



**PROSTATE
CANCER UK**

2019/20 Major Awards: Call for research proposals to accelerate immunology and immunotherapy research in prostate cancer

Guidance Notes

Introduction

Prostate Cancer UK has an ambitious aim; to tame prostate cancer within 10 years. To achieve this, we need to not only add new treatment options to our arsenal, but also to be smarter with how and when we use these therapies to achieve maximum effect.

In recent years, we have seen the emergence of a number of exciting immunotherapeutic approaches for the treatment of cancer. Checkpoint inhibitors have been shown to deliver clinical benefits in immunogenic tumours such as melanoma, lung cancer and other solid cancers, and CAR T cells have shown promising results in blood cancers; However, we are yet to see the same level of impact in the treatment of prostate cancer. Experimental and clinical studies have delivered limited responses to checkpoint inhibitors and other immunotherapeutic approaches for reasons that remain unclear. Notwithstanding this, we believe that harnessing the immune system holds huge potential for the treatment of prostate cancer and that such approaches will deliver significantly better outcomes for men by increasing the length and quality of their lives and giving them valuable additional time with their loved ones.

In June 2018, Prostate Cancer UK brought together leading researchers from across the world, and from a variety of different disciplines, for a 'Frontiers Meeting' to discuss the immunology of prostate cancer and the future of immunotherapy for its treatment. Participants were tasked with identifying the main challenges for the delivery of effective immunotherapeutics for the treatment of the disease. The key outcome of the Frontier Meeting was the identification of the 5 most significant knowledge 'gaps', the addressing of which would accelerate progress and enable immunotherapy, in its various guises, to become a clinical reality for men with prostate cancer.

Remit

This funding call seeks proposals which address at least one of the 5 areas detailed below, in order to advance our understanding of prostate cancer immunology and thereby provide the framework for new immunotherapeutic approaches for treating prostate cancer.

The five most significant knowledge gaps:

1. Understanding the tumour microenvironment and how it influences the immune landscape

Our understanding of the tumour microenvironment and its influence on the immune landscape of the patient is incomplete. We therefore need to develop a better insight into the immunological context of the normal prostate and how this changes as cancer arises and progresses (or does not). We need to determine the cellular composition of the prostate microenvironment, in order to better understand immune cell infiltration and its influence on the development, establishment and progression of prostate cancer.

2. New targets/novel strategies – immunotherapeutic approaches that trigger a sustained immune response

To date, existing immunotherapeutic approaches have had limited success in treating prostate cancer, and so we need to explore innovative new concepts and novel approaches. Although interest in developing new immunological therapeutics for the treatment of prostate cancer is growing, to date these have tended to focus on the same targets (namely PD1/PD-L1 & CTLA-4). We need to look beyond these and identify other targets that may be of more relevance for prostate cancers, and which have the potential to trigger a sustained, protective immune response against the cancer. Research into the identification of completely novel approaches that are not yet being considered by pharmaceutical companies presents an opportunity to make significant advancements in this area.

3. Developing the rationale for optimising the use of existing therapies

We need to optimise the use of existing therapies to get the most out of them. This could be through combination with other approaches, optimal sequencing of therapies, and/or through identifying the most responsive disease setting (is earlier necessarily better or are more advanced tumours likely to be more responsive to immunotherapies?). Studies addressing these questions will generate the evidence base needed to underpin and optimise the use and success of existing therapeutic approaches.

4. Discovery & validation of assays to find the responders to immunotherapeutic approaches

We need to develop and validate accurate and reliable assays that can identify those men with the greatest likelihood of responding to immunotherapies. This will involve the identification of reliable markers that are predictive of treatment response and can be translated into clinical practice. Techniques and technologies need to be standardised, robust and repeatable in order to remove the huge inter (and even intra)-lab variability that is experienced with current assays.

5. Better understanding of how the host and/or the microbiome effects immune response

Beyond the immune system itself, and the tumour microenvironment, it is becoming clear that we must consider the patient as a whole and how the host environment influences immune capacity. This includes the microbiome, as we currently do not know how this influences the immunology of the host as prostate cancer develops (However, we know from other diseases and pre-clinical models that the effects can be significant). Not only could this have therapeutic implications by identifying novel therapeutic approaches and/or by predicting response to treatment, but it could also inform earlier diagnosis and disease stratification by identifying potential initiator events.

Applications **not** directly aiming to tackle (at least) one of the 5 areas detailed above **will not** be considered. The primary focus of this call is to investigate the underpinning immune biology in relation to prostate cancer. Although applications for clinical trials are still eligible, an extremely compelling case will need to be made for such a proposal.

Underpinning the above 5 knowledge gaps, it is recognised that there are research barriers and bottlenecks that are preventing or slowing progress in this field. Research endeavours are being hampered by the limited supply of, and access to, deeply analysed and well annotated clinical material (including specimens representative of the normal/healthy prostate), as well as a lack of clinically relevant, immune-competent pre-clinical models that can more accurately reflect the human prostate immune environment. These barriers should not form the sole focus of proposals submitted under this scheme; however, applications which do also look to address either of these barriers, whilst still primarily seeking to address one of the 5 knowledge gaps listed above, will be looked upon favourably.

Research not covered by this call

Researchers with proposals which are not within remit for this call but which are innovative and address one or more of the areas outlined within our [research strategy](#) should consider applying to our [Research Innovation Awards Scheme](#). All [funding opportunities](#), including our response mode Research Innovation Awards, are detailed on our website and are advertised through our [Research Newsletter](#).

