

**Translational Project Grant** 

**Guidance notes** 

## New Treatments in Low-Grade Serous Ovarian Cancer: 2024

#### Note 1 - Principal Investigator

- The Principal Investigator must be from a UK University, Hospital, Clinical Trials Unit or a Research Institute affiliated to one of these organisations.
- The Principal Investigator must be resident in the UK and the project and employment must also take place in the UK.
- The Principal Investigator is the lead applicant who has overall responsibility for supervising the planned research programme.
- The Principal Investigator's Organisation will be the designated Host Organisation for this award and responsible for the administration of the award as set out in Target Ovarian Cancer's Standard Conditions of Grant.
- We particularly encourage applications from early career researchers, who may apply with a more senior co-applicant from the same institution who holds a permanent position. Both applicants must already hold salaried positions covering the duration of the project. The role of the senior co-applicant – in relation to the project – should be explained.
- The majority of the Principal Investigator's existing research programme should be located within the Host organisation.
- The contact details provided here shall act as Target Ovarian Cancer's primary contact point for this application.

## Note 2 - Period of Support

- The maximum period of support is 36 months.
- Please ensure the Proposed Start Date is after Target Ovarian Cancer's date for offer of funding (end of November 2024).
- Target Ovarian Cancer requires that all Grants start within 3 months of the Proposed Start Date, unless prior written approval has been sought.

#### Note 3 - Total Funds Requested

• The maximum funding available in this grant round is £200,000.

## Note 4 - Scientific Abstract

- This should allow the expert reader to understand the essential elements of the project and provide context to how the proposed work fits into the ovarian cancer research landscape, and how it will advance better treatment for low-grade serous ovarian cancer.
- If the project is linked to an approved clinical trial please reference the trial within the abstract.
- The style of writing should be similar to peer reviewed publication abstracts.
- Applications with abstracts longer than 250 words will not be considered for funding.

#### Note 5a - Lay Summary

Patients play a key role within all aspects of Target Ovarian Cancer's work including our Research Programme. As described in our Research Grant Review Process, grant applications will be assessed by our Scientific Advisory Board and lay reviewers. Therefore, we attach great importance to the Lay Summary and ask that applicants complete this section in accordance with the guidelines below.

The lay case must answer the questions set out below, structured within the sub-headings. Unless unavoidable we advise against the use of jargon and encourage detailed explanations. However there is no need to explain the generic importance or impact of ovarian cancer, or to summarise complex methodology. The use of nonscientific analogies to explain complex ideas is encouraged. Images and diagrams are also acceptable as an aid, but not as an alternative, to narrative explanation. Your lay case should be written at the level of a science feature in a broadsheet newspaper.

It is crucial that your lay case conveys relevant information in a form comprehensible to a lay readership. Target Ovarian Cancer will request re-submission of lay cases that fall short of this standard, and funding decisions may be delayed pending an adequate lay case. Expert reviewers may be requested to confirm that the content of the Lay Summary is consistent in meaning with the scientific proposal.

Further FAQs and an example Lay Summary can be found at Appendix 1.

We suggest that you "test" your lay case with an informed lay reader before submission. Your lay case should be structured as follows and be a maximum of 700 words for the whole of section 7a.

Objectives	Briefly state the objective(s) of your project.
Clinical	It is very important that you communicate, with as much
benefits	detail as possible, the impact on stakeholders that your
	research will have. Explain how achieving your research
	objectives will benefit patients, either as a direct result of
	your findings, or to inform future research that may result in
	clinical benefit. If your research fits into the latter category,
	please suggest a research pathway towards direct patient

	benefit.
Context	Briefly and clearly explain the context of your research: the particular area(s) that your project seeks to address, and the need for further understanding or treatment options.
Questions	What questions do you want to answer? Summarise the evidence that led you to formulate your questions and objectives.
Justification	Provide some justification and context for your objectives. For example, explain why you believe that the particular biochemical pathway, protein or clinical measure that you plan to research is so important to the understanding of a disease process or holds particular promise for patient treatment or care.
Novelty	Explain why your research is novel.

