Research Innovation Awards: Stage 2 Guidance Notes 2022/23

Research Strategy

Prostate Cancer UK has an ambitious research strategy, setting out how we will invest in the most innovative research to create a step change in our knowledge of prostate cancer. We have to be smarter in how we detect and treat prostate cancer at every stage, and we need to develop personalised approaches for every man to achieve the best outcome. Ultimately, we want to see fewer men dying from prostate cancer!

We have identified three key areas where there are substantive gaps in our knowledge or expertise and we would welcome innovative research proposals targeted towards:

- **Better Diagnosis**

  (including risk stratification & disease prognosis)
- **Better Treatment**

  (for both localised & advanced disease, including improved prediction of which treatment(s) will be effective for an individual)
- **Smarter Use of Data**

Research Innovation Awards – Eligibility

All proposals must align with our research strategy (see above) 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.

The application process and assessment of your proposal will reflect our increased focus on innovation and potential impact. You should make every effort to detail how your proposal meets those criteria.

This call is for bold, innovative research that has the real potential to impact the way prostate cancer is diagnosed and treated. As such, we want to see novel game changing research!

There are no financial restrictions as to what you can request – you should simply apply for what you need. You may adjust the proposed budget from your Expression of Interest, as long as the changes are necessary and sufficiently justified. 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; however again you should apply for however long you need. Projects that are shorter or longer than 1-5 years are still eligible, but must be sufficiently justified.

This scheme will fund both fundamental and clinical research (and all stages in between); However, research at all stages will be expected to have a focus on eventual benefit to men. Applicants will 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 that benefit to men.

We will also consider applications that bring innovative ideas from other cancer types and 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 agreed 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).

- Lead Applicants must have a minimum of 5 years' post-doctoral experience. Lead Applicants with between 5 and 10 years' post-doctoral experience must have a senior academic (usually the research group head) named on the proposal as a Joint Lead Applicant or Co-Applicant.

We are keen to grow good post-doctoral researchers towards independence, and 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. Therefore, it is permissible for a Lead Applicant with between 5 and 10 years' post-doctoral experience to include their salary within the application budget. In this instance, they must truly be leading the research, and a detailed justification must be provided explaining how the salary support, and the research funding applied for, will support the individual in their career progression by achieving independence by the end of the project. A statement should also be provided by an appropriate authority at the host institution detailing how the individual will be supported by the institute at the end of the project (if awarded).

We will not be prepared to meet the salary of a post-doctoral Lead Applicant more than once and we would expect a post-doctoral Lead Applicant 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 our Research Strategy
- 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 have any queries about completing the application form please contact the Research Team **in advance** of the submission deadline (email: research@prostatecanceruk.org).

Once the deadline has passed, you will no longer be able to submit your proposal. If your application has not been submitted AND approved by all necessary parties before the deadline, then your application will no longer be considered. There will be no opportunity to debate individual circumstances. Applications which are incomplete or which do not meet the requirements detailed above will be rejected without being sent for further review.

Assessment Process

Deadline: Shortlisted applicants must submit their second stage proposals and ensure that all online declarations and approvals have been completed by the relevant parties before **1pm** on **7 March 2023**.

Peer Review: Submitted applications will then be subject to external peer review (in line with **AMRC guidance**). The peer reviewers' comments will be sent to the applicants (anonymously) via our online system in **w/c 1 May 2023**. Applicants will have an opportunity to submit a response to the reviewers' comments.

Decision: All applications, reviews and rebuttals will then be considered by our **Research Advisory Committee** in **June 2023** who shall make final funding recommendations to our Board of Trustees. Clinical applications will also be assessed by our Patient and Public Involvement Representatives.

Notification: Final funding decisions are made and applicants will be notified as to the outcome of their submission via email in **July 2023**.

We recognise that the outcome of your application is important to you and we appreciate your patience during this time.

Contracting: Once notified of our intention to award, we will begin the contracting process immediately (subject to any conditions of award). Successful projects should aim to get underway as soon as possible or at least within six months of completion of contracting.

Making your application

Stage 2 applications will automatically be created for shortlisted candidates via our online system, and will pull through information you have provided in your Expression of Interest. To access your application form you must log in to our online CC Grant Tracker system, click on 'My Applications' and the form should be there for you to click into to edit.

