Monday Morning Practice Pearls # 63

When is it appropriate to enroll the participant onto protocol 01C0129?

The screening protocol (01C0129) is used when screening a patient or healthy volunteer to determine eligibility for enrolling on a primary intervention protocol.

The screening protocol is NOT to be used for a consult or to see a patient for a second opinion.

> *Note:* The procedures/tests used to evaluate eligibility for an intervention protocol are performed in the context of a research protocol, and therefore they could be considered research.

What screening procedures can be done under 01C0129?

The procedures that can be done are directed by the intervention protocol for which the individual is being screened. Please refer to the table in the screening protocol (01C0129) to determine what tests/procedures can be conducted for all adults, adults unable to consent, pregnant women and minors.

What if the participant is undergoing a procedure for screening (e.g., bone marrow aspiration) and the same procedure is needed for a baseline test on the primary intervention protocol?

Specific research samples required for the primary intervention protocol may be collected on the screening protocol to avoid repeating potentially painful tests again at baseline. Analysis will not be done unless deemed eligible for the primary intervention protocol and the participant has consented to participate in the primary protocol.

Do I have to take the patient or healthy volunteer off 01C0129?

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

- The patient or healthy volunteer is unwilling or unable to complete the protocol.
- At discretion of the responsible treating physician.
- The patient or healthy volunteer completes screening procedures and either enrolls onto another NIH study or is returned to the care of their local physician.
- A healthy volunteer becomes incapacitated or cognitively impaired during the screening process.
- Death

REMINDERS:

- Document in CRIS:
  - Reason for enrollment
  - Protocol(s) for which the participant is being screened
- Examples of *inappropriate* documentation for enrollment reason:

  "Clinical trial discussion", "Consultation", "Discuss study *X* enrollment", "for work up of *Y* associated conditions", "Evaluation for surgical biopsy", "Second opinion", "To discuss treatment options for untreated *Z* disease".