

## Consumer Advisory Panel Concept Review Process

This document has been developed to outline the steps required for the efficient and effective review of new clinical trial concepts. This process will be followed where possible but the timeline may require some flexibility to accommodate late submissions within the 28 day period. In some instances CAP reviews may need to be undertaken without all the steps being completed such as provision of a Reviewers Report.

The committees and individuals involved in the process are:

- Operations Executive Committee (OEC)
- Lead investigator
- Concept Reviewer
- Consumer Advisory Panel (CAP)
- CAP/SAC Liaison
- Scientific Advisory Committee (SAC)
- Executive Officer (EO)
- Associate Oncology Program Manager (AOPM)

The steps are:

- 1) OEC determines which concepts will be presented to SAC  
*At least 28 days out from SAC meeting*
- 2) Lead Investigator provides Concept Outline to OEC  
*Concept outline draft - 5 days*
- 3) OEC nominates Concept Reviewer and provides Concept Outline for review  
Concept reviewer to prepare a Scientific Review  
*Concept Outline review - 5 days*
- 4) In parallel to step 3, Lead Investigator drafts the Concept Lay Summary  
*Concept Lay Summary draft - 5 days*
- 5) Concept Lay Summary and Scientific Review reviewed by CAP Chair and CAP/SAC Liaison  
*Review of lay summary and scientific review - 5 days*
- 6) CAP reviews Concept Lay Summary and Scientific Review and provide unidentified comments and questions via Survey Monkey tool  
*CAP review - 5 days*
- 7) Executive Officer circulates teleconference agenda and survey results  
*Within 1 day of CAP review deadline and at least 2 days before teleconference*
- 8) Teleconference held to work through comments and questions and determine recommendation to SAC  
*1 - 5 days prior to SAC meeting*
- 9) CAP Chair presents recommendations and comments to SAC (joined by the working party Chairs at the open meetings of the SAC)

If a concept is further refined after a SAC meeting and presented again at a subsequent SAC meeting the process should be followed again to facilitate the review of the amended concept.