You must fill out **all sections of the application form** (guidance below) and you also have this opportunity to update and/or elaborate on any of the information you provided in your Expression of Interest form. Once all sections have been completed, **yourself**, the **Head of Department** and the **University/Institute Research Grants office** (or finance office) must complete the online declarations in order for your application to be accepted.

Any **Joint Lead Applicant (if applicable) and all Co-Applicants** must confirm their involvement in the proposal **and** must also approve the application before it can be submitted.

Collaborators do not need to 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.

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.

Completing your Application Form

Lead Applicant Details

CV information and publications

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 (except for publications). 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:

- You will need to include your ORCID ID, please add this 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 'Publications' section of the Lead Applicant Details page.

COVID-19 impact

We recognise that the impact of the coronavirus pandemic will have affected the work of many researchers. Please detail if and how the pandemic has impacted you and/or your research activities. (up to 500 words)

Please note, where this is applicable, we're not looking to capture the details of what happened but ask that you focus on the consequences and impact on your career, or your ability to deliver your research. This can include but is not limited to:

- Change in personal circumstances such as inability or reduced ability to work due to illness or additional caring responsibilities.
- Pause on experiments/research plans/access to facilities (potentially as a result of a notable period of furlough).
- Clinical responsibilities (working on the front line, required to back-fill posts, etc) and any ongoing impacts during the transition back to research.
- Delays in publishing/submitting a key paper(s) or other outputs and markers, e.g. panel membership, presentation invitations, conference participation, promotions.

Click the help icon '?' in this section of the online application form for examples of how to capture this. For further information, please read the cross-funder statement on the impact of COVID-19.

We ask that you only disclose personal information that you would be comfortable being seen by our external reviewers and committee members. For the same reason please do not disclose any information that is about a third-party including name, circumstances, or information that allows them to be identified.

Panel members will be asked to consider this information as part of their assessment to prevent applicants from being penalised for things beyond their control. For example, the

applicant's individual circumstances will be noted when assessing track records, impact on publications and any delays or setbacks in the progress of their research as a result of the pandemic.

Your role

In this section you will also be asked to provide details on your role.

Experienced post-doctoral researchers

If the Lead Applicant is an experienced post-doctoral researcher (defined as an individual with greater than 5 and less than 10 years post-doctoral research experience), please explain why they are suitable to jointly lead on this proposal.

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.

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.

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

You **must** then provide sufficient explanation (under 'Role Description') to justify the need for a Joint Lead Applicant, as well as which aspects of the proposal they will be leading on and why they are appropriate to lead on that aspect of the project.

Personnel

This section allows you to add the details of any Co-Applicants and Collaborators involved in the proposal. Contacts will automatically pull through from your Expression of Interest, but please update the personnel to reflect any changes made if applicable. You must also clearly specify each individual's role in the project, and provide any letters of support from the named Collaborators.

Co-Applicants:

Please include details of all Co-Applicants to be involved in the project. It is our expectation that all Co-Applicants must have an active role in the proposed project (any other personnel should be listed as a Collaborator).

To add Co-Applicants, 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.

Co-Applicants added at the Expression of Interest stage will automatically be pulled into the second stage application form and will not receive an automated email. It is the Lead Applicant's responsibility to contact these Co-Applicants themselves and let them know what's required of them.

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. 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 (detailed above). 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 the Lead Applicant with a supporting letter.

Collaborators added at the Expression of Interest stage will automatically be pulled into the second stage application form and will not receive an automated email. It is the Lead Applicant's responsibility to contact these Collaborators directly and obtain a letter of support.

You **must** then detail how **each** Collaborator will be involved in the project, as with the Co-Applicants. A letter of support from each Collaborator must be uploaded via this section, alongside the corresponding Collaborators. 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). It is our expectation that projects should be between 12 and 60 months in duration (projects shorter or longer than this are still eligible, but you should justify why funding for this length of time is required).

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), explaining why your research meets the selected priority area(s) (in no more than 100 words).