If you are unsure about the eligibility of your proposal, or if you have any queries about completing the application form, you should contact the [Research Team](#) **in advance** of the submission deadline and **no later than Friday 5 July 2019** in order for you to submit by the **Monday 22 July 2019 deadline**.

Eligibility

All proposals must align with our [research strategy](#) and must clearly demonstrate the innovative nature of the research and how it will lead to improved health and wellbeing of men affected by, or at high risk of, prostate cancer.

We want to see novel game changing research! As such, there are no financial restrictions as to what you can request – you should simply apply for what you need. However, please note that value for money will be a consideration in making final funding decisions, and so we would advise applicants to ensure that the amount they are requesting is a realistic reflection of what is needed.

We would expect projects to be between 1 to 5 years in duration; nevertheless, you should apply for however long you need. All proposals are expected to have a focus on accelerating the use of immunotherapies to improve the lives of men living with prostate cancer, by addressing (at least) one of the 5 knowledge gaps highlighted within this call. This scheme will fund both fundamental and clinical research (and all stages in between); however, the primary focus of this call is to investigate the underpinning immune biology in relation to prostate cancer. Although applications for clinical trials are still eligible, an extremely compelling case will need to be made for such a proposal. Applicants will also be expected to set out a logical and realistic path of work that will need to happen at the end of the award in order to deliver benefit to men.

We will also consider applications that bring innovative ideas from other cancer types and other diseases to be tested or translated for prostate cancer and we encourage applicants to build teams that include experts from other disciplines and other countries where that will improve the project.

To apply to this call, the following criteria must also be met:

- Awards are available to established researchers working within a recognised academic or clinical institution in the UK (including N. Ireland). Applicants should have a strong track record in their field, and we welcome proposals from academics not currently working on prostate cancer (however, in such cases an expert from the prostate cancer research community should be named as a Co-Applicant on the proposal).
- Lead Applicants will normally hold tenured or tenure-track academic appointments, or for clinical applicants, they should hold an honorary academic contract at a recognised academic institution.
- Lecturers on fixed term contracts or post-doctoral researchers holding competitively-awarded external fellowships can be Lead Applicants, as long as their contract extends at least 6 months beyond the duration of the project **or** the host institution has undertaken to award a permanent position at the end of the fixed term.

- Lead Applicants who are already in receipt of funding from Prostate Cancer UK are still eligible to apply to this scheme. Applicants should however make a clear case as to why they are the most appropriate person to lead the project and provide reassurance that they will have sufficient time to oversee the delivery of the project. We will check whether the proposed time commitments towards the project would be feasible (for example, a 0.5 FTE commitment from someone already committing 1.0 FTE on an existing grant would clearly not be feasible).
- Researchers with greater than 5 and less than 10 years post-doctoral research experience can also be a Lead Applicant. We recognise that experienced post-doctoral researchers who have the expertise and experience required to lead a research project may not yet have their salary met by core institutional or fellowship funding. As we are keen to grow good post-doctoral researchers towards independence, where an eligible post-doctoral researcher is to lead the research as Principal Investigator it is permissible for their salary to be included in the grant budget. In this instance, they must truly be leading the research and must have a senior academic (usually the research group head) as a Co-Applicant or Joint Lead Applicant.

We will expect a justification of how the salary support, and the research funding applied for, will lead to independence for the individual at the end of the project, and a statement should be provided by an appropriate authority at the proposed host institution detailing how the post-doctoral researcher will be supported by the institute at the end of the award. We will not be prepared to meet the salary of a post-doctoral Lead Applicant more than once and we would expect post-doctoral Lead applicants to spend a minimum of 80%FTE on the funded project. Any subsequent successful fellowship applications should result in their salary being removed from this grant at the point that the fellowship is taken up.

- Projects can include a period of research outside the UK where there is a Co-Applicant or Collaborator based overseas. However, research must be conducted predominantly in the UK and Prostate Cancer UK will not make any direct payments to non-UK institutions or pay invoices in any currency other than UK pounds.
- Funds requested in your proposal must be in accordance with our [Finance Eligibility Guidelines](#).

Please note that we will NOT accept applications that:

- Do not fit the remit of this funding scheme
- Are intended solely or primarily to purchase substantial equipment and/or infrastructure
- Are led and submitted by researchers based entirely or primarily outside the UK
- Are submitted by commercial organisations
- Are incomplete or have been completed incorrectly

If you are unsure about the eligibility of your proposal, or if you have any queries about completing the application form, you must contact the [Research Team](#) **in advance** of the submission deadline and **no later than Friday 5 July 2019** in order for you to submit by the **Monday 22 July 2019 deadline**.

Once the deadline has passed, you will no longer be able to submit your proposal and there will be no opportunity to debate individual circumstances. Applications which are incomplete, which do not meet the requirements detailed above and which are deemed to be outside of our [research strategy](#) will be rejected without being sent for further review.

Assessment Process

Applicants must submit their application **and** ensure that all online declarations and approvals have been completed by the relevant parties before **12pm (noon)** on **22 July 2019**. Applications will be checked by the Research Team at Prostate Cancer UK to ensure that they comply with the basic eligibility for this funding call. Any proposals which do not meet the remit of this call will be rejected without peer review. All remaining applications will be peer reviewed by at least three independent referees in accordance with the guidelines set out by the [Association of Medical Research Charities \(AMRC\)](#).

