

## HCC Operations for Human Research Subject Registration Procedures

### 1. BACKGROUND:

This document outlines the appropriate procedures for subject registration and other registration situations that may arise. To quickly locate a specific topic, please use the hyperlinks below:

|                                                          |                                                                   |
|----------------------------------------------------------|-------------------------------------------------------------------|
| <a href="#">Registration at Institutions using Epic</a>  | <a href="#">Updating Subject Status (Off-Treatment/Off-Study)</a> |
| <a href="#">Subject Registration (De-centralized)</a>    | <a href="#">Co-Enrollment to Multiple Protocols</a>               |
| <a href="#">Centralized Registration</a>                 | <a href="#">Re-registration to the Same Protocol</a>              |
| <a href="#">External Site Subject Registration</a>       | <a href="#">Subject Transfers between Sites</a>                   |
| <a href="#">Procedures for Summary Accrual Reporting</a> | <a href="#">Subject Replacement</a>                               |

### 2. ASSOCIATED HCC POLICIES:

#### 2.1. [REGIST-101](#)

### 3. PROCEDURE:

#### 3.1. Registration at institutions using Epic:

- 3.1.1. Once informed consent is obtained, the registering person will enter the subject into OnCore on the Consent Tab.
- 3.1.2. The study team is responsible for updating OnCore (or notifying The Office of Data Quality (ODQ) for Centralized Registration protocols) should the subject later be determined ineligible.
- 3.1.3. If a subject is determined to be ‘Eligible’, the applicable registration process below is followed to place the subject ‘On study and ‘On treatment’ in OnCore.

#### 3.2. Subject Registration (De-centralized)

- 3.2.1. The designated research team member registering the subject is responsible for ensuring that the treatment information in OnCore matches the treatment assignment recorded on the eligibility checklist.
- 3.2.2. 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.
- 3.2.3. The designated research team member registering the subject must verify the success of the subject registration in all HCC systems, to ensure that treatment orders may be processed.

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- 3.2.4. Research teams are responsible for maintaining subject status information in OnCore when participants come Off Treatment and Off Study. If this is not updated in a timely manner, subjects may be blocked from enrolling on other clinical trials at any other HCC member institution.

### 3.3. Centralized Registration

- 3.3.1. REGIST-101 specifies when Centralized Registration must be used. The PI or designated research team member provides the completed eligibility checklist and all pages of the informed consent document to ODQ. For protocols without eligibility checklists (see REGIST-100), a [Protocol Registration Form](#) must accompany the signed subject consent form.
- 3.3.2. When ODQ receives the registration materials, the documents are reviewed to ensure that all fields are complete and that all values are within the acceptable range allowed by the protocol. If any information is missing, the ODQ Clinical Research Systems Specialist contacts the PI or designated research team member.
- 3.3.3. The ODQ Clinical Research Systems Specialist verifies the following to assure that a new subject should be registered to the protocol: the status of the protocol, the accrual level, and that the subject is being registered to an open arm or blinded arm.
- 3.3.4. The ODQ Clinical Research Systems Specialist is responsible for randomizing subjects to treatment arms for investigator-sponsored research:
- 3.3.4.1. The statistician in the Department of Biostatistics and Computational Biology provides ODQ with any necessary randomization sheets and instructions specific to the protocol.
- 3.3.5. Once all of the registration documents have been received, the ODQ Clinical Research Systems Specialist registers the subject in OnCore. Protocol registration and confirmation is required before protocol orders can be written.
- 3.3.6. For non-blinded protocols: The ODQ Clinical Research Systems Specialist documents the randomization assignment in OnCore. For blinded protocols: The ODQ Clinical Research Systems Specialist enters a Blind (BLD) Arm in OnCore and then conveys the randomization assignment to the appropriate departments as directed by the randomization instructions.
- 3.3.7. OnCore auto-generates an electronic confirmation of registration which is automatically sent to the Registering Person, Treating Physician, Lead Study Coordinator, Research Manager, Study Coordinator, and Sub-site Lead Study Coordinator as applicable. A helpdesk ticket to RIO is required to add any additional staff role as a customized recipient on a case-by-case basis. Hard copies may be regenerated by navigating to the Reports Section in OnCore (see guidance within the [OnCore WIKI](#)).

