Research Innovation Awards: Stage 2 Guidance Notes 2024/25

Research Strategy

We have 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 longer than 5 years are still eligible, but must be sufficiently justified. Longer term / broader proposals that comprises of inter-connected work streams may be more aligned to our Transformational Impact Awards. We will also consider applications for small scale pilot grants or 'blue sky' research in this call.

This scheme will fund both fundamental and clinical research (and all stages in between) and we expect proposals 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. 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 Joint Lead Applicant or Co-Applicant on the proposal).

- Lead Applicants should 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.

- Individuals with greater than 5 years postdoctoral experience (for clinical researchers) or 10 years (for non-clinical researchers) can apply as independent PIs.

- Experienced Early Career Researchers (see definition below) who wish to apply as a Lead Applicant must have a senior academic (usually the research group head) named on the proposal as a Joint-Lead Applicant.

  We define an experienced Early Career Researcher as:
  - Non-clinical researcher: someone who has between 5-10 years post-doctoral experience.
  - Clinical researcher: someone who has 0-5 years post-doctoral experience.

- Experienced Early Career Researchers may include their salary within the application budget (if it's not already covered through other means such as core institutional funds or fellowship funding). In this instance, they must truly be leading the research and spending a minimum of 80% FTE on the project. A detailed justification must be provided explaining how this 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. If the individual secures a tenured position or fellowship funding then we expect their salary to be removed from the grant.

- 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 we will not make any direct payments to non-UK institutions or pay invoices in any currency other than British pounds (GBP).

- Funds requested in your proposal must be in accordance our Finance Guidance.

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
- Are solely intended to be a PhD studentship or Clinical Fellowship

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. Please be aware, you may be asked to make changes to your application in the week following submission.

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).

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 **4 March 2025**.

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 **late April / early May 2025**. 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 2025** 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 2025**.

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

The deadline for application submission is 4 March 2025 (1pm).

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 must confirm their involvement in the proposal but do not need to approve the application.

Approval from the Head of Department and the Research Grants/Finance Officer will be required both before and 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.

Some of the information in this section is automatically populated from your contact record and will be read only. Please ensure that your Employment, Education and Basic Information are up to date via the 'Manage My Details' section of your account. 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:

- ORCID ID - All applicants must have an up-to-date ORCID account and the ORCID ID must please add this to the corresponding section under 'Basic Information' via 'Manage My Details'. Our committee will refer to your ORCID account for further details about your career and track record. **Please ensure that you have populated your ORCID record and set visibility to 'public'.** For more details, please visit the ORCID website.

Publications
Please enter up to 10 of your most significant/relevant publications for this application.

Grants
Please enter up to 10 of your most significant/relevant grants for this application.

Your role
Briefly describe your role on the project (up to 200 words)

Narrative CV – Evidencing your contributions to the field

This section is designed to help you capture your achievements, skills and contributions to the research sector (aside from grants and publications) that are of particular relevance to this application. Please ensure you highlight your specific contribution when giving examples so that reviewers can clearly understand the role you have played in advancing our understanding of prostate cancer and in supporting the wider research community.

How have you contributed to the generation of knowledge?
(up to 500 words)
Highlight how you have contributed to the generation of new ideas, tools or techniques. Please describe what you have discovered/developed, your specific contribution to it, why it is important and what its impact and influence have been in your field.
Please also consider research outputs beyond purely publications and grants, such as delivery of clinical trials, contribution to consortia, awards you have received, patents, open datasets, software, novel assays, reagents etc.

How have you contributed to the development of others?
(up to 500 words)
Please highlight how you have supported others in the field and where your experience and expertise has been critical to the success of others, either within a team, part of a collaboration, or through mentorship**.**
Examples: Teaching activities, involvement in workshops or summer schools, supervision, mentoring, strategic leadership, involvement in establishing collaborations etc.

How have you contributed to the wider research community?

(up to 500 words)

Describe your contributions and engagement with the local and international research community.

Examples: editing, reviewing, refereeing, committee membership and your contributions to the evaluation of researchers and research projects. The organisation of conferences/events and how they benefitted the research community. Any contributions to improving research culture (research integrity, equality, diversity and inclusion, mobility of researchers, reward and recognition of researchers' various activities), and appointments to positions of responsibility within your department/institution or other organisations

How have you contributed towards broader society (in a research capacity)?
(up to 500 words)

Please highlight any examples of societal engagement and knowledge exchange in relation to your research.

Examples may include any outreach/STEM activities in schools, engagement with the public sector or the broader public, and/or with industry. You may wish to highlight positive stakeholder feedback, inclusion of patients in your research, or collaboration and engagement with particular societal or patient groups. You could also use this section to mention any occasions where you've provided advice to policy-makers at local, national or international level, experience of communication and information dissemination through media/press/social media, and any other impact across research, policy, practice and business.

Experienced Early Career Researcher
If the Lead Applicant is an Experienced Early Career Researcher, please explain why they are suitable to jointly lead on this proposal.

We define an Experienced Early Career Researcher as:
- Non-clinical researcher: someone who has between 5-10 years post-doctoral experience.
- Clinical researcher: someone who has 0-5 years post-doctoral experience.

