Concept Development Form (all Studies including OASIS)

- Please ensure that your concept addresses the 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 ANZGOG Research Advisory Committee and the Consumer Research Panel.
- Email your completed concept development form to john.andrews@anzgog.org.au
- If you have any questions, please email John Andrews at john.andrews@anzgog.org.au

GUIDELINES FOR COMPLETION 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 or www.clinicaltrials.gov

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?
- Provide supporting data as part of study summary.

STUDY DESIGN AND STATISTICS

- Has a statistician reviewed the study design?
- 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?
- Is the study feasible?
  - Is it feasible to recruit the number of subjects required for the sample size in Australia and New Zealand, during a 1-2 year period? Would other countries need to be considered?
  - Outline the proposed sources of subjects and estimated recruitment rates. Provide details about how many sites would be engaged in Australia and New Zealand, how many patients are expected to be recruited at each centre.

SUBJECT POPULATION

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

STUDY DRUGS OR INTERVENTION

- Briefly describe actions to be taken
- Have you contacted the pharma/biotech company or manufacturer about access and/or provision of study drug?
- If access to study drug will not be granted now, what are the timelines?

FUNDING

- Is there any financial support for the study?

TRANSLATIONAL RESEARCH

- Is there a translational research component? Briefly describe any rationale, pilot data and methods, including anticipated biospecimen collection, if known.
- TR-ANZGOG Network Laboratory support is available to assist with collection, processing and storing biospecimens for ANZGOG trials, and provision of specialised media as required.
  The TR-ANZGOG Biospecimen Processing Manual (available upon request to the Project Manager, TR-ANZGOG), outlines flexible, standard processing recommendations for a variety of biospecimen types. Please liaise with the Project Manager, TR-ANZGOG Claire.Davies@anzgog.org.au regarding trial requirements, if applicable.

OTHER

- Have QOL and Health Economics assessments been included? If yes, please outline.
-

PI Name: **ANZGOG Concept Development Form – all studies**

Study Short Title:

Please ensure that all fields are completed within the form, including a lay summary. If any information is missing, the form will be returned to the applicant for completion.

CONCEPT SUBMISSION (non OASIS)

AND QUERIES RE STUDY DEVELOPMENT OR ASSESSMENT

Submit your completed study concept to John Andrews or if you have any questions about general concepts or ideas, the submission and review process contact:

John Andrews, Manager Research Programs and Pipeline
email: john.andrews@anzgog.org.au

OASIS SUBMISSIONS

Submissions to be included as an OASIS Initiative project are keenly encouraged from **ALL** ANZGOG members.

The OASIS Initiative

OASIS brings laboratory and clinical researchers, patients and advocates together to advance a series of innovative, targeted clinical trials that link molecularly-defined subsets of ovarian cancer patients to newly developed cancer drugs. To researchers it provides:

- operational support for *innovative signal-seeking Phase II* trials in well-defined subsets of patients with ovarian cancer. Philanthropic funding is also available from time to time.

- Support from ANZGOG to foster the talent and ideas of Australian and New Zealand ovarian cancer researchers.

Concepts or ideas which meet OASIS criteria are still subject to Tumour Working Group development and Research Advisory Committee review and approval. Projects submitted may be well developed and ready for review and assistance to seek funding *or* a basic idea seeking the experience of the OASIS initiative group for further development.

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

OASIS CRITERIA FOR RESEARCH PROJECTS

All submitted concepts must meet **all** criteria listed below to be considered as an OASIS project:

Phase Ib/II signal-seeking or molecularly targeted clinical trial in ovarian cancer.

Study developed by ANZGOG member located in Australia or New Zealand (home grown) or a collaborative international study, with a meaningful contribution developing the study idea/protocol by an ANZGOG member.

Strong scientific rationale, with preclinical or pilot study data.

Includes a translational backbone.

Has potential to be expanded to / lead onto a Phase III study (if primary endpoint met).

Recruitment is anticipated to be completed in a reasonable timeframe (2 years or less).

Please direct any questions about OASIS, concepts, or the submission and review process to

Kathryn Alsop, OASIS Project Manager
email: kathryn.alsop@anzgog.org.au

Study Short Title:

Date of submission:	

APPLICANT / Study Chair

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

Investigator/s

Names of ALL Investigators 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

Application must include a 1-page track record summary for each Investigator.

Investigator/s (list all)
Affiliations (list all the institutions)

Checklist for submission:

☐Completed Concept Development Form
☐Draft protocol (if applicable)
☐Trial budget (draft or final – if applicable)
☐Principal Investigator's CV
☐1-page track record summary for each Investigator

Study Short Title:

Concept Title	
Which category of research does your application belong to?	☐ Clinical ☐ Translational sub-study ☐ Pre-clinical
Study Phase	☐ Phase I ☐ Phase II ☐ Phase III ☐ Other
Speciality	☐ Medical ☐ Surgical ☐ Radiation oncology ☐ Quality of life/Symptom benefit ☐ Rare tumour research ☐ Other ……
Cancer Type	☐ Ovarian ☐ Endometrial/Uterine ☐ Cervical ☐ Vaginal ☐ Vulvar ☐ Other
Cancer subset	☐ None ☐ List _____
Specific ANZGOG Research Initiative your project could sit within	☐ OASIS ☐ EDEN ☐ TR-ANZGOG ☐ GENERAL Refer to ANZGOG Strategic Plan and website for further information https://www.anzgog.org.au/about/our-goals/
Background and Significance	
Study Summary	Aims:
	Hypothesis:
	Objectives:
	Endpoints:
Subject Population	
Study Procedures	
Statistical Considerations	
Feasibility	
Biospecimen Collection /Translational Research	TR sub-study overview (if applicable):
	Biospecimens to be collected per participant: ☐ Existing archival collection (compliant with patient consent) ☐ Prospective collection ☐ To be determined
	Example of biospecimens in below table (if known):

Sample type (blood, FFPE, fresh tissue, ascites)	Volume	Timepoint/s

Quality of Life Assessment	
Health Economics	
How will your project contribute to improving everyone with a lived experience of gynaecological cancer? [Alignment with strategic priorities.] [100 words]	
Lay summary for consumer research adviser and public communications [must be included] [250 words]	
Risks and Feasibility Considerations (Consider access to study drug, recruitment timelines, competing studies, funding. When considering recruitment, take into account incidence rate and size of population in Australia and New Zealand.)	
Funding	☐ Budget developed ☐ Funded ☐ Pending ☐ None Funding options for consideration: ☐ Govt Grant ☐ Local Institution ☐ Industry ☐ ANZGOG ☐ Other ……
Drugs and sponsorship	Drug: Pharma Co: Will pharma provide drug? Yes ☐ No ☐ N/A ☐ Pharma contact information:
List other collaborative trial groups involved	
Protocol	In development: ☐ Yes ☐ No
ANZGOG involvement requested	☐ Multi-centre trial with ANZGOG Study Identification ☐ Other research study seeking ANZGOG Study Identification Number (collaboration with an agreement): Describe …… ☐ Limited or single centre study (pilot study) …… ☐ Unknown, to be determined
TR-ANZGOG Network Laboratory involvement requested	☐ Biospecimen processing at site ☐ Biospecimen processing by a TR-ANZGOG Network Laboratory ☐ To be determined