## Note 5b - Lay involvement in study design

Women living with ovarian cancer, their relatives and friends play a key role within all aspects of Target Ovarian Cancer's work including our Research Programme. Please use this section to show how you have engaged the lay audience to strengthen your application.

## Note 6 – Prior Submissions

 If this proposal or a substantively related proposal has been submitted to another funding body / bodies please provide the details here, including dates of submission and decision rendered.
 If you are still awaiting a decision please provide the date when a decision will be made.

## Note 7 – Joint Funding

Target Ovarian Cancer will consider funding proposals jointly with other funding bodies providing such applications are in accordance with our research strategy and our Standard Conditions of Grant.

- Please clearly state from which funder(s) additional resources are being sought and the total amount being requested.
- Briefly outline how this money is to be spent (staff, non-staff, equipment) and how this funding contributes to / complements the research outlined in this proposal.

## Note 8 - Co-Investigators

• Please list the Co-Investigators in order of their time per week spent contributing to this project, the greatest contributor by FTE first.

## Note 9 - Use of Animals

Target Ovarian Cancer is committed to the principles of reduction, replacement and refinement in animal studies. For further information please read our <u>research policies</u>.

- If the use of animals is required for your research programme please can you outline the species you intend to use and provide an indication of how many animals will be required to complete the work and show how you arrived at this number.
- You will need to provide justification for the use of animals and indicate what alternatives were considered and why these are not suitable.

#### Note 10 - Staff Costs

- This Award cannot be used to fund PhD studentships.
- This Award cannot be used to fund / make any contribution to the salaries of the Principal Investigator or any of the Co-Investigators.

- Please ensure you allow for annual pay increments when calculating your yearly salaries.
- Please include any outstanding pay awards due in the first year of the award into your calculations for Year 1.
- To cover pay awards for years 2 and 3 (if applicable) please factor in the % increase of the most recent pay award applicable to your Organisation and the Staff Grade. Please show the amount and percentage in the indexation field.
- Space has been allowed for up to 2 posts on the form if further posts are required please copy and paste blank staff details and extend form as required.

## Note 11 - Non Salary Costs

Ensure these calculations are as accurate as possible as monies cannot be varied between budget headings without prior written / email approval from Target Ovarian Cancer.

- Please ensure the consumables budget requested is for use directly for this project.
- Please itemise any equipment over £500 and list in order of priority. Fridges and freezers to be primarily used for sample storage should be listed under the Sample Collection / Storage budget heading.
- All equipment over £500 must be justified individually in Section 12.
- This Award is not intended as a major equipment grant and equipment in excess of £5K will not be funded.
- If some services (e.g. DNA sequencing, Micro-Arrays, Antibody production) are to be outsourced these should be detailed under the Professional Services Budget Heading.
- The sample collection / storage budget is designed to facilitate projects which require access to samples from approved clinical

trials. Costs such as UK travel between clinical centres to harvest samples, specialist shipping (i.e. dry ice), fridges and freezers required for storage of samples should be entered under this heading.

Please e-mail Target Ovarian Cancer

 (hdickens@targetovariancancer.org.uk) for advice if you have major items of spend (>£5000) which cannot be categorised under any of the listed headings.

## Note 12 - Justification of Costs

Please provide a brief summary of how you calculated your budgets under each heading and how these costs relate to the planned proposal of investigation.

- Please provide evidence of how your total budget for consumables was calculated and individually list and justify any major (>£1000) items.
- All equipment over £500 must be justified individually clearly stating why no alternative is available within the Host Organisation or associated Research Partners / Organisations.
- This Award is not intended as a major equipment Grant and equipment in excess of £5K will not be funded.
- The Justification of the use of animals is covered in Section 11, please use this space to demonstrate how the final budget figure was arrived at, i.e. breakdown of costs of purchase, housing, feed etc.
- If this Award is to fund a PostDoc at greater than 75% FTE please make allowance for and breakdown the costs for, Travel / Registration costs to one UK and one overseas conference during the duration of the Award. Please justify any significant deviations from this.

