SOP#: ADGC-2	**Consultation by Center for Cancer Research Providers**
Version #: 1.0	**Next Review Date: 02/2026**
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NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.02.14 09:19:38 -05'00'

POLICY

On occasion, it is in the best interest of both an individual patient and the Center for Cancer Research (CCR) to provide consultation services, either in-person or remotely (e.g., telephone, telehealth platform). This consultation results in providing the patient with recommendations for care or confirmation of an existing treatment plan.

All individuals who receive a consultation by a CCR provider must first be enrolled on protocol 04-C-0165. For an in-person consultation, this protocol allows for routine clinical procedures for evaluation of their disease (e.g., bloodwork, pathology review and/or radiology review).

Note: This does not apply to consultations ordered in CRIS for individuals on another Institute/Center's protocol.

PURPOSE

To provide guidance to investigators when consultations are requested of CCR providers for individuals who are not currently on an NIH IRP protocol and have a consultation order in CRIS.

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*
  - ADCR-13: *Clinical Center External Location Registration*
  - PM-2: *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric)*

PROCEDURES

STEP 1: Ensure CRIS Medical Record Number

- All individuals who receive a consultation by a CCR provider must be a Clinical Center patient and have a CRIS Medical Record Number. See SOP ADCR-13: *Clinical Center External Location Registration* for more information on obtaining a medical record number.

STEP 2: Obtain Informed Consent

- All individuals who receive a consultation by a CCR provider must be consented to protocol 04-C-0165 PRIOR to any consultation discussion – see SOP PM-2: *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric).* Document the informed consent process in CRIS.
- After the consent has been signed by the individual and the consenting investigator, proceed with consultation.

STEP 3: Documentation of Consult

- After the consultation, the CCR provider will document the consultation in CRIS using the "Outpatient First Registration Note." The mandatory sections of the note (i.e., starred sections of the note) must be completed, but optional sections are up to the discretion of the consulting provider.
- If a fellow or trainee provides the consultation, the case should be discussed and evaluated with a member of the junior or senior medical staff who are required to countersign the note.

STEP 4: Register Individual in PRES

- See SOP ADCR-2: *CCR Participant Registration and Status Updates*
- Select the Consult Cohort when registering in PRES.