After external peer review, applicants will be offered the opportunity to respond to the referees' comments. The referees' comments shall be made available to applicants in a non-identifiable format via our online system the week commencing **14 October 2019**, and responses must be submitted by **12pm (noon)** on **28 October 2019**. Further information about responding to the referees' comments will be provided to applicants at the appropriate time.

The applications will then be further assessed our Research Advisory Committee and co-opted members with particular expertise needed to assess applications to this call. Final funding decisions will be made in **December 2019** and applicants will be informed of the outcome by email shortly afterwards.

We recognise that the outcome of your application is important to you and your staff and we will inform you of the outcome as soon as possible. However, we would like to remind applicants that contacting the Research Team during this time will not speed up the process. We appreciate your patience.

Once notified of our intention to award, we will begin the contracting process immediately. It is our expectation that contracting should be completed within one month of notification of award (or once any conditions of award have been addressed and/or any financial assessment completed). In any instance, successful projects should commence within six months of completion of contracting.

Making your application

The closing date for the receipt of applications is 12pm (noon) 22 July 2019.

Applications **MUST** be made by the Principal Investigator and using our online Prostate Cancer UK [CC Grant Tracker system](#).

You must fill out **all sections of the application form** (notes below) and any Joint-Lead Applicant (if applicable) and all Co-Applicants must confirm their involvement in the proposal before it can be submitted. Any Collaborators need not complete an online declaration; however, they should provide a letter of support specifying and confirming their involvement in the project, which must be uploaded by the Lead Applicant within the corresponding section of the form.

Once all sections have been completed, the **Lead Applicant**, the **Head of Department** and the **University/Institute Research Grants office** (or finance office if not applicable) must complete the online declarations for your application to be accepted.

Approval from the Head of Department and the Research Grants/Finance Officer will be required after the proposal has been 'submitted'. The proposal must be submitted and approved by all relevant parties in advance of the submission deadline.

The application form consists of 16 sections, each of which are outlined below:

Lead Applicant details

The Lead Applicant must be the Principal Investigator who will lead the research and be responsible for delivering the project.

Information in this section is automatically populated from your contact record. Please ensure that your CV and Basic Information are up to date via the 'Manage My Details' section in the left hand menu. Please note that this section is not accessible directly from the application form, and so to update your personal details you must first 'Save & Close' your application and then click on the 'Manage My Details' link in the left hand menu.

When updating your personal details please note the following:

- An [ORCID ID](#) must be added to the corresponding section under 'Basic Information' via 'Manage My Details'.
- Your 10 most significant/relevant publications for this application must be entered in the section below.

Personnel

This section allows you to add the details of any Joint Lead Applicant, Co-Applicants and Collaborators involved in the proposal. You must also clearly specify each individual's role in the project, and provide any letters of support from the named Collaborators.

Joint Lead Applicant:

We would ordinarily expect a project to be led by a single Lead Applicant; however, in exceptional circumstances you may include ONE Joint Lead Applicant.

If you wish to include a Joint Lead Applicant on the proposal, you must provide sufficient explanation in the 'Role Description' below to justify the need for Joint Lead Applicants, as well as which aspects of the proposal each person will be leading on and why they are appropriate to lead on that aspect of the project. If the Joint Lead Applicant is to be an experienced post doc, then you must also justify why they are suitable to be a Joint Lead Applicant and upload a statement (from an appropriate authority at the proposed host institution) detailing how they will be supported by the institute at the end of the award.

To include a Joint Lead Applicant onto the proposal, click on 'Add Joint Lead Applicant', input their name within the corresponding search fields and either select the contact if already on our database or otherwise input their details. Once added, an email will be sent to the potential applicant inviting them to take part in this application.

The Joint Lead Applicant **must** accept this invitation to confirm their participation on the proposal.

Once confirmed, their CV details will automatically be appended to the application PDF.

As with the Lead Applicant's details, the Joint Lead Applicant must ensure their relevant details are filled in accurately by going to the 'Manage My Details' section.

The Joint Lead Applicant must confirm their participation AND approve the application BEFORE the proposal can be 'submitted'.

Co-Applicants

To include a Co-Applicant onto the proposal, click on 'Add Co-Applicant', input their name within the corresponding search fields and either select the contact if already on our database or otherwise input their details. Once added, an email will be sent to the potential Co-Applicant inviting them to take part in this application. Repeat this procedure for all Co-Applicants on the proposal.

Each Co-Applicant **must** accept this invitation to confirm their participation on the proposal. Once a Co-Applicant has confirmed their participation, their CV details will automatically be appended to this section (click on the magnifying glass next to the corresponding name to view their CV).

As with the Lead Applicant's details, each Co-Applicant must ensure that their relevant details are filled in accurately by going to the 'Manage My Details' section.

All Co-Applicants must confirm their participation AND approve the application BEFORE the proposal can be 'submitted'.

You **must** then detail how **each** Co-Applicant will be involved in the project. To do so, click on 'Add Co-Applicant Role', select the relevant name from the dropdown list provided and input their role in the corresponding section. Please repeat this for all Co-Applicants on this proposal.

Collaborators

To include a collaborator onto the proposal, click on 'Add Collaborator' and follow the same procedures as with adding a Co-Applicant. Repeat this procedure for all collaborators on the proposal.

Collaborators are not required to confirm their participation via the on-line system; however, each collaborator will receive an email to inform them that they have been selected to be involved on this application and will be asked to provide you with a supporting letter (which you must upload in this section).