We also ask that you highlight any significant changes you have made to your proposal since your Expression of Interest and how you have responded to the feedback provided by our Research Advisory Committee (in no more than 300 words). You must then select up to 6 keywords from the list provided which best describe the project.

Your scientific abstract will pull through from your Expression of Interest; however please do take this opportunity to review and amend accordingly. Your abstract must be no more than 300 words, and should outline 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 refer to references by number in this section and list them in full under the 'References' section (a maximum of 100 references are permitted).

Please be aware that your abstract will be sent to potential peer reviewers to establish their ability to review the proposal, and if funded, will also be shared with the Association of Medical Research Charities (AMRC), the National Cancer Research Institute (NCRI) and the International Cancer Research Partnership (ICRP) and any other organisation as specified in the grant terms and conditions.

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

Key Hypotheses, Aims, Objectives and Milestones

Please summarise the main aims of the project in no more than 100 words.

Detail the main hypotheses to be investigated, along with a brief timetable of milestones, in no more than 500 words (this section will be auto-populated from your EOI form). All proposals should articulate a strong, central research question and be placed in the context of current knowledge and the potential benefit for men affected by prostate cancer. This scheme is aimed to support hypothesis-driven research. Proposals that are not sufficiently hypothesis-driven are likely to be rejected in all but exceptional circumstances. Please speak to the Research Team at Prostate Cancer UK if you have any queries about eligibility.

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.

Project Delivery

Please provide details about your proposal by answering **all** of the questions within this section:

What is innovative about your application? *(auto-populated from your EOI form - 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.

Brief summary of the background to the project

(auto-populated from your EOI form - up to 500 words)

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.

Preliminary data

(up to 750 words)

Please detail any preliminary/pilot data that supports your application, including strengths and weaknesses (methodological or field-specific) in the rigour of the prior research within this section (in no more than 750 words) and via the 'Optional preliminary data figure attachments' section.

Figures can be included by uploading up to 3 MS Word or PDF files (each upload should not exceed 10MB in file size) via the '*Optional preliminary data figure attachments*' section and following the on-screen prompts. Papers that have been accepted for publication but are not yet in print can also be uploaded here if you wish for them to be seen by the reviewers (However, manuscripts under review or in preparation should not be provided as additional information).

Detailed plan of investigation

(auto-populated from your EOI form - up to 1,200 words)

Describe the methodology you will use to address each hypothesis, along with the timescales for each section of the research. Projects using human or animal tissue samples should state the source and indicate the availability of tissue.

Please ensure you include details of your planned statistical analyses. If relevant, you should highlight any statistical methods you will employ and your approach to the analysis. Clinical studies should refer to the 'Clinical Research' section to include information on power calculations and patient recruitment.

Where there are multiple components to your proposal, please clarify who shall be leading/delivering each component or sub-study.

An additional figure attachment may also be uploaded (MS Word or PDF files only) in this section.

Potential problems and contingency plans

(up to 200 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.

Patient & Public Involvement

Will men with prostate cancer, or their relatives/partners etc., be involved in the design, planning or management of this research? *(auto-populated from your EOI form - 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. You should 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.

For more information on involving patient representatives in your research, please visit our website. Prostate Cancer UK has established a Patient Representative Network, consisting of patient representatives with an interest in being involved in research and who may be able to help you with your proposals. To be put in touch with members of our Patient Representative Network to support your research, please visit our website and complete the request form.

Clinical Research

This section only applies to those projects that include a clinical component such as recruiting people/patients, patient data analysis or collecting samples from people/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 then answer the following questions:

Payment of Excess Treatment Costs (ETC's)

Investigators conducting clinical research are required to complete the Schedule of Events Cost Attribution Tool (SoECAT). This 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 form is mandatory for studies to be eligible for the NIHR portfolio, and the support this provides (including access to excess treatment cost payments).

Important note: External sign-off via the tool is required to confirm the study cost attribution complies with the Department of Health and Social Care AcoRD guidance. This will need to be done ***before*** you attach your SoECAT form 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 this web page. Once you have completed your SoECAT form, 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 recommend submitting your SoECAT form to your LCRN at least 3 weeks before the grant submission deadline in order to have it authorised and returned back to you before the application submission deadline.

