Concept Development Form

Please ensure that your concept addresses the majority of points noted in the Concept Development Form below. A checklist is provided below to aid investigators in preparing their concept for submission to ANZGOG.

Concepts are reviewed by the Research Advisory Committee, consumers and our collaborative partners, NHMRC CTC.

Email to: concepts@anzgog.org.au

Date of submission:	

Concept Title	
Study Phase	☐ Phase I ☐ Phase II ☐ Phase III ☐ Other
Cancer Type	☐ Ovarian ☐ Cervical ☐ Endometrial ☐ Other
Background and Significance	
Study Summary	Aims:
	Hypothesis:
	Objectives:
	Endpoints:
Subject Population	
Study Procedures	
Statistical Considerations	
Feasibility	
Biospecimen Collection /Translational Research	
Quality of Life Assessment	
Health Economics	
Funding	☐ Budget developed ☐ Funded ☐ Pending ☐ None Funding options for consideration: ☐ NHMRC/CA ☐ Local Institution ☐ ANZGOG ☐ Other ……
Drugs and sponsorship	Drug: Pharma Co:

	Will pharma provide drug? Yes ☐ No ☐ N/A ☐ Pharma contact information:
Lay summary for consumer review (250 words)	
List of other collaborative trial groups involved	
Protocol	In development: ☐ Yes ☐ No Assistance required from ANZGOG to develop further: ☐ Yes ☐ No
ANZGOG involvement requested	Multi-centre trial with ANZGOG Study Identification: ☐ coordinated by the ANZGOG/CTC Collaboration ☐ coordinated by another centre …… ☐Other research study seeking ANZGOG Study Identification: Describe …….. …….. ☐ limited or single centre study …… ☐ Unknown, to be determined

Study Chair

Name:	Organisation:
Speciality:	Email:
Phone:	Mobile:

Investigator/s

Investigators' names should be supplied in the surname-last format with the initial in capital. Institutional affiliations should be indicated with superscript numbers following the author name.
All affiliations should contain institution, city and country.

Example:

J Smith[1], S Doe[1]
[1] Department of Oncology, XYZ Hospital, Sydney, Australia

Investigator/s (list all)

Affiliations (list all the institutions)

Guidelines for completing your concept

CONCEPT TITLE

- Should be in the PICO format (ie the title should hold information on the Participants, Intervention and Comparison groups, and the Outcomes of the trial).

BACKGROUND AND SIGNIFICANCE

- Have you addressed the scientific validity?
- Is it an important question?
- Size of population defined?
- Sufficient rationale to proceed?
- Is it clinically relevant?
- Have you searched ANZCTR and other registries? www.anzctr.org.au

STUDY SUMMARY

- Aims:
  i. Are they clearly stated?
- Trial objectives
  ii. Do they match aims?
- Hypotheses:
  iii. Are they clearly stated?
  iv. Do they match aims and objectives?
- Endpoints:
  i. Are they measurable?
  ii. Are they suitable to answer trial questions?

STUDY DESIGN AND STATISTICS

- Phase of study?
- Is design appropriate to address the question?
- Are treatment arms clearly described?
- What is the sample size estimate?
- Is the sample size justified in terms of primary endpoint?
- Is the study likely to detect a clinically significant difference?
- Has a statistician reviewed the study design?
- Is the study feasible? Outline the proposed sources of subjects and estimated recruitment rates.

SUBJECT POPULATION

- Target population and setting should be described briefly. Main inclusion criteria – are they clearly stated and clinically relevant?

STUDY INTERVENTION

- Briefly describe actions to be taken

FUNDING

- Is there any financial support for the study?

OTHER

- Is there a translational research component?
- Have QOL and Health Economics assessments been included?
- Is there collaborative support from other trials groups