You **must** then detail how **each** collaborator will be involved in the project. To do so, click on 'Add Collaborator Role', select the relevant name from the dropdown list provided and then input their role in the corresponding section. You will also be required to upload their letter of support via this section as well. Please repeat this for all collaborators on this proposal.

Project Summary

Provide a concise scientific title as well as a lay title for your project, and include the duration of the research project (in months).

Priority area and key knowledge gap

Within this section you must indicate which one (or more) of the Prostate Cancer UK priority areas your project shall address (please refer to our [Research Strategy](#) for further details). You must also indicate which of the 5 knowledge gaps (detailed in the Remit section above) you will be aiming to address.

Scientific Abstract

Please provide a concise scientific abstract (in no more than 500 words), outlining the background to the application, the proposed aims of the research to be undertaken and the expected outcomes. All proposals must clearly state how the planned research aims to improve the health and wellbeing of men affected by, or at high risk of, prostate cancer.

Please be aware that your abstract may be sent to potential peer reviewers to establish their ability to review the proposal, and if funded, the abstract will also be shared with the National Cancer Research Institute (NCRI), the International Cancer Research Partnership (ICRP), the Academy of Medical Research Charities (AMRC) and Europe PubMed Central.

Therefore, please do not include any confidential or commercially sensitive information in this section.

Key Hypotheses, aims, objectives and milestones

Main aims

Briefly summarise the overarching aim(s) of the proposal. This section will be used to complete the main aims section of the contract if your application is recommended for funding, so please summarise the main focus of the project as succinctly as possible.

Key hypotheses, objectives and milestones

This section is meant to provide an 'at a glance' summary of your project plan for reviewers and the Research Advisory Committee, so please keep it succinct and to the point.

How will this research increase the understanding of prostate cancer immunology and/or accelerate the use of immunotherapy in prostate cancer?

Our vision is that a greater number of men living with, or at risk of, prostate cancer will benefit from immunotherapy. You should therefore indicate how your proposal will bring us closer to this goal. Please refer to the remit section.

Lay summary

Describe the research proposal under the headings provided, in terms understandable to a reader with no specialist scientific or medical knowledge. It is advised to pitch the summary at a level similar to that of a medical research report in a newspaper. Do not include scientific jargon or abbreviations without further explanation. We highly recommend asking a lay audience to review this section before submitting the application. Further guidelines for the involvement of lay representatives and how our Patient Representative Network can strengthen your application can be found on our [website](#).

Warning: Do not include any confidential or commercially sensitive information in this section!

This lay summary will be used by Prostate Cancer UK to publicise our research portfolio should your application be successful in receiving funding. In line with the recent implementation of GDPR, please ensure this summary does not contain any information

that could be considered confidential or sensitive regarding an individual or commercial activity, or likely to be considered as such in the future. Please ensure you are happy for all information in this section to be publicised at a later date.

Within this section of the form, the following questions must be completed:

- What are you proposing? *(up to 200 words)*
- Why are you proposing it? *(up to 200 words)*
- How are you proposing to do it? *(up to 200 words)*
- What evidence or supporting data do you have to support this project? *(up to 200 words)*
- What are the expected, short term outcomes of this study?
(i.e. what are you expecting to achieve by the end of this project/funding period, and what will need to happen next in order to realise the potential benefit to those living with, or at risk of, prostate cancer?) *(up to 100 words)*
- How will this study bring immunotherapies closer to improving the lives of men living with prostate cancer?
(i.e. how could your research accelerate progress in the use of immunotherapies to treat men affected by prostate cancer? How do you envision your research impacting clinical practice and the way that men are treated?) *(up to 100 words)*
- Summary of the project in one sentence *(up to 50 words)*

In this section, please do not refer to any references, diagrams or acronyms included elsewhere in your proposal. This section should make complete sense when read in isolation to the rest of your application. Prostate Cancer UK staff will take no responsibility for translating the science if the lay summary is inadequate

Project Description

Please describe your proposal by answering **all** the questions within this section:

What is innovative about your application? *(up to 500 words)*

We want to see innovative research which has high potential to make a real impact on the lives of men with, or at high risk of developing, prostate cancer. You should therefore make a clear case as to what is innovative about your application (in no more than 500 words). Prostate Cancer UK will only fund novel and innovative research, and so this question is of great importance. You should also explain why such a study is needed now and how it will differ from or complement any planned, ongoing, or recently completed studies.

Background to the project *(up to 1,000 words)*

Please detail the most relevant background information necessary to understand the wider context to your proposed approach and how this will develop the area of immunology and immunotherapy in prostate cancer.

Introduce only the most relevant background information necessary to understand the wider context of your proposal – do not write a literature review. You should describe both your own and others' results that provide a basis for doing this research now, as well as any ongoing work that may impact either positively or negatively on your proposed study. It is advised that you place your proposal into a patient-centred context rather than focussing on scientific questions alone.

Please refer to references by number in this section and list them in full under the 'References' section (a maximum of 100 references are permitted).

Optional preliminary data

If you have any pilot or preliminary data that will strengthen your proposal you may upload an appending document here (MS Word or PDF only and no more than 10 pages).

Detailed plan of investigation *(up to 1200 words)*

Please detail the proposed programme of work, broken into work packages where relevant. The focus here should be on the structure, timings and delivery of the programme of work etc. Describe the methodology you will use to address each hypothesis, along with the timescales for each section of the research. Where there are multiple components to your proposal, please clarify who shall be leading/delivering each component or sub-study.

This section should give reviewers a clear understanding of the work proposed, along with planned timeframes and anticipated outputs, outcomes and impact.