Once your SoECAT form has been signed off, please upload your completed (and approved) form in this section of the application.

Please tick ALL the following that apply:

Please note that 'sample' can include, images, data and human tissue/fluid samples.

The proposed study is

- **A clinical trial**- Select this option if you will be evaluating the effectiveness and safety of new tests and treatments on recruited patients

- **A prospective sample collection**- Select this option if the proposed work will involve the collection of patient samples

- **A retrospective analysis of an existing collection of clinical samples**- Select this option if the proposed work involves 1) collection of existing patient samples 2) analysis of data originally collected for a different purpose e.g. in-depth analysis of trial databases, repositories of patient data, images and/or patient samples

If your proposal includes a **clinical trial,** please answer the following questions:

Type of trial

Please specify if the trial is an observational study or a treatment/intervention trial.

What Phase will the trial be?

Please specify the phase of the proposed clinical trial e.g. Phase II, Phase III

Please upload a trial schema of the proposed study (single-side of A4).

This should capture the study design highlighting the flow and number of patients. Please include additional information such as eligibility, screening, randomisation and any subsequent activity through to follow-up.

Please clearly describe your power calculations. *(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/retention or 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.

What are the arrangements for the support, management and oversight of the trial? *(up to 500 words)*

We want to know what existing infrastructure you have or will have in place to support clinical trials at the institutions involved (e.g. a dedicated Clinical Trials Unit, nursing support, data management and data analyst support).

We also want to know whether there are appropriate governance arrangements in place to ensure expert advice and monitoring that is independent of the trial team e.g. a Trial Steering Committee (TSC) and Independent Data Monitoring Committee (IDMC)?
Note, where a TSC is in place, we expect to have observer status and reserve the right to attend TSC meetings.

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

Please describe (in words or via upload of a patient flow chart) 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 development 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.

Insert Patient flow chart (optional)

A flow diagram which shows the flow of participants through each stage of the trial.

---------- End of Clinical Trial Section ----------

If your proposal includes a **prospective sample collection,** please answer the following questions:

Please provide details on how and when the samples and/or data will be acquired including the type of material that will be obtained and how many samples will be required. *(up to 500 words)*

Will the samples be obtained from existing infrastructure and if so, has that access been approved? Have you considered existing sample repositories? We want to know why there is a need for this prospective collection and whether the number and quality of samples is suitable and fit for purpose.

Please detail how the samples and/or data will be appropriately stored and managed. *(up to 300 words)*

We're looking for information on how the samples and/or data will be stored and made available to appropriate researchers. If necessary, do you have the required approvals?

What measures will be in place to allow the samples/data to be accessible as an open resource for future work? *(up to 300 words)*

We're looking for information on whether (and how) the samples will be made available for other researchers to access in the future.

---------- End of Prospective Sample Collection Section ----------

If your proposal includes a **retrospective analysis of an existing collection of clinical samples,** please answer the following questions:

Where will the proposed samples and/or data come from? What are the practical considerations in order to access the relevant samples/data? *(up to 500 words)*

We want to know which clinical trial/repository you will be accessing the proposed data/samples from, and whether the relevant parties have agreed and/or you have approved access to this resource. We'd like to know how you will access the samples/data/images required for your proposal and whether there are any logistical considerations to be aware of.

It is our expectation that all approvals or agreements in principle from all relevant parties are in place at the point of submission of your application. If you have been granted approval from the relevant parties of the original trial/biobank, to access the samples/data you're intending to use, please upload a letter of support from the relevant parties here as confirmation. However, if you have yet to obtain approval, please state why this has not yet been obtained.

What added value would the proposed research provide, over and above that of the original trial and/or other published data? *(up to 300 words)*

We want to know why your proposed research is important and what new knowledge would be generated that builds upon the findings of the original trial and/or any other published data in the area of your proposal. You should also explain why such a proposal is needed now and how it will differ from or complement any other planned, ongoing, or recently completed studies.

----------End of Retrospective Analysis of Samples Section----------

Outputs and Impact

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 academic 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)? *(auto-populated from your EOI form - 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? *(auto-populated from your EOI form - 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.

Lay Summary

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

In line with 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 that you are happy for all information in this section to be publicised at a later date.

