# Monday Morning Practice Pearls # 64

## When is it appropriate to enroll an individual onto protocol 04C0165?

Protocol 04C0165 can be used to provide consult, treatment, and medical follow-up for patients, including genetic education and counseling as well as cell/marrow donors to NCI patients and other individuals needed to be seen within the CCR.

It is Clinical Center policy that all individuals being seen or treated are enrolled on a protocol. This protocol will also allow for a repository of information on enrolled participants to allow for hypothesis generation for future research ideas.

## There are 4 cohorts for this study. How do I know which cohort to use and when?

| Cohort Name | Description | When to Use |
|---|---|---|
| 1-Consults | Patients being seen as a consult and undergo evaluations for their disease, including second opinions. These evaluations are those that are required for the routine diagnosis, work-up, and clinical and supportive care of the participant, and may include standard pathologic review and confirmation testing. | • Request to see a patient for a second opinion or to provide information about potential clinical trials at the CCR<br>• Request from an outside provider to consult on a patient including record review and meeting with the patient either in person or remotely<br>• **Not to be used to screen for a clinical trial** |
| 2-Patients<br><br>**NOTE**: Enrollment to this cohort **MUST** be pre-approved by the OCD using the exception request form **BEFORE** consenting to the protocol. | Patients being enrolled for treatment or follow-up of their disease according to the guidelines of medical care. | • Patient needs bridging cancer treatment while waiting for enrollment onto a protocol<br>• Patient needs oncologic routine and standard medical care following established guidelines<br>• Patient previously enrolled on a protocol but needs to have disease follow-up when returning to a community provider is not feasible<br>• DO NOT use if patient is not eligible for a clinical trial but you will follow an existing intervention protocol schema |
| 3-Donors | Individuals being seen to obtain cell products for transplant donation. Further clinical use of these products is also permitted, such as determination of donor chimerism. | • Used to obtain cell/bone marrow from transplant donors using routine care collection procedures<br>• Should not be used if any research will be conducted on the donor or products. The donor will need to enroll on the research protocol |
| 4-Genetic Follow-up | Individuals previously enrolled on a protocol in which genomic research analysis identified a clinically actionable | • This cohort will be typically used by the CCR genetic consultation service |

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| | germline pathogenic or likely pathogenic gene variant will be offered CLIA confirmation. The same may be offered to biologic family members where genomic research analysis identified a clinically actionable germline pathogenic or likely pathogenic gene variant in a deceased participant previously enrolled on a protocol. | |

## There are 2 arms for this study – see CCR SOP ADGC-7. How do I know which arm to use and when?

There is one main arm for this study which applies to all participants. However, if a participant transitions from the consult cohort, Cohort 1, to the Patient cohort, Cohort 2, please use the Crossover Event of Significance in PRES. You can then select Arm 2 for the crossover.

## Do I have to take the individual off 04C0165?

YES. All participants who meet the off-study criteria MUST be taken off study in PRES. Off study reasons include:

- Participant completes consult and recommendations provided
- Participant completes treatment, follow-up and/or returns to the care of their local provider
- Participant completes genetic testing and counseling
- Donor completes donation process and follow-up care
- Participant decision to discontinue participation
- Principal Investigator/provider discretion
- Death

## Associated SOPS:

- ADGC-2 *Consultation by Center for Cancer Research Providers*
- ADGC-7 *Treatment and Follow-up by Center for Cancer Research Providers*

## REMINDERS:

- For treatment cohort: (See SOP ADGC-7)
  - Enrollment **MUST** be pre-approved by the OCD using the exception request form **BEFORE** consenting to the protocol.
  - All appropriate treatment/procedure consent(s) needs to be signed prior to the intervention/procedure.
- Document the reason in CRIS for enrollment to 04C0165 regardless of cohort:
  - Patient being seen as consult.
  - Patient being enrolled for treatment or follow-up.
  - Donors of cellular/marrow products.
  - Patient requiring a genetic consultation and/or CLIA confirmation based on known/suspected genetic mutation.