An additional figure attachment (no greater than 10MB in file size) may also be uploaded (MS Word or PDF files only) in this section.

Please detail how your team of investigators and collaborators is best placed to deliver the proposed programme of work? *(up to 500 words)*

Explain here why this team is most suited and well positioned to conduct this work.

Potential problems and contingency plans *(up to 500 words)*

It is acknowledged that research projects often do not run entirely to plan. Please highlight the problems this project is mostly likely to encounter and explain how they will be dealt with.

Dissemination & data sharing *(up to 300 words)*

Describe how you intend to disseminate the outcomes of your research to the prostate cancer research community, during and at the end of your project. Please also describe how you will make any data, cell lines, tissue samples, excess material etc. freely available to others in the research community.

In addition, it is expected that research directly involving men affected by prostate cancer has a clear plan for feeding back results to participants at the end of the project, as well as more widely to the general public.

What will be the impact of your proposed project (both in the short and long term)?

(Up to 500 words)

We wish to understand the potential impact of your research both in the short and longer term. Our ultimate aim is to deliver clinical impact as quickly as possible to improve the lives of men affected by, or at high risk of, prostate cancer. Your response should focus on the impact to these men rather than just academic outputs.

What would need to happen after this grant (if successful) to realise the long term impact for men described above? *(Up to 500 words)*

We wish to understand how your research fits into the wider research landscape and the potential impact of your work across a timescale longer than this project to assess your plans for achieving impact.

We are aware that several additional steps and significant follow on funding may be required in order to deliver longer term impact. Please provide brief details of those subsequent steps and how you intend to fund them (including proposed funders and funding schemes, if relevant, or describe any plans to fund future work through commercial licencing or exploitation).

Our ultimate aim is to deliver clinical impact as quickly as possible to improve the lives of men affected by prostate cancer. Your response should focus on the impact to these men rather than pure academic outputs.

Patient & Public Involvement *(up to 500 words)*

Prostate Cancer UK is supportive of the active involvement of patients and the public in research activities as it can ensure that the research remains patient focused. Please describe whether men with prostate cancer, or their relatives/partners etc., will be involved in the design, planning or management of this research, and if so, what their role will be. Please note, we do not consider the recruitment of patients to take part in a study as involvement in research.

Further guidelines for the involvement of lay representatives and how our Patient Representative Network can strengthen your application can be found on our [website](#).

Clinical Research

This section only applies to those projects that include a clinical component and require the recruitment of patients. If this section does not apply to you, please select 'no' to the question 'Does this project involve clinical research?'

If your proposal does include a clinical component, please respond 'yes' to this question and the answer the following questions:

Payment of Excess Treatment Costs (ETC's)

As of 1st October 2018, there is a new system in place and researchers are now required to complete a Schedule of Events Cost Attribution Tool (SoECAT) for clinical research. The tool provides a standardised approach for attributing the costs of health and social care research and development (AcoRD) across England.

If your proposal includes **any** clinical element at one or multiple study sites in England, then you **MUST** complete this form. Completion of the SoECAT is mandatory for studies eligible for the NIHR portfolio and the support this provides (including access to excess treatment cost payments).

Important note: External sign-off of the form is required to confirm the study attribution complies with the Department of Health and Social Care [AcoRD guidance](#). This will need to be done before you attach your SoECAT to your grant application, and before the grant application is submitted to Prostate Cancer UK.

A blank copy of the SoECAT form including some helpful guidance notes can be downloaded from the [National Institute for Health Research \(NIHR\)](#). Once you have completed your SoECAT, we advise you to contact your [Local Clinical Research Network \(LCRN\)](#) as early as possible to obtain sign-off. Please ensure you factor this approval into your timelines, we advise submitting your SoECAT at least 3 weeks before the grant submission deadline in order to have it authorised and returned back to you before you submit your application.

Please attach your completed and approved SoECAT form within this section of the online form.

What Phase will the trial be?

Please specify the phase of the proposed clinical trial.

Please clearly describe your power calculations and statistical analysis plan

(up to 500 words)

You should provide a clear justification for your power calculations, sample sizes, stratification factors, randomisation ratio etc. to provide the reviewer with sufficient reassurance that the study has been suitably powered. Studies which are underpowered and unlikely to answer the research hypothesis will not be considered favourably by the Research Advisory Committee.

Please specify your chosen primary and secondary end points (including how they will be measured), along with any proposed interim analysis and early stopping rules

(up to 300 words)

What are you looking to measure in this study in order to address the research question? Please also detail the length of follow up required and the proposed early stopping criteria, and whether you intend to conduct any interim analyses during the study.

What will be your inclusion and exclusion criteria for recruiting patients? (*Up to 300 words*)

Please specify who will and won't be eligible to enrol in the study and why.

Patient Recruitment Strategy (*up to 500 words*)

You should describe your planned recruitment strategy and your anticipated rate/timescale of recruitment. If available, please provide any pilot evidence to demonstrate feasibility of recruitment. Please specify the number of sites to be involved in the study (and where they are located), and the timeframes in which you anticipate them to be set up and begin recruitment.

If patient samples are to be collected, please specify the type of tissue that will be obtained and how many samples will be required.

Recruitment contingency (*up to 300 words*)

We appreciate that recruitment of patients to a trial may not always go to plan. Please provide further detail as to the likely challenges you may experience with patient recruitment/sample collection and what steps you will take to mitigate the risk of not recruiting a sufficient number of patients and/or the loss of patients during follow-up.