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### 3.4. External Site Subject Registration

- 3.4.1. External site subjects are only registered in OnCore for HCC Investigator-sponsored research.
- 3.4.2. External site subjects are registered by research staff at the HCC Coordinating Center. Research staff are only able to register external site subjects in OnCore once they have completed additional OnCore training on the external site registration process. Users must email the site contact designated on the [HCC New Research Staff Checklist](#) to request OnCore user access to the external sites and be assigned any necessary training.
- 3.4.3. External sites must be added to OnCore and activated prior to the registration of any subjects to the site. Please refer to guidance within the [iRIS WIKI](#) on submitting an add-site amendment.
- 3.4.4. The HCC Coordinating Center is responsible for ensuring external site subjects are registered in OnCore as required. The Coordinating Center will ensure external sites have a copy of the HCC External Site Subject Registration form and understand subject registration procedures. The Coordinating Center may opt to provide additional registration tools (e.g., a checklist of source documentation to be submitted) to external sites.
- 3.4.5. The external site study team is responsible for consenting and screening their local subjects. An appropriately qualified member of the research team at the external site will complete the HCC [External Site Subject Registration Form](#). The completed form, along with any additional documentation indicated in the protocol, will be submitted by the external site to the Coordinating Center.
- 3.4.6. The [OnCore WIKI](#) contains specific data entry steps for registering external site participants. The Coordinating Center is responsible for ensuring that these steps are followed and data entry is accurate. The HCC Coordinating Center will notify the external site once registration has occurred.

### 3.5. Procedures for Summary Accrual Reporting

- 3.5.1. REGIST-101 specifies the requirements for use of the summary accrual functionality. Once the decision is made to use summary accrual, and accrual data has been entered into OnCore, a protocol cannot revert to individual subject registration. Protocols using summary accrual are identified by a “Yes” in the “Summary Accrual Info Only” field in OnCore (Main > Details).
- 3.5.2. Summary accrual information must be entered into OnCore at least monthly while the protocol is open to accrual, regardless of the number of subjects accrued. Each combination of institution/gender/race/ethnicity must be entered as a separate row.
  - 3.5.2.1. If no subjects were accrued during a certain time period, the research team must enter at least one row of zero accrual (gender, race, ethnicity can be set to Unknown in this case). This is

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necessary to verify that all accruals are being captured in a timely manner.

3.5.3. To enter summary accrual in OnCore, follow the steps below:

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. In the PC Console, enter the Protocol number and go to the Accrual section.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2. Click Update and enter the following data fields: <ul style="list-style-type: none"> <li>a. From date: Date of first accrual</li> <li>b. Through date: Date of last accrual</li> <li>c. Accrual: Total number of accruals within the above timeframe for the selected combination of institution/gender/race/ethnicity</li> <li>d. *Institution: Select the institution responsible for accruing subjects.</li> <li>e. *Institution type: Automatically populates based on chosen institution</li> <li>f. *Gender: If known, select male or female</li> <li>g. *Race: If known, select the appropriate race</li> <li>h. *Ethnicity: If known, select the appropriate ethnicity</li> </ul> |
| 3. Click Add                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4. Repeat the steps above for each group of accruals. Previous entries can be copied or edited as necessary.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

\* Required field

### 3.6. Updating Subject Status

3.6.1. A subject's OnCore registration must be updated immediately to reflect a change to the subject's status when the subject has reached the end of a protocol intervention/treatment phase (Off-Treatment), or when the subject has concluded participation on the protocol/reached the end of a protocol follow-up phase (Off-Study).

3.6.2. The Off-Treatment Date is the date a decision was made to discontinue protocol treatment (or the end of the treatment phase if otherwise defined in the protocol). The Off-Study Date is entered as the last date the patient was being followed on protocol or Date of Death.

### 3.7. Co-Enrollment to Multiple Treatment Protocols

3.7.1. The investigator and research team are responsible for assessing the clinical and/or safety implications of allowing co-enrollment and ensuring the protocol and all applicable HCC and institutional policies are followed.

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- 3.7.2. OnCore prevents a subject from being active on more than one protocol that has the ‘Involves Therapy’ field set to ‘Yes’. ODQ maintains the ‘Involves Therapy’ field as a safety mechanism.
- 3.7.3. To concurrently enroll a subject on two treatment protocols (or a treatment protocol and a BMT Treatment Plan), the PIs of both protocols/treatment plans must agree and provide written approval to ODQ. Email is acceptable. Send to: [ODQ@dfci.harvard.edu](mailto:ODQ@dfci.harvard.edu).
- 3.7.3.1. In some cases, the PI(s) may provide blanket approval to allow co-enrollment of future subjects to a specific combination of protocols/treatment plans. In this case, ODQ will enter a notation in the applicable protocol record in OnCore.
- 3.7.3.2. Upon receipt of the required approvals, ODQ will perform a temporary toggling of the ‘Involves Therapy’ field to allow the second registration to proceed. ODQ will immediately return the ‘Involves Therapy’ field to ‘Yes’ to ensure this safety mechanism is in place for future enrollments.