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.

It is in your interest to take a great deal of care over this section. If your lay summary does not clearly convey the importance of your research project for men affected by prostate cancer, then it will adversely affect the chance of your application being funded.

This section should make complete sense when read in isolation to the rest of your application, therefore, please do not include any references, diagrams or acronyms included elsewhere in your proposal. We recommend that you consider getting a patient representative to review this section of your application as Prostate Cancer UK staff will take no responsibility for translating the science if the lay summary is inadequate.

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 200 words)*
- What are the expected, long term outcomes of this study?
  (i.e. how could your research make a difference to the lives of those affected by prostate cancer in the long term, and how do you envision your research impacting clinical practice and the way that men are diagnosed and/or treated?) *(up to 200 words)*
- Summary of the project in one sentence *(up to 50 words)*

References

You may 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 (upload must not exceed 10MB in file size).

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, and why this specific model was chosen. In particular, please carefully consider:

- 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 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.

As stipulated in our Terms and Conditions, we consider Intellectual Property (IP) to include:

all materials, patent rights, know-how, trademarks, 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 your 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. 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).

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.

You may adjust the proposed budget from your Expression of Interest, as long as the changes are necessary and sufficiently justified (there is a specific section for you to explain any significant deviation from your Expression of Interest – see below). 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. Budget items **MUST** be broken down in as much detail as possible and entered as separate items under the following headings:

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).

Whilst Research Innovation Awards are not a mechanism to solely support PhD Students or Clinical Fellows, it is 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 Research Innovation Award 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.

Where applicable, 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.

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.

Please explain any deviation from the budget estimated in your Expression of Interest *(up to 300 words)*

It is permissible to revise the budget from the Expression of Interest stage, as long as any significant deviation is clearly justified. The Research Advisory Committee will be considering value for money when assessing your application and any additional or excessive costs will be queried and may be removed.

Declarations

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).

Declarations – Candidate

The application must be approved by the Lead Applicant, the Joint Lead Applicant (if applicable), all Co-Applicants, 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.

Declarations - Head of Department

To add a Head of Department click on 'Add Head of Department' 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 with adding a Co-Applicant). The Head of Department must then log in to the system and complete the rest of this 'Declaration - Head of Department' section.

Experienced post-doctoral researchers: if the Lead Applicant is an experienced post-doctoral researcher, then the Head of Department must also justify how the salary support and research funding applied for, will lead to independence for the individual at the end of the project. The Head of Department should also include any information on how they will be supported by the host institution at the end of the award.

Anti-Bullying Policy: Prostate Cancer UK will only award funds to institutions with official policies and procedures in place to appropriately handle instances of bullying. Please provide a link to your institution's policy, or a brief description of the policy in this section.

Scientific Integrity: Grants will only be awarded to institutions that have official policies and procedures designed to protect and uphold scientific integrity. Please provide a link to your institution's policy, or a brief description of the policy in this section.

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

Please follow the same procedure with the Finance officer within the 'Declaration - Finance Officer' section. The Finance Officer must then log into the system and access the 'Declaration – Finance Officer' section of the application form and complete the declaration question.

Approving the application will confirm that the approver acknowledges the Terms and Conditions and agrees to abide by them if a grant is awarded. Approving this declaration also confirms that the institution will administer any grant awarded and will ensure the funds are used for the purpose for which they have been given.

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. Any such discrepancies will be flagged under the 'Validation' section of the online form, and 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.

The application will require approval from the Head of Department and the Finance Officer after the proposal has been 'submitted'. The proposal must be submitted by the Lead Applicant and approved by the Head of Department and the Finance Officer in advance of the submission deadline. Applications which have been submitted but do not have the necessary approvals will not be accepted.

Once submitted and approved by the Head of Department and Finance Officer, 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 application details screen.

Key Dates

- **7 March 2023 (1pm):** Deadline for second stage application submission
- **w/c 1 May 2023:** Applicants invited to submit a rebuttal to reviewer comments
- **15 May 2023 (12pm noon):** Deadline for rebuttal submission
- **June 2023:** Final funding decisions will be made
- **July 2023:** Notification of funding decisions

Contact Us

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