What is your experience of delivering studies in a clinical setting? (*up to 200 words*)

Please specify your past experience of delivering studies of this nature.

Please detail what would be expected of a patient enrolled to this study? (*up to 300 words*)

Please describe the level of commitment, number of visits etc., expected of those recruited to the study, and how you have considered the trial protocol to ensure that it will be acceptable and sensitive to the situations of potential research participants.

Careful consideration from the patient perspective as to the expectations of the trial participants will help facilitate recruitment to your study (as a trial that is considered unacceptable to the majority of patients will struggle to recruit sufficient numbers).

If you wish to be put in touch with patient representatives to be involved in the develop of your study, we have established a Patient Representative Network - a group of lay representatives who are willing to help with any stage of your research. For more information visit the [Patient and Public Involvement](#) page on our website.

References

Include up to 100 full references which have been referenced within the Project Description section (in Vancouver format).

Gantt chart

Insert a Gantt chart detailing the main goals, milestones, deliverables and associated major costs and staffing for the grant duration. These will be the key goals and timelines from which the progress of your project shall be measured against, so please ensure that they are achievable within the given timeframe. Attach as a MS Word or PDF document.

Other Sources of Funding/Approvals and licences

Other sources of funding

Please provide details of any other funding received, or applied for, on the topic of this application (up to 200 words per section). In the case of funding already received, it is important to explain how this proposal differs from ongoing work and forms a discrete project. For recent funding applications, it is acceptable to have submitted the same project to another funder; however, please give an indication as to when you will know the outcome of the other submission(s). You must inform the Research Team of the outcome as soon as it is known. If your proposal shall involve an industry partner, please specify whether they will be providing any financial or in kind contributions towards the research (e.g. free or discounted provision of drugs for the project).

Approvals and licences

All necessary regulatory approvals and licences for the project must be in place before the corresponding work can commence. In most instances, approvals and licences should be in place before the grant begins, and so should not be included within the project schedule/Gantt chart. We appreciate that some proposals may not require specific approvals until the later years of the project (e.g. where a clinical trial is not scheduled until after some initial pre-clinical studies). In this instance, it is permissible for the approvals to be obtained at the relevant time; however, this must be approved by Prostate Cancer UK in advance of the grant commencing.

Funding will not be released until all necessary approvals and licences are in place (unless specifically agreed in advance with Prostate Cancer UK, in which case payments may be withheld during the grant until the necessary approvals are in place).

If approvals/licences have already been obtained, please attach the corresponding letters in this section (MS Word or PDF only). If submissions are in process, please indicate the status of the application(s) and when a final decision is expected. If approvals are obtained after the submission deadline, please inform the Research Team immediately. Please also note that it is a requirement that any cell lines to be used in the proposal are authenticated / validated appropriately at the outset of the project, and as such you may include reasonable costs in your application to conduct these checks.

The UKCRC Tissue Directory and Coordination Centre supports the work of biobanks by improving access to their human tissue samples for research purposes. The Tissue Directory aims to maximise the use of new and existing human tissue sample collections and allows

searching based on various criteria and available datasets. For further advice and guidance please refer to the [UK Clinical Research Collaboration website](#).

Use of Animals

If the project involves the use of animals, you must detail the number and species of animal to be used and whether the animals will be genetically modified. You must clearly justify why an animal model is necessary to advance this research. You should clearly describe why an animal model is necessary and why this specific model was chosen. In particular, taking into careful consideration:

- whether the research question can be addressed via other means, without the use of animals
- whether the potential benefit justifies the possible adverse effects to the animals
- why the specific approach/model is the most appropriate
- how to optimise the experimental design and statistical analysis to minimise the number of animals required
- what steps will be taken to minimise any pain, suffering, distress and lasting harm to the animals, and what will happen to them at the end of the experiment (including the use of humane endpoints)
- how the results and resources can be shared with the research community

You should also consider whether anyone else has already generated the model(s) required for this study and if so, why it is not feasible to obtain the necessary materials from them and/or why new models need to be generated.

Please also describe how the proposed sample size has been determined and how the project plan has been refined to adhere to the 3Rs by using the minimum number of animals possible and causing the least suffering, whilst also ensuring that the study is sufficiently powered and reproducible (please refer to www.nc3rs.org.uk for further details).

We require this information to ensure that all necessary approvals are/will be in place and to collect data for the Association of Medical Research Charities (AMRC) on the use of animals within our grant portfolio. If the appropriate approvals are already in place, please provide the Home Office Number and upload the licence in the corresponding section within the form (MS Word or PDF only).

The NC3Rs offers a free online tool, the [Experimental Design Assistant](#) (EDA), which provides guidance for researchers in the design of their experiments. The tool helps to ensure that researchers use the minimum number of animals required to achieve the scientific objectives, as well as the most appropriate methods to reduce subjective bias and to optimise the statistical analysis. For further advice and guidance please refer to www.nc3rs.org.uk.

Finally, please also indicate whether the research will involve the use of stem cells, providing further justification if embryonic stem cells are to be used.

Intellectual Property

Please note, it is our expectation that any foreground IP arising from Prostate Cancer UK funded research should be owned by and vest in the Research Institution, and that any net revenue generated from its commercial exploitation shall be shared in accordance with our [terms and conditions](#).

Please detail your institution's current processes and available expertise in managing IP, including contact details of your IP/Technology Transfer Office (up to 500 words).

