Participant Protocol Registration

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SOP #: ADCR-2	**Next Review Date: 06/2012**
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Purpose: To identify the steps to register a participant on a CCR protocol with the Central Registration Office (CRO).

STEP 1: Access the CCR Central Registration Office (CRO) Homepage

1. Enter the following URL in a browser (Internet Explorer or Firefox) to access the CCR Central Registration Office homepage: http://intranet.cancer.gov/ccr/welcome.htm. For assistance, call the Central Registration Office Help Line at 301-402-1732 or email NCI Central Registration Office at ncicentralregistration-1@mail.nih.gov. CRO hours of operations: 8:30am-5:00pm, Monday-Friday
    - For registrations after hours, the registration will not be processed until the following business day.
    - **Note:** *Not for "Special Exemption" protocols*.

STEP 2: Click on Branch to Access an Index of Open Protocols per Branch

1. Click on the desired protocol number to access the *Protocol Registration*form.
    - The protocol registration form includes the participant demographic information and the protocol eligibility criteria questions.
    - Special Exemption protocol registration is accessed here.

STEP 3: Complete the Protocol Registration Form

1. Verify the protocol accrual ceiling has not been reached.
2. Print a copy of the *Protocol Registration* form and complete form.
   OR
   Open the *Protocol Registration*form, complete online, and print.
    - All responses must be complete and accurate for the registration to be processed by the CRO Staff.
    - Signature on *Protocol Registration* form by team signifies that the information has been verified by the team member.
    - Registration should occur within one business day of the participant signing the informed consent document.
    - If registering a participant from an institution other than the NCI, list the name of the registering institution in the Patient Information section.

STEP 4: Fax the Completed Protocol Registration Form to the NCI Central Registration Office

1. Fax the *Protocol Registration*form to the Central Registration Office.
    - Fax number: 301-480-0757
    - Any faxes received by the Central Registration Office after 5:00pm will be processed the next business day.

STEP 5: Review of Protocol Registration Form for Completeness and Accuracy

1. The CRO will review the *Protocol Registration* form for completeness and accuracy.
2. If the *Protocol Registration* form is complete and accurate, the Clinical Center pharmacy will be informed of the registration by the CRO for NCI patients and drug will be released.
3. If the *Protocol Registration* form is incomplete or inaccurate, the CRO will contact the team member to resolve the issue(s). The Pharmacy will **not** be notified of registration until the issues are resolved. No drug will be released until that time.
   Note: *The Clinical Center pharmacy will only be contacted for NCI patients on treatment studies.*

STEP 6: Confirmation of Registration Will Be Sent to the Study Team Member

1. A confirmation e-mail including *Verification of Registration* form, will be sent to the team member who registered the patient acknowledging the patient has been registered and the Clinical Center pharmacy has been informed.
2. Multi-Institutional Studies where the CCR is the Coordinating Center: When patients are directly registered with the CRO by outside sites, the site will be sent a confirmation email. The sites will be responsible for informing their pharmacies.
3. **Randomized Studies**: The randomized treatment assignment will be provided on the *Verification of Registration form.*
4. **Masked studies**: The sequence number will be provided on the *Verification of Registration* form.