### 3.8. Re-registration of a Subject to a Protocol

- 3.8.1. By default, OnCore will not allow duplicate registration of a subject to the same protocol. ODQ is responsible for setting the ‘Allow Duplicate Enrollment?’ field.
- 3.8.2. Ultimately, the investigator and research team are responsible for ensuring the protocol and all applicable HCC and institutional policies are followed. While ODQ may facilitate this process with the proper approvals, ODQ will not independently assess the clinical and/or safety implications of allowing re-registration.
- 3.8.3. To re-register a subject to the same protocol, written approval from the PI and Sponsor must be provided to ODQ. Email is acceptable. The protocol should also provide appropriate language that a subject may be re-enrolled, or prospective IRB approval must be obtained.
- 3.8.4. Upon receipt of the required approvals, ODQ will toggle the ‘Allow Duplicate Enrollment?’ field.

### 3.9. Transfer of a Subject Between Institutions/Sites

- 3.9.1. Subject transfers can occur when another IRB-approved institution accepts responsibility for the care of that subject in the conduct of a clinical trial. Details of a subject transfer to or from an external (non-HCC) institution or within HCC institutions must be recorded on the [Subject Transfer Form](#).

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3.9.2. A subject transfer, for protocol procedures or follow-up, is allowed only if the following criteria are met:

- Both institutions have received Institutional Review Board (IRB) approval for the protocol.
- The sponsor has approved the arrangement (as applicable).
- The Treating Physicians at the accepting and receiving institutions approve the arrangement.
- All appropriate documentation requested by the receiving institution has been transferred by the original institution (including any relevant research records and the completed Subject Transfer Form).

3.9.3. When an HCC institution is receiving the transferred subject, the receiving institution will request copies of relevant medical and research records from the original institution, as well as a copy of the informed consent document signed by the subject. The original institution is responsible for submitting all available data required by the protocol up to the date of transfer. The receiving institution is responsible for all subsequent data entry and follow up.

3.9.4. When an HCC institution is receiving the transferred subject from a non-HCC site, the subject must sign a copy of the most current IRB-approved informed consent document available on the Oncology Protocol System (OncPro) and be registered in OnCore prior to the start of research activities at the receiving institution.

3.9.4.1. For subjects that are registered with the sponsor and have begun receiving protocol treatment, it is not necessary to complete the HCC eligibility checklist or re-assess eligibility unless otherwise required per protocol.

3.9.5. ODQ is responsible for completing all fields in OnCore related to subject transfers. The designated research team at any involved HCC institution(s) (e.g., the original institution, accepting institution, or lead site) is responsible for contacting ODQ at [ODQ@dfci.harvard.edu](mailto:ODQ@dfci.harvard.edu) and providing 1) the completed Subject Transfer Form and 2) a signed HCC Consent (as applicable).

3.9.5.1. Study teams with extensive experience entering subject transfer information in OnCore may continue to complete fields in OnCore related to subject transfers. ODQ can assist with quality checking the transfer entry if needed.

3.9.5.2. It is sometimes necessary to temporarily reopen the protocol to accrual if an external site subject is transferred to an HCC site. ODQ may temporarily reopen the protocol and then immediately close it once the transfer is completed.

### 3.10. Subject Replacement

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- 3.10.1. Subject replacement occurs when a subject registered to the protocol is determined to be unevaluable, and a decision is made to enroll a different subject in their place (i.e., to replace the unevaluable subject's "slot").
- 3.10.2. The sponsor must approve all subject replacements (as applicable). For HCC Investigator-sponsored trials, approval from the protocol biostatistician is also required.
- 3.10.3. If the protocol specifically **allows** for subject replacement, follow the procedures outlined in the table below:

| Study team action                                                                                                                                                                               | ODQ Action                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Submit a subject replacement request at:<br><br><a href="https://dfci.quickbase.com/db/bqcs36csz?a=nwr&amp;originalQid=td">https://dfci.quickbase.com/db/bqcs36csz?a=nwr&amp;originalQid=td</a> | Approves the request or contacts the study team for further information as needed. When the request is approved, increases accrual # by (x) in OnCore, and updates protocol status as applicable in OnCore to allow for the subject replacement registration. |
| After receiving ODQ approval, register the subject in OnCore.                                                                                                                                   | For HCC, PI-initiated randomized trials only, registers the subject in OnCore.                                                                                                                                                                                |

- 3.10.4. If the protocol **does not allow** for subject replacement, follow the procedures outlined in the table below:

| Study team action                                                                                                                                                                                                                                                                                                                    | ODQ Action                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Submit an amendment via iRIS to increase accrual by (x) or add language to the protocol to specifically allow replacements.<br><u>Note: Consider submitting an amendment to update any subject replacement language in the protocol, especially if the team believes that there may be multiple subject replacement occurrences.</u> | Reviews and activates the amendment once approved. Updates protocol status at activation, when necessary.<br>(ODQ will update the Accrual goal in OnCore). |

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|                                                             |                                                                                |
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| After amendment activation, register the subject in OnCore. | For HCC, PI-initiated randomized trials only, registers the subject in OnCore. |
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