• Target Ovarian Cancer would expect the Grant Holder / Host Organisation to ensure best value is achieved for outsourced services. Where any spend is in excess of £10K with an individual company Target Ovarian Cancer requires at least 3 competitive quotes are received. Target Ovarian Cancer may request to see these quotes.

## Note 13 - Project Plan

Please provide a detailed plan of your research proposal using the subheadings below. This project plan will be sent to our independent peer reviewers so please ensure the level of detail and feasibility of the planned studies would be understood by such a reader. Please **limit the entire Project Plan (i.e. section 14) to 6 A4 pages** (Calibri font 12).

Aims & Purpose	State clearly the rational for this research and what the desired aims of the study are.
Background	Outline how this proposal fits into the current low- grade serous ovarian cancer research landscape and the gaps in knowledge this research addresses.
Plan of Investigation and Methodology	Please describe the plan of study with timelines and techniques to be used. Where new / complex methodologies are to be undertaken please describe in detail so expert peer reviewers can make a feasibility assessment.
	If using clinical specimens please detail logistical plans for collection and storage; how many samples are to be analysed; and how this number relates to the statistical power of the study.
Milestones	As a charitable funder we have a duty to our donors to ensure the work we fund has discernible outcomes and that our research projects are providing value for money. We attach great importance to the 6 monthly milestones and the 6 monthly research updates as a

	method for assessing the progress of a project. Therefore, please ensure your milestones are challenging, clear and achievable.
Integration with the Principal Investigator's current research programme	Explain how this proposal fits into the Principal Investigator's current research programmes and expertise. Reviewers will want to ensure the Principal Investigator has the necessary research knowledge to undertake the project.
Value of Research to Academic Community and Ovarian Cancer Patients	Explain how this proposal will take low-grade serous ovarian cancer research forward and crucially how it either directly or indirectly will bring benefit to patients.
List of Collaborators (NOT Co- Investigators)	Please list here, and explain the contribution to this proposal, of any academic collaborators working with either the Principal Investigator or Co-Investigators.

## Note 14a - Intellectual Property

Target Ovarian Cancer is keen to ensure that any intellectual property arising from the work it funds is protected properly in accordance with our Standard Terms of Grant (section 7). Additionally, Target Ovarian Cancer wants to ensure that all intellectual property is correctly accredited to help facilitate possible commercialisation. Please ensure you provide all details of the current/ongoing/pending patent estate pertinent to this application.

#### Note 14b – Current Source of Support

- Please clearly state the current source of financial support for both the **Principal Investigator's** and Co-**Investigator's** salaries.
- Funding for both Principal Investigator's and Co-Investigator's

must be guaranteed for the entire period of this grant.

• Co-Investigator status shall not be given to any person whose salary is being sought to be funded by the Grant.

## Note 15 – Approvals

- Applications without all the required signatures will not be considered.
- By signing this all parties are agreeing to Target Ovarian Cancer's Standard Conditions of Grant.

## Links

Our Research Policies

Application and review process

## Appendix 1

#### **FAQs For Lay Summary**

#### What is expected from the lay summary?

Firstly, the lay summary should avoid bland scientific convention or the use of jargon that assumes technical knowledge of the field. For example, terms such as "cell signalling", "downstream events" and "cellular differentiation" are not in common use either by informed members of the public or health care professionals. Secondly, it should explain why this area of science is important and why the approach you want to take is the right one. It could incorporate evidence that this approach has been successful, for example, in other areas of medicine. For studies that involve basic cellular and physiological mechanisms, you will need to explain to understanding the causes, assessment, or outcomes from ovarian cancer. The methods you propose should be explained using simple analogies to give the reader the sense, if not the detail, of what you are planning to do. You should also give an idea of how your work fits in with other research in the field.

# Do you have examples of how I can communicate what are complex issues to a general (but informed) readership?

The lay summary should be written as if it were to be published in the science pages of a major broadsheet paper or a journal such as The Economist. Bill Bryson's book, 'A short history of nearly everything', is a good example of how everyday objects and activities can be used to describe complex areas of science including nuclear physics and astronomy.