Joint-Lead Applicant
We would ordinarily expect a project to be led by a single Lead Applicant; however, 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 <u>confirm</u> their participation AND <u>approve</u> the application BEFORE the proposal can be 'submitted'.

The Joint-Lead Applicant should ensure that the Basic information (including ORCID ID) on the 'Manage My Details' page of their account is up to date as these will populate on the application form.

In this section, you will also need to ask the Joint-Lead Applicant to complete the Narrative CV questions.

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.

If the Lead applicant is an Experienced Early Career Researcher, a senior academic must be added as either a Joint-Lead Applicant or Co-Applicant.

Additional information of relevance to the review of your application

Please use this section if you wish to highlight details of any significant breaks or reduction in activity in the research careers of the Lead and/or Joint-Lead applicants.

Note: The details in this section will be used by our reviewers to make appropriate adjustments when assessing an individual's track record, outputs and career progression

Personnel

This section allows you to add the details of any Co-Applicant(s) and Collaborator(s) 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.

Co-Applicant(s):

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

To add Co-Applicant(s), 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-Applicant(s) on the proposal.

Co-Applicant(s) 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-Applicant(s) themselves and let them know what's required of them.

All Co-Applicant(s) must <u>confirm</u> their participation AND <u>approve</u> the application BEFORE the proposal can be 'submitted'.

You **must** then detail how <u>each</u> Co-Applicant will be involved in the project. Please repeat this for all Co-Applicant(s) on this proposal.

Collaborator(s):

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 Collaborator(s) on the proposal.

Collaborator(s) added at the Expression of Interest stage will automatically be pulled into the second stage application form and will not receive an automated email.

We no longer require letters of support from all of your Collaborator(s), but instead they are required to **confirm** their participation before submission. However, you may include any letters of support from your Collaborator(s) where you think it will provide crucial additional details regarding their involvement in the study, which has not already been described elsewhere in your proposal (e.g. where delivery is fundamentally dependant on access to patient samples/datasets/drugs/models/services).

All Collaborator(s) must confirm their participation BEFORE the proposal can be 'submitted'.

You **must** then detail how **each** Collaborator will be involved in the project, as with the Co-Applicant(s). Please repeat this for all Collaborator(s) 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) 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 (email: research@prostatecanceruk.org).

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. 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 and via the 'Optional preliminary data figure attachments' section.

Figures can be included by uploading up a PDF file (10 pages max) via the '*Optional preliminary data figure attachments*' section and following the on-screen prompts.

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 optional document attachment may also be uploaded (PDF files only, 10 pages max) in this section. 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).

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

Our Patient and Public Involvement (PPI) representatives will read and assess only the information you provide in the plain English summary, patient and public involvement and clinical research sections.

PPI in research is research done 'with' or 'by' patients and the public, not 'to', 'about' or 'for' them. It is a two-way conversation and working collaboratively with patients and the public throughout the research life cycle. Patient and public engagement focuses on raising awareness, sharing research knowledge and findings.

Please describe whether men with prostate cancer, or their relatives/partners etc., have and/or will be involved in the design, planning or management of this research, and what their role will be.

We support the active involvement of patients and the public in research activities enabling high quality patient focused research. Involving people affected by prostate cancer throughout all stages of your research will likely lead to better quality funding applications and improved outcomes of research, thus resulting in applications that are more likely to be successful.

Tips for including PPI in your research:
- You can use our Patient Representative Network to discuss your proposed research question(s) with people affected by prostate cancer to ask whether your planned research is relevant to them, and how they might be involved throughout your project.
- Refer to NIHR involve PPI guidelines for good PPI practice.

Any PPI described in the questions below **must be relevant** and **specific** to the studies outlined in this application.

How have you involved men with prostate cancer, or their relatives/partners etc., to date in the development and planning of this proposal?

(up to 300 words)

You may wish to include who you have involved, their role, the impact of their involvement etc.

How will men with prostate cancer, or their relatives/partners etc., be involved in the delivery and management of this research, if funded?
(up to 300 words)

You may wish to include who you plan to involve; how they will be involved/what their role will be; what impact you hope their involvement will bring etc*.*

How do you plan to engage with the wider community and disseminate your research findings to people affected by prostate cancer?
(up to 400 words)

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 study, as well as more widely to the general public.

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)

IMPORTANT NOTE Please be aware that the process for completing SoECAT forms has recently changed.

If your planned project includes the recruitment of participants, you 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.

Your application should be accompanied with the Funder Export from the online SoECAT, obtainable via the NIHR Central Portfolio Management System (CPMS). We strongly advise submitting your SoECAT at least **3 weeks** *before* the grant submission deadline in order to have it authorised (by the AcoRD specialist) and returned back to you *before* you submit your application.

In order to create a SoECAT, you will need to create an account and follow the steps in the user guide. Once your account has been created and is active, you can proceed.

