SOP#: ADGC-7	**Treatment and Follow-up by Center for Cancer Research Providers**
Version #: 1.0	**Next Review Date: 08/2026**
Approved Date: 08/2024	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James L. Gulley -S Digitally signed by James L. Gulley -S Date: 2024.08.01 17:40:06 -04'00'

POLICY

All individuals seen at the NIH Clinical Center are required to enroll on research protocol in order to be seen and/or receive care at the institution. On occasion, it is in the best interest of both the individual and the Center for Cancer Research (CCR) to provide treatment and/or follow-up to the individual. Protocol 04-C-0165, *Data Collection, Clinical Care and Interventions in CCR, NCI,* allows the NCI a mechanism to provide treatment and medical follow-up for patients. This protocol has 4 cohorts and the appropriate cohort for these individuals is cohort 2.

Prior approval from the CCR Office of the Clinical Director will be required for all individuals to receive treatment or follow up care on 04-C-0165. Failure to acquire approval may result in the PI being charged for associated costs for travel, drugs, etc. in addition to discussions on future use of the protocol by that PI. If approved, the individual must have a CRIS Medical Record Number, be consented to protocol 04-C-0165 and be registered in the CCR Protocol Registration and Enrollment System (PRES).

If the individual was initially enrolled to 04-C-0165 under the consultation cohort (see SOP ADGC-2: *Consultation by Center for Cancer Research Providers*) and transitions to the treatment/follow-up cohort, use the Crossover Event of Significance in PRES and select arm 2.

PURPOSE

To provide guidance to investigators when treatment or follow up care is requested by a CCR provider for individuals who are not currently on a CCR protocol.

RESOURCES

- Protocol 04-C-0165: for current version, see the Clinical Center's PROTRAK Query System (PQS)
- CCR Policies/Standard Operating Procedures (SOPs) website
  - ADCR-2: *CCR Participant Registration and Status Updates*
  - ADGC-2: *Consultation by Center for Cancer Research Providers*
  - PM-2: *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric) – General Information* and applicable sub-SOPs
- NIH Clinical Center MAS Policies website
  - M93-9: *Provision of Care at the Clinical Center*
  - M11-2: *Policy for Safe Prescribing of Chemotherapy/Biotherapy Agents for Malignancy, Conditioning and Graft vs. Host Disease*
- NIH CC Consent Forms, also found in iMEDConsent

PROCEDURES

STEP 1: Request Approval for Treatment/Follow up

- If a CCR provider would like to provide treatment or follow up (i.e., post study participation) to an individual according to medical care guidelines, approval must be granted from the Office of the Clinical Director (OCD).
- Requests for approval must be submitted using the exception request form. Select "Use of 04-C-0165" for question number four (4) of the form.
- If an individual initially enrolled to 04-C-0165 under the consultation cohort and didn't meet the criteria to be removed from the protocol but now will be needing treatment, prior approval from the OCD is still required.

STEP 2: After OCD approval, obtain Informed Consent (if not already currently enrolled on 04-C-0165)

- All individuals who receive, or will be receiving, medical care or follow up must be consented to protocol 04-C-0165 AND, if appropriate, be consented to the treatment/procedure per Step 3 below PRIOR to receiving treatment or follow up care.
- Document the informed consent process in CRIS using the Documentation of Research Consent structured note.
- Document in CRIS that the individual is being enrolled for treatment or follow up and the anticipated plan of care.

STEP 3: Obtain Consent for Treatment/Procedure

- Obtain consent for either chemotherapy/biotherapy, radiation therapy, surgery or other procedure (e.g., LP, BM biopsy, blood products) or other appropriate procedure consent (iMedConsent or paper form). For example:
  - *Consent to Chemotherapy/Biotherapy* (Form NIH-3005)
  - *Consent for Standard Radiation Therapy Treatment* (Form NIH-2935*)* – also available in Spanish
  - *Request for Administration of Anesthesia and for Performance of Operations and Other Procedures* (Form NIH-2626)
- The above and other procedure consents can be found at NIH CC Consent Forms, also found in iMED.

STEP 4: Documentation

- All interactions with the patient must be documented in CRIS. For chemotherapy or biotherapy, please use the chemo/bio structured note.

STEP 5: Register Patient in PRES

- Within 2 business days of 04-CC-0165, register in PRES - see SOP ADCR-2: *CCR Participant Registration and Status Updates*.
- Select the Treatment Cohort (2) when registering in PRES. However, if the patient is crossing over from the consult cohort to the treatment cohort, use the Crossover Event of Significance in PRES and then select Arm 2 for the crossover.