We strongly advise completing this section of the application with support from your Technology Transfer Office. Please provide the contact details of your Technology Transfer Office and a brief outline of your current processes regarding the identification and management of FOREGROUND and BACKGROUND IP.

Intellectual Property

As stipulated in our [terms and conditions](#), we consider Intellectual Property (IP) to include:

all materials, patent rights, know-how, trade marks, service marks, registered designs, copyrights, database rights, design rights, confidential information, applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above.

FOREGROUND IP

We require all considerations surrounding IP to be declared and agreed upon upfront, before any award can commence. Any potential to develop new, FOREGROUND IP should be identified and detailed within the application, along with your proposed plans to suitably protect and utilise the IP.

Any new, Foreground Intellectual Property arising from a Prostate Cancer UK funded project shall be owned by and vest in the host institution. The host institution should use reasonable endeavours to identify, protect and commercially exploit any Foreground IP arising from the project, and should promptly notify Prostate Cancer UK of any such IP as it arises. We expect to be consulted on the exploitation of any new FOREGROUND IP and for any profits from exploitation to be shared in accordance with our grant [terms and conditions](#). If the host institution decides not to protect or to abandon any such IP generated through this project, then Prostate Cancer UK shall have the right, but not the duty, to protect and exploit the IP commercially. Please refer to our [terms and conditions](#) for further information.

BACKGROUND IP

We recognise that your research may build upon or utilise pre-existing Background IP, generated and owned by yourselves or others. For this reason we want to be clear upfront regarding what existing Background IP is in place, and what new, Foreground IP may be generated through Prostate Cancer UK funded research. We therefore require that you declare all relevant Background IP specifically relating to this proposal, how this will be utilised in this

project and whether your proposed study is likely to add significant commercial value to this existing IP.

Where Background IP has already been protected, we do not expect ownership of that IP to change. However, if research funded by Prostate Cancer UK adds significant value to the Background IP that may strengthen its potential for commercialisation, its value at the point of commercialisation, or may provide opportunities for additional commercial exploitation, then we would expect to enter discussions with the relevant parties regarding a revenue share, royalty payments or other form of reimbursement to acknowledge the charity's contribution towards the development of the resultant asset.

For all relevant Background IP already associated with this work, please specify the owner of that IP, whether discussions have been held with them regarding access to this IP/provision of materials (e.g. provision of drug, biomarker etc.) and whether any agreements are already in place covering the potential future exploitation of this background IP. If possible, it will strengthen your proposal if you can provide a letter of support from any third party/parties whose Background IP shall be utilised with this proposed study (upload all letters as a single MS Word or PDF only).

Please refer to our [terms and conditions](#) for further information.

IP Commercialisation

Prostate Cancer UK requires any intellectual property generated to be properly identified, secured and exploited. Where Prostate Cancer UK funds have supported the generation of Foreground IP, or added significant value to pre-existing Background IP, and that IP is subsequently commercially exploited, then our contribution towards the discovery and/or development of this IP should be recognised through a revenue share, royalty payments or another form of reimbursement to enable the charity to continue to pursue its charitable objectives.

Where significant value is likely to be added to a commercial asset as a result of Prostate Cancer UK funding, please explain the proposed arrangements for revenue sharing, royalty payments or other reimbursement from the party commercialising the asset to your host institution and/or to Prostate Cancer UK.

Please also clarify whether you have already (or if you expect to) entered into any commercialisation agreements with a third party(ies) as a result of the work proposed in this application.

Finances

Please refer to our [Finance Eligibility Guidelines](#) for further details regarding cost eligibility.

Your budget **MUST** be broken down in as much detail as possible and entered as separate items under the relevant headings below. Any items which appear excessive or which have not been suitably justified will be queried by Prostate Cancer UK staff and may be removed from the budget if the application is recommended for funding.

Where applicable, please note that applications should be costed in line with the [AcoRD framework](#) for attributing the costs of clinical research, and our standard terms and conditions regarding eligibility of certain costs apply. Those applications with a clinical element must complete a Schedule of Events Cost Attribution Tool (SoECAT) as outlined in the Clinical Research section earlier in these guidelines.

Salary costs:

Include salary details for the personnel who will be employed directly on this project (please include names on individuals where already known). Grants cannot be used to cover departmental/institutional support staff or services, and must not be used for off-setting the salary of any applicant or supporting role whose salary is supported from core institution funds, or by another external source such as a fellowship. If specialist expertise is required, for instance a statistician or a health economist etc., then you may include a reasonable allocation for the proportion of their time that would be committed to the grant, as long as suitable justification is provided.

Eligible staff costs may include the employee's basic salary, any employer's contribution and London allowance where applicable. You should also include allowances for annual pay awards and inflation (your university/institute finance office should be able to advise on appropriate pay and inflation levels).

These Awards are not a mechanism to solely support PhD Students or Clinical Fellows. However, in very exceptional circumstances it may be permissible to include an allowance for a PhD Student or a Clinical Fellow working towards a PhD qualification. In such instances, the studentship/fellowship must form part of a larger project and must be robustly justified as the most appropriate way to deliver the proposed research. If you are considering including a PhD Studentships and/or Clinical Fellowship in your application, we strongly recommend that you discuss this with a member of the Research Team at Prostate Cancer UK before submitting your proposal.

Research expenses:

Detail all expenses that will be directly incurred by the project, except for any animal costs (these should be included separately in the corresponding sections). If you are including fees for the use of any core research facilities – for example, DNA sequencing or flow cytometry –

please state the cost per hour or per sample. These costs must be fully justified within the 'Justification of Budget' section.

