## 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 and the Consumer Research Panel.

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 Consideration | Yes (will be integrated into protocol) ☐ No ☐<br>If 'No', please provide reasoning: |
| Health Economics Consideration | Yes ☐ No ☐ |
| Funding | ☐ Budget developed<br>☐ Funded ☐ Pending ☐ None<br>Funding options for consideration:<br>☐ NHMRC/CA ☐ Local Institution ☐ ANZGOG ☐ Other<br>…… |

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