2019/20 Major Awards Guidance Notes
Existing Trials: New Answers

Call for research proposals to capitalise upon existing clinical trial & patient data/biobanking infrastructure to answer new questions

Introduction

Over the past decade, many clinical trials have and are taking place internationally which are changing the way prostate cancer is diagnosed and treated. Many of these trials have not only produced practice-changing results, but in addition have amassed large quantities of clinical data and patient samples which hold huge potential to help the research community investigate a number of unanswered questions. In addition, organisations such as Biobank UK and UK Clinical Research Collaboration have developed valuable resources to help researchers access patient data and samples to investigate the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses.

If the data and samples amassed through these clinical trials and other initiatives could be used to answer those questions, we may be able to significantly and quickly improve the way prostate cancer is diagnosed and treated.

If we are to achieve our aim of taming prostate cancer, we must make the most of the existing resources, data and patient samples that are available through recent and ongoing clinical trials and other collections/repositories. This will not only allow us to capitalise on past investments (from both us and other funders), but also prevent duplication and delay by building on good quality resources that are already available, rather than starting again from scratch.
**Remit**

This funding call is specifically for projects looking to utilise and interrogate existing patient samples and/or data from recently completed or ongoing prostate cancer clinical trials, or from other data/sample repositories. Capitalising on these existing resources, proposals must seek to answer new and innovative questions, which if addressed, could make a significant impact in the way prostate cancer is diagnosed or treated. This could be the in-depth analysis of trial databases, repositories of patient data, images and/or patient samples, to investigate new hypotheses that could, for instance, help identify responders/non-responders to particular therapies, or to discover biomarkers which may more accurately distinguish aggressive cancer from indolent disease etc.

**Proposals must have a strong central hypothesis.** Applications that are not hypothesis-driven and which are seeking to only collect or curate