Another good example is the Max Perutz science writing prize, awarded each year to scientists who communicate their work in an accessible way. Examples from previous winners can be viewed <u>here</u>.

#### How will my lay summary be used in assessing the fundability of my

#### research?

The lay summaries are reviewed, in conjunction with the full application and the peer reviewers' comments by the Scientific Advisory Board (SAB), comprising of 6 leading cancer researchers and 2 lay members. The current list of members can be found <u>here.</u>

# Surely there will be some research that defies explanation even to an informed lay audience?

This would be disappointing, as it should be the aim of all scientists to make their work comprehensible to those who stand to benefit from it.

## Example of a Lay Report (Hypothetical)

#### Lay Title and Objectives:

'Further development of a novel biologic drug for the treatment of ovarian cancer'

Support from Target Ovarian Cancer would enable us to advance a novel strategy for the treatment of ovarian cancer. This approach is based on a new biologic drug, which we have shown reduces disease in animal models of ovarian cancer. Development of this treatment has now reached a stage where we must now consider the future clinical application of this approach. Studies will:

- 1. Consider aspects of its safety
- 2. The potential effectiveness as a therapy in humans
- 3. Drug design

#### **Clinical Benefits:**

Biologics are a novel class of disease-modifying drugs, designed to treat cancers such as ovarian cancer. These drugs have been developed through a better understanding of how the body turns against itself to promote tumour growth. This knowledge has allowed development of drugs, which target specific molecules involved in this process. Although this has led to some new and effective treatments, not all patients respond to these drugs and potentially harmful side effects remain a fundamental concern. We need to develop additional biologics with alternative modes of action that may be more suitable for certain individuals or that have less harmful side effects. The development of a new biologic for clinical use, which involves transferring our knowledge from animal models to patients with ovarian cancer, must be carefully managed. The outlined proposal represents the first steps in this process, likely to take around 3 years altogether, and will consider aspects of safety and drug design. Such studies are critical and will inform decisions relating to the future clinical translation of our work.

#### Context:

Over the last decade, we have developed a novel strategy for the treatment of ovarian cancer, based on a biologic that is naturally found in our bloodstream. In ovarian cancer patients, we have found that there are insufficient levels of this biologic, and that supplementation can correct the deficiency and slow / stop tumour growth. However, we have also noted that patients with ovarian cancer have antibodies that specifically block this biologic, potentially reducing the effectiveness of our proposed therapy. This study will assess whether these antibodies are associated with tumour progression and whether they block the beneficial outcomes associated with this biologic. This information may allow us to design modifications to the biologic, reducing the impact of the antibodies and improving its effectiveness.

#### Questions:

We have detected antibodies in ovarian cancer patients that are specific for the biologic being developed for use in inflammatory arthritis. Consequently, we would like to know:

- 1. How does the presence of these antibodies relate to disease progression or treatment?
- 2. Will these antibodies affect the therapeutic benefit provided by the biologic?
- 3. Can we define which part of the biologic molecule is recognised by the antibody?
- 4. Will we be able to modify the biologic to reduce the impact of these antibodies, without affecting its therapeutic benefit?

#### Experimental plan:

We will be collecting samples of blood from patients suffering from ovarian cancer and from patients with no history of cancer in order to compare levels of antibody between disease and non-disease groups, and to determine the relationship of antibody level to disease progression. The levels and activity of the antibodies will also be assessed in ovarian cancer patients during the course of their treatment. In the laboratory, we will examine the activities of these antibodies in detail. In an animal model of ovarian cancer, we will determine the effectiveness of new versions of our biologic that have been modified to reduce the impact of blocking antibodies.

#### Novelty:

The biological therapy being considered is novel and has not yet been tested in humans. The biology associated with this work builds upon the development of another biologic, TOCmab, which has reached late stage clinical trials for use in breast cancer. The proposed investigation will, however, consider the clinical relevance of antibodies, which may interfere with the effectiveness of these biological approaches. While the characterisation of these antibodies is an essential requirement for testing the safety of the therapy being considered, the study will also provide information relating to potential modifications in drug design, whilst the identification of antibodies in ovarian cancer may have a practical value in predicting disease activity.