Monday Morning Practice Pearls # 64

When is it appropriate to enroll the participant onto protocol 04C0165?

The protocol 04C0165 can be used I to provide consult services, treatment/interventions and/or follow-up to an individual, as well as to individuals (e.g., transplant donors) that are essential to the care of CCR patients.

It is Clinical Center policy that all individuals being seen or treated be enrolled on a protocol. This protocol provides the administrative vehicle to care for patients and healthy volunteers in the intramural research program.

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

Cohort Name	Description	When to Use
Consults	Patients being seen as a consult	• Request to see a patient for a second opinion • Request from another NIH staff member to consult on a patient
Patients	Patients being enrolled for treatment or follow-up of their disease	• Patient needs non-oncologic, supportive treatment while waiting for enrollment onto a protocol • Patient needs oncologic standard of care treatment (i.e., in medical guidelines) • Patient previously enrolled on a protocol but needs to have disease follow-up when returning to the community is not feasible • Should **not** be used if patient is not eligible for a clinical trial but you will follow the intervention protocol schema to treat the patient
Donors	Donors of cellular products	• Used to obtain cell products from transplant donors **Note:** Any research use of the cell products or any deviation from standard of care collection procedures will require enrollment in a research protocol
Genetic Follow-up	Individuals with a known/suspected germline genomic research incidental pathogenic or likely pathogenic variant, and/or who require CLIA confirmation	• This cohort will be typically used by the CCR genetic consultation service • Patient enrolled on a protocol where a clinically actionable genomic finding is identified at a later time

Do I have to take the patient or healthy volunteer off 04C0165?

Yes. All participants who meet the off study criteria must be taken off study in PRES. Off study reasons include:

- The patient refuses to continue participation.
- The patient is returned to the care of their local physician.
- The Principal Investigator and patient decide that continuing care is not in the patient and NCI's best interest.

REMINDERS:

- Do not administer any investigational therapies under this protocol.
- Document the justification for safety and plan for safety assessments if the patient is going to receive the standard of care treatment under the protocol.
- Document the reason for enrollment per protocol cohorts:
  - Patient being seen as consult.
  - Patient being enrolled for treatment or follow-up.
  - Donors of cellular products.
  - Patient requiring a genetic consultation and/or CLIA confirmation based on known/suspected genetic mutation.