Animal purchase costs:

Animal costs should be listed separately from other research expenses and must be split into purchase and maintenance costs under the corresponding headings within the form. Within the 'Animal purchase costs' section, please detail the species of animal(s) to be used, along with the number of individuals required, the aim/sub-study this relates to, as well as the associated purchasing costs. If more than one species of animal is to be used, please enter these separately.

Animal maintenance costs:

As with above, please detail the maintenance costs relating to the species of animal(s) to be used. Again, please detail the species of animal(s) to be used, the aim/sub-study this relates to and the associated maintenance costs. If more than one species of animal is to be used, please enter these separately.

Other costs:

Please also include costs associated with conferences and equipment in this section. Publication costs should not be included within the project budget. Instead, requests to cover open access publication charges arising from successful applications should be made directly to the Prostate Cancer UK Research Team once the manuscript has been accepted for publication by the journal. Additional funds will be granted (outside of the project budget) to cover the cost of successful claims.

Equipment should only be included if essential for the project and must be purchased within the first half of the grant and should not represent a substantial proportion of the overall budget.

Any items which appear excessive or which have not been suitably justified will be queried by Prostate Cancer UK staff and may be removed from the budget if the application is recommended for funding. Please note that after funding is awarded, any changes in budget allocations must be approved in advance, in writing by Prostate Cancer UK, and increases in the total budget will not be permitted under any circumstances. Make sure you include allowances for annual pay awards and inflation – your university/institute finance office should be able to advise on appropriate inflation levels.

Prostate Cancer UK does not pay Full Economic Costs; do not include indirect, estate or any other non-attributable overhead costs in your budget. Applications containing these costs will not be considered. Please refer to our [Finance Eligibility Guidelines](#) for further details.

Justification of Budget *(up to 500 words)*

Please provide a brief justification of the costs that you expect to incur (in no more than 500 words). In particular, you should justify the number and seniority of any staff to be employed on the project, and the inclusion of any costly equipment (or any other significant expenditure) deemed essential for the proposed project.

If the project will include a clinical element, please also state whether the study is likely to receive support from a research network and, if so, the support that will be provided. If the amount requested does not cover the full study costs (e.g. where the work would be part funded by another grant) please also provide brief details as to how the remaining costs of the study will be met.

Declarations

The application must be approved by the Lead Applicant, the Head of Department and the Finance Officer who will be responsible for administering any grant that may be awarded. Both the Head of Department and the Finance Officer must be registered on the on-line Prostate Cancer UK [CC Grant Tracker](#) system to approve the application, and must complete their corresponding 'Declarations' section within the online form.

Declaration – Candidate

Where did you hear about this funding opportunity?

Please indicate where you heard about the 2019 Major Awards in Immunology and Immunotherapy.

Candidate Declaration

Accept the terms and conditions by clicking the box marked 'Candidate Acceptance'.

Declarations - Head of Department

Click on 'Add Contact' within the 'Declaration – Head of Department' section and follow the steps to select and invite your Head of Department to participate (following the same procedure as adding a 'Co-Applicant'), The Head of Department must then log in to the system and complete the rest of the 'Declaration - Head of Department' section.

Anti-Bullying Policy

Prostate Cancer UK will only award funds to institutions with official policy and procedures in place regarding anti-bullying. Please provide either a link to your policy or a brief description of the policy.

Scientific Integrity

Grants will only be awarded to institutions that have official policy and procedures designed to protect scientific integrity. Please specify if this is indeed the case and include a link to your policy.

Head of Department Declaration

The Head of Department must then approve the declaration, confirming that they have read the [terms and conditions](#) and agree to abide by them if a grant is awarded.

Declarations – Finance Officer

Click on 'Add Contact' within the 'Declaration - Finance Officer' section and follow the steps to select and invite your Finance Officer to participate (following the same procedure as with adding a 'Co-Applicant'). They must then log into the system and access the 'Declaration – Finance Officer' section of the application form and complete the declaration question.

Finance Officer Declaration

Approving the application will imply that the approver has read the [terms and conditions](#) and agrees to abide by them if a grant is awarded.

Submitting your application

Once you have completed all sections of the form you must go to the 'Validation' tab in the left hand menu of the online application. This will highlight any sections which still need completing, or that exceed the stipulated word limits or which require confirmation and/or approval from others.

Please note that all mandatory sections of the form must be completed (within the stipulated word limits), and the Joint-Lead Applicant (if applicable) and all Co-Applicants must confirm their involvement and approve the proposal before the application can be submitted. You will be unable to submit your application until these have been resolved.

When all sections are complete and all necessary approvals have been made, the application is ready to be submitted. You must 'Save and Close' the application and this will then take you back to the application details page. The Submit button on the right-hand side should now be activated, and you can click this to submit your proposal. Once submitted you should receive an automated email confirming your submission. Please note you may also download a PDF of the submitted application via the 'View/Print' button on the right-hand side of the screen.

Key dates

- **7 May 2019:** Call opens
- **22 July 2019 (12pm noon):** Deadline for application submission
- **w/c 14 October 2019:** Applicants invited to submit a rebuttal to reviewer comments
- **28 October 2019 (12pm noon):** Deadline for rebuttal submission
- **Early December 2019:** Final funding decisions will be made
- **Late December 2019:** Notification of funding decisions

Contact Us

If you have any queries regarding your application, please contact the Research Team at Prostate Cancer UK via:

Email: research@prostatecanceruk.org