON-100.

~~5.1.1.1.1.1. The subject is screened to determine eligibility to participate in the research and the eligibility checklist is completed, in accordance with REGIST-104.~~

~~5.1.2. If not otherwise specified in the protocol, all laboratory tests must be completed within 14 days prior to the date of registration. Diagnostic tests, such as MRIs and CT scans, must be performed within 30 days of the date of registration.~~

~~5.1.3. For BMT protocols, if not otherwise specified in the protocol, all eligibility tests must be completed within 42 days of registration.~~

~~5.2. For sponsor or cooperative group initiated studies: The Overall PI or designated research team member must register an eligible subject with the sponsor or cooperative group, if applicable.~~

~~5.2.1. Subject registration with the sponsor or cooperative group may occur once the subject has been determined as eligible by a clinical member of the research team, but while the Enrollment Monitor is performing their source documentation review.~~

~~5.2.2. Documentation of the sponsor assigned treatment must be available prior to the start of treatment.~~

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.

~~5.2.3.~~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 Overall PI or designated research team member ~~registering~~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 ~~the treatment~~each subject's registration status in OnCore is accurate and up to date.

~~5.3.~~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 ~~matches the treatment assignment recorded on the eligibility checklist.~~ .

~~5.3.1. If there is any change to the treatment being administered (example: an escalated dose, crossover to another treatment arm, etc.), the designated research team member is also responsible for updating a subject's record to reflect this change.~~

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~~5.4. The designated research team member registering the subject must verify the success of the subject registration in all DF/HCC systems, to ensure that treatment orders may be processed.~~

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.

~~5.4.1.~~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.

~~5.4.2. The minimum documents that must be submitted to ODQ are:~~

- ~~Completed Informed Consent Form (ICF);~~
- ~~Completed Eligibility Checklist;~~
- ~~Confirmation of the subject registration provided by an external sponsor, if applicable.~~

~~5.4.3. ODQ may request additional documentation from the study team if needed to verify a subject's eligibility and/or the accuracy of data in OnCore.~~

5.7. ~~For~~ **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.

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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.

~~5.5.~~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 ~~the above~~ registration steps ~~in order for registration to occur~~ outside of business hours, when necessary.

~~5.5.1.~~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 ~~as per institutional practice and~~ no later than the next business day.

~~5.5.2.~~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 ~~QC of~~RESOURCES:

REGIST-OP-1: Subject ~~Enrollment Data for OnCore~~Registration Procedures

~~7. RELATED RESOURCES:~~

~~None~~

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