

2021/22 Major Awards in Curative Treatment

More Cures, Less Harm - Supporting research to improve the outcome for men treated in the curative setting

Introduction

If prostate cancer is caught in time, when it is still localised to the prostate or has spread to the area just outside the prostate, we have treatments that can cure it. However, we still face two significant challenges:

- We need to be sure that when prostate cancer is detected it is treated appropriately and effectively. There are still too many men who are treated for early prostate cancer, only for their cancer to return. Sometimes this will be because we don't give the most appropriate treatment. Sometimes because we thought they had early and potentially curable cancer, when in fact they didn't.
- Far too many men end up with harm from their treatment, harm such as urinary incontinence, erectile dysfunction or troublesome bowel symptoms. This is terrible in all men, but especially so if that harm is done to men who had indolent disease that would never have killed them, to men who were under-staged and could never have been cured, or to men who have undergone one type of treatment when another may have been more effective for them.

We believe men deserve better. They deserve a future where they don't have to fear being harmed by treatments or having their cancer return. They deserve a future where their lives and bodies are not harmed by prostate cancer.

One of the key strategic aims of Prostate Cancer UK's research strategy '[More Cures, Less Harm](#)' is on improving outcomes for men with localised disease. We need more effective treatments that can prevent the cancer from coming back, and we want to reduce side effects from current treatments, so no man has to sacrifice their quality of life for a cure. We also need more research that helps us identify stage and prognosis of disease more accurately.

This is largely aligned with Movember's strategic priority as identified in the [Movember Prostate Cancer Landscape Analysis](#). Supported by extensive consultation with experts in the field and men with prostate cancer, it has been recognised that Movember should focus on supporting highly translational research that will lead to the earlier identification and optimal treatment for men with clinically significant disease. It is envisioned that success in this research program will significantly reduce the number of men progressing to advanced, treatment-resistance disease, as well as ensuring the best possible quality of life for men with prostate cancer.

Prostate Cancer UK and Movember have been jointly funding a range of research programmes since 2012 and we are pleased to continue this partnership in the design and delivery of this initiative that will hopefully provide the best possible treatment for a man's particular disease and improve outcomes for men with prostate cancer.

Remit

Following on from the success of last year's Major Awards funding call into curative treatments, Movember and Prostate Cancer UK are launching a second round on this joint initiative. We want to fund research that can improve the outcomes for men treated in the curative setting. This can be research that helps men select the most appropriate treatment for them, research aimed at increasing the effectiveness of initial treatment in terms of cancer control, or research focused on reducing side effects from initial treatment, without reducing cancer control.

The focus of this call is to support clinical (or translational) research to improve initial treatment with curative intent, either through greater precision of treatment modalities or through better informed treatment decisions which will result in the best outcomes for that individual. Through this call we aim to support research into the treatment of localised disease as well as research aimed at curing locoregional disease (for example, T3/T4 disease and/or true N1 M0 disease). Research into the treatment of oligometastatic/metastatic disease, or biochemical recurrence, are not in the scope of this call.

Through this call we will support:

1. **Clinical trials** in the research areas highlighted below.
2. **Translational research** that will lead to commencement of clinical work either towards the end of the project or as the immediate next step following completion of the grant (projects must be able to articulate a clear pathway to impact and have a good idea of the subsequent clinical trial).
3. **Research using patient samples/data/images from existing clinical trials** to address any of the research themes highlighted below.

We anticipate a total budget for the call of £3m, dependent upon the quality and scale of proposals we receive, their proximity to both Prostate Cancer UK and Movember's research strategies and the fundraising environment between now and December. There is no upper limit set for individual projects, however applicants must ensure that the amount requested is a realistic reflection of the research proposed (value for money will be a key consideration in making final funding decisions). Please contact the Research Team at Prostate Cancer UK before submitting your proposal if you are wanting to apply for more than £750k.

Eligible Research

Through this call we would particularly like to support research into:

- **Surgical trials.** Particularly research into new techniques/technologies to improve cure rate and/or reduce side effects. We would also be keen to support studies investigating the use of imaging to improve outcome from surgery, as well as head to head comparison of surgical approaches.
- **Radiotherapy trials.** Particularly research into new techniques/technologies to improve cure rate and/or reduce side effects. We would also be keen to support studies into the scheduling and dosing of radiation therapy, as well as the use of imaging to improve treatment outcomes.
- **Brachytherapy trials:** Research into new techniques and alternative doses for both low dose rate and high dose rate brachytherapy.
- **Treatment combinations.** We would like to see studies into radiotherapy/drug combinations in the curative setting, as well as the investigation of adjuvant medical or radiation treatment and the optimal timing of adjuvant treatment. We also wish to support research looking at molecular/biological determinants of response.
- **Alternative approaches to treatment.** Trials investigating the use of focal therapies or other new approaches which have the potential to effectively treat localised disease, whilst offering an improved side effect profile would be welcomed. We would also like to see head to head comparisons of these approaches, particularly against surgery and/or radiotherapy (but which are not a duplication of existing head to head trials).
- **Patient stratification/treatment selection.** Research that makes treatment choices easier for men and ensure that they receive the most optimal treatment for them with the greatest chance of them being cured. We also wish to see research seeking to gain a detailed understanding of the biology of localised and locally advanced prostate cancer in order to more accurately classify the disease to help inform treatment decisions (as long as this will feed into a clinical study in the near future, and/or capitalises on existing clinical studies). This includes decisions to intensify or de-intensify treatment, or inform the choice between one particular treatment option over others. The use of large data sets and AI approaches to help treatment selection based on clinical characteristics or genetic/genomic/radiomic information will also be eligible.
- **Imaging studies.** We are looking for research to improve the accuracy and consistency of cancer staging, to definitively identify those men with truly localised disease and who are potentially curable, whilst more reliably finding the men with disease that is currently understaged and undertreated (or incorrectly treated). As stated above, we also wish to support studies utilising imaging modalities to guide the use of treatments in order to achieve better outcomes for men.

- **Capitalising on existing trials.** Research that builds on existing trials in this disease setting, for example additional analyses of existing datasets, meta-analyses combining trial results and the use of samples from patients recruited to those trials to accelerate our understanding and impact are also considered appealing.

The above is not a definitive list. If you are unsure, please contact the Research Team at Prostate Cancer UK to discuss your proposal.

Research not covered under this strategic initiative

Through this initiative we will not consider:

- Research into the management of side effects associated with localised treatment, for example self-management support, treatments or devices for side effect management, behavioural/psychosocial research etc.
- Research that is not hypothesis driven and/or is solely focused on data/sample collection, patient surveys etc.
- Research into the treatment of oligometastatic, metastatic disease or biochemical recurrence.
- Studies on the treatment of advanced prostate cancer, even where the techniques used are more normally used to treat localised disease (i.e. focal therapy, surgery or radiotherapy).
- Research focused on the biology of disease or discovery and validation of biomarkers that does not focus on informing localised disease treatment decisions.
- Pre-clinical research that does not have a clear and rapid pathway to clinical impact and which would not lead directly into clinical studies by the end of the grant.

If your research does not meet the remit for this funding call, you may wish to consider the [Research Innovation Awards](#) scheme which will be launching later in the summer. You can keep up to date with all future funding opportunities via the [Prostate Cancer UK website](#) and by following [@ProstateUKProfs](#) on Twitter.

Eligibility

All proposals must align with the research strategies of [Prostate Cancer UK](#) and Movember, and must address the remit of this call.

- 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).
- 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, but only when their salary is not met through core institutional or fellowship funding. 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.
- There are no financial restrictions as to what you can request – you should simply apply for what you need. However, funds requested in your proposal must be in accordance with our [Finance Eligibility Guidelines](#). 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 and that the likely impact of the proposal is commensurate with the funding requested. Please contact the Research Team at Prostate Cancer UK before submitting your proposal if you are wanting to apply for more than £750k.
- We would expect projects to be between 1 to 5 years in duration; However, again, you should apply for however long you need. We recommend that you contact the Research Team at Prostate Cancer UK before submitting your proposal to discuss eligibility if you are wanting to apply for longer than 5 years.

Please note that we will NOT accept applications that:

- Do not fit the research strategies of Prostate Cancer UK or Movember and the remit of this call.
- 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

Applicants must submit their proposal **and** ensure that all online declarations and approvals have been completed by the relevant parties before **12pm (noon) on 2 August 2021**.

All 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 the online system the week commencing **4 October 2021**, and responses must be submitted by **12pm (noon) on 18 October 2021**. Further information about responding to the referees' comments will be provided to applicants at the appropriate time.

Applications will then be assessed by our Research Advisory Committee in November 2021. Applications will also be assessed by our Patient and Public Involvement Representatives (a lay review panel consisting of people affected by prostate cancer). Once the final funding decisions have been confirmed applicants will be informed of the outcome by email in **December 2021**.

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 at Prostate Cancer UK 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 (subject to any conditions of award). If applicable, the budgets for successful applicants will be checked to ensure that costs associated with the research have been correctly attributed (in accordance with the [Department of Health's cost attribution guidelines – AcoRD](#)).

All awards will be made in accordance with our standard grant terms and conditions, and it is our expectation that contracting should be completed within three months 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.

Successful applicants must not disclose any details of their proposal publicly until contracting has completed and a communication strategy has been agreed upon with Prostate Cancer UK and Movember.

Making your application

Applications **MUST** be made by the Principal Investigator and using our online [Grant Management System](#).

You must fill out **all sections of the application form** (guidance below) and **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

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 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.

ORCID ID:

All applicants must have an up to date [ORCID](#) account. Please ensure that you include your ORCID iD number in the corresponding section under 'Basic Information' via 'Manage My Details'.

Publications:

Please select your most significant/relevant publications for this application (a maximum of 10 to be selected). Publication details must be entered under the 'My Research Outputs' section in the left-hand menu (as above, this section is not accessible directly from the application form, and so you must first 'Save & Close' your application and then click on the 'My Research Outputs' link in the left-hand menu).

Within the 'My Research Outputs' section you may import your publications via Europe PubMed Central (by selecting the 'Import' link in the left-hand menu, selecting Europe PMC as the source and clicking on 'Select Records'). Using the search criteria to find the publications you wish to add to your contact record. Select the relevant publications and click on 'Complete Import'. These papers will be saved against your contact record. If you are unable to import a particular publication, you may manually enter the details by clicking the 'New' button and providing the necessary details.

Back within your application form, all of the publications will now appear in a dropdown list within the 'Lead Applicant Details' section. You may select up to 10 relevant publications you wish to be listed within your proposal.

Personnel

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

Joint Lead Applicants:

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 (under 'Role Description') to justify the need for a Joint Lead Applicant, 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-doctoral researcher whose salary is to be included in the proposal, then you must also upload a letter justifying why they are suitable to be a Joint Lead Applicant, and what support they will receive from the host institution at the end of the grant.

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 that their relevant details are filled in accurately by going to the 'Manage My Details' section. As mentioned above, **the Joint Lead Applicant must confirm their participation AND approve the application BEFORE the proposal can be 'submitted'.**

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 their information, 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.

As above, **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 the application PDF. Again, 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 (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.

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' role. 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).

You must then select up to 6 keywords from the list provided which best describe the project, and provide a scientific abstract (in no more than 300 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 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), Movember, the National Cancer Research Institute (NCRI) and the International Cancer Research Partnership (ICRP).

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

Within this section you must also provide a rationale as to how your proposal addresses the remit of this call (in no more than 100 words).

Key hypotheses, aims, objectives and milestones

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

Detail the main hypotheses to be investigated, along with a brief timetable of milestones, in no more than 500 words. 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.

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. 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*)

Project Description

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

Brief summary of the background to the project

(*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. 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.

Preliminary data (*up to 500 words*)

Please detail any preliminary/pilot data that supports and strengthens your application within this section (in no more than 500 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

(*up to 2,500 words*)

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.

Sample sizes, power calculations and any assumptions must be clearly stated and justified. Clinical studies must include additional information via the 'Clinical Research' section to describe the number of people to be recruited, the recruitment strategy, feasibility of full recruitment etc. Clinical trials must describe how the study is statistically powered and for what endpoint. Projects using human or animal tissue samples should state the source and indicate the availability of tissue.

An additional figure attachment (no greater than 10MB in file size) 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.

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)?

(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 impact for men described above?

(up to 750 words)

All proposals must have a clear and rapid pathway to realising patient benefit. We wish to understand what the immediate next steps would be following this proposal in order for this research to benefit men with prostate cancer. Clinical studies should have a clear plan as to how the work will be progressed into subsequent, larger-scale trials (if successful), and eventually implemented into clinical practice. Pre-clinical research must have a clear plan as to how the work will translate into a clinical study towards the end of the grant, or immediately following the completion of the grant.

We are aware that additional steps and follow on funding may be required in order to realise this impact. Please detail any 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. **Time to impact will be a key consideration for the panel. Applications without a clear and rapid plan to realise this impact are unlikely to be successful.**

Patient & Public Involvement

Will men with prostate cancer, or their relatives/partners etc., be involved in the design, planning or management of this research?

(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. Please contact the Research Team at Prostate Cancer UK if you require assistance with patient and public involvement.

Clinical Research

Please use this section to provide further details of your proposed clinical study. If your proposal does include a clinical component, please respond 'yes' to the question 'Does this project involve clinical research?' and then answer the subsequent questions (as detailed below).

If your application does not include a clinical component, please select 'no' to the question 'Does this project involve clinical research?' and then provide further details as to your plans for translating this research into clinical studies by the end of the grant. Please note that we would expect applicants to have a clear and rapid plan as to how this will translate into a clinical study immediately following the completion of the grant. You should detail your plans for clinical translation and give a description of what the subsequent clinical trial will look like.

Time to impact will be a key consideration for the panel. Applications without a clear and rapid plan to translate into clinical studies are unlikely to be successful.

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.

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 reviewers 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).

This question will be considered by our lay representatives with direct experience of prostate cancer, so please think carefully about the impact on the patient. Please contact the Research Team at Prostate Cancer UK if you require assistance with patient and public involvement.

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).

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, 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.

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).

This funding call is 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 include costs associated with publications, conferences and equipment in this section.

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.

Declarations

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 [Research Management System](#) to approve the application, and must complete their corresponding 'Declarations' section within the online form.

Declarations – Finance Officer

To add a Finance Officer, click on 'Add Finance Officer' 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.

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.

Declarations - Head of Department

Please follow the same procedure with the Head of Department under the 'Declaration – Head of Department' section. The Head of Department must then log in to the system and complete the rest of this 'Declaration - Head of Department' section.

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.

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

- **2 August 2021 (12pm noon):** Deadline for application submission
- **w/c 4 October 2021:** Applicants invited to submit a rebuttal to reviewer comments
- **18 October 2021 (12pm noon):** Deadline for rebuttal submission
- **November 2021:** Final funding decisions will be made
- **December 2021:** Notification of funding decisions

Contact

If you have any questions about this funding call or whether your proposal is within remit, please contact the Research Team at Prostate Cancer UK: research@prostatecanceruk.org