

## Concept Stage

At the time of concept submission, please make sure the following items are included if this study will encompass the AYA (Adolescent and Young Adult) age range.

- Clearly list the one responsible NCTN Group on Concept.

Since only one NCTN group can be listed as the lead group, responsible for coordinating the study, a list of “champions”/ vice chairs from the other NCTN groups including COG (if not leading the trial) can be included in the cover memo that accompanies the concept. Investigators should note that if not included with the cover memo, the names of the individuals as “champions” **must** be included at the time of protocol submission to CTEP.

Concept PI may want to consider including one vice chair from another NCTN Group, such as an adult Group inviting a COG vice-chair or COG PI inviting one adult NCTN Group vice chair at the concept stage. Then, if the concept is approved, include study champions from all the other Groups for protocol development. This step-wise inclusion of collaborators may avoid having too many conflicted Group reviewers at the time of the Scientific Steering Committee concept review.

- If COG is being included and is not the lead group, please make sure to include accrual projections from COG as well as the other NCTN groups in your accrual estimates.
- Note approval from lead NCTN group leadership when LOI/concept is submitted on cover memo that accompanies the concept
- Reference the patient population (either adolescent or young adult or adolescent and young adult) in the title of the protocol.
- Provide a brief explanation in the cover memo why the lower age limit is not 12 years of age to document that it has been considered and, in some situations, is not appropriate. Per the ASCO/Friends recommendations to modernize eligibility criteria, including children, when appropriate in adult oncology trials, should be considered.  
<http://ascopubs.org/doi/full/10.1200/JCO.2017.74.4144>

## **Protocol Stage**

At the time of protocol submission, additional requirements include:

- Include a protocol information sheet/assent if patients < 18 years of age are eligible for the trial.

If COG is not the lead Group, the lead Group should work with COG to create an information sheet/assent that will work best for sites enrolling patients < 18 years of age (COG sites and other NCTN sites).

This is expected to be done in a timely manner so as not to impact the OEWG timeline. The COG representative on the trial should be able to lead this process. The NCI CIRB will expect to review the assent and informed consent at the same time.

- Background section should include relevant toxicity and safety data for patients <18 and if none are known, explicitly state that none are known.
- Treatment and dosing sections of the protocol should include dosing guidelines for patients < 18 years of age if these patients are eligible.

Guidelines for modifications as appropriate should be included for the agents on the study and the ages of patient. If no modifications are necessary for age, this should be stated in the protocol. Similarly, the protocol should reflect and include guidelines for supportive care and toxicity monitoring and management appropriate for patients < 18 years of age. These issues should be worked out with the COG “champion”/co-investigator for the study if COG is not leading the study.