Further Guidance on how to complete your SoECAT form can be found within the online tool, as well as on the Online SoECAT Guidance page

Please note that completion of the **SoECAT may not be necessary** when applying for funding to support: overarching programmes with no specific research study protocol, infrastructure,

fellowships, anything where the grant is to be used for direct employment of a member of staff or purchase of an asset, and data or diagnostic reviews where recruitment data is not collected. Such applications should provide rationale in the Finance Section - 'Justification of Budget' to explain why a SoECAT was not submitted in this instance.

Once your SoECAT form has been signed off, please upload your completed (and approved) **SoECAT Funder Export** in this section of the application and provide the name of the AcoRD Specialist that approved the SoECAT form.

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.

Please detail the steps that you will take to ensure that the patient cohort is representative of the diversity seen in the UK population. **We know that prostate cancer disproportionately affects black men and so please also detail your strategy to recruit black men specifically.** 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)*
What are the likely challenges with patient recruitment/retention? Have any allowances been made for patient drop out and/or slower rate of recruitment? What steps will you take to mitigate the risk of not recruiting a sufficient number of patients, or sufficiently diverse population, and ensuring appropriate strategies for retention?

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.
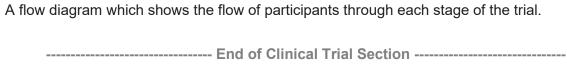
Please detail what would be expected of a patient enrolled to this study?
(up to 300 words)
Please describe (in words or via upload of a patient flow chart) the level of commitment, number of visits etc., expected of those recruited to the study, and how you have considered the trial protocol to ensure 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 explain how you will ensure the sample cohort represents the diversity of those affected by prostate cancer. *(up to 300 words)*

We know that prostate cancer disproportionately affects black men and so please also detail your strategy to ensure samples are collected from black men specifically. Please give this careful consideration as if successful you will be required to report on this over the life of the project.

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.

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.

Plain English Summary

Please ensure this summary does not contain any information that is commercially sensitive, or likely to be considered as such in the future, as this plain English summary may be used by Prostate Cancer UK to publicise our research portfolio should your application be successful in receiving funding.

It is in your interest to take a great deal of care over this section.
Our Patient and Public Involvement (PPI) representatives will read and assess only the information you provide in the plain English summary, clinical research (if applicable) and patient and public involvement sections.

Describe the research proposal under the provided headings, in terms understandable to a reader with no specialist scientific or medical knowledge. This section should make complete sense when read in isolation to the rest of your application so don't refer to any references, diagrams or acronyms included elsewhere in your proposal.

Quick tips for writing a plain English summary:
- Pitch the summary at a level similar to that of a medical research report in a newspaper.
- Ask someone without a scientific background to read the summary before submitting your application.
- Do not include scientific jargon or abbreviations without further explanation.

For more help writing a clear and informative plain English summary please look at this guidance on plain English summaries.

This section is broken-down into the following:

- 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)
- Who will this research benefit? (up to 200 words)
- What evidence or supporting data do you have to support this project? (up to 200 words)
- What are the expected outcomes? (up to 200 words)
- How could it make a difference to the lives of men affected by prostate cancer? (up to 100 words)
- Does this study involve access to existing patient samples and/or data?
- Has the necessary consent from the patients who provided the samples and/or data for use in this study been obtained?

Further guidelines for the involvement of lay representatives and how our Patient Representative Network could strengthen your application can be found on our website.

Prostate Cancer UK staff will take no responsibility for translating the science if the plain English summary is inadequate. If your plain English summary is not clear then the reviewer may not be able to see the importance of your research project for men affected by prostate cancer, and you may fail to secure funding as a direct result.

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 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 (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 (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 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 Guidance](#) 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:

Please refer to our [Finance Guidance](#) for information on eligible 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 Studentship 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:

Please refer to our [Finance Guidance](#) for information on eligible costs.
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).

Animal purchase costs:

Please refer to our [Finance Guidance](#) for information on eligible costs.
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:

Please refer to our [Finance Guidance](#) for information on eligible costs.
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 refer to our [Finance Guidance](#) for information on eligible costs.
Please also include costs associated with 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.

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 Guidance](#) for further details.

Justification of budget *(up to 500 words)*
Please provide justification of the costs that you expect to incur (in no more than 500 words). You should provide a direct justification for each salary, research expense, animal purchase/maintenance or other cost line you have included in the finance section. You should also 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.

This budget justification should be written and laid out in such a way that it provides Prostate Cancer UK, peer reviewers, and the Research Advisory Committee with the necessary information and clarity to confidently assess the funds you have requested. Failure to do so could hinder the review of your application.

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. **Please note** – If the Head of Department is the Lead or Joint-Lead Applicant, a suitable deputy, with sufficient authority to approve, must be assigned to complete the approval.

If the Lead Applicant is an Experienced Early Career 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. Please ensure that the link can be accessed by those outside of your host institution.

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. Please ensure that the link can be accessed by those outside of your host institution.

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

- **04 March 2025 (1pm):** Deadline for second stage application submission
- **w/c 25 April 2025:** Applicants invited to submit a rebuttal to reviewer comments
- **09 May 2025 (12pm noon):** Deadline for rebuttal submission
- **June 2025:** Final funding decisions will be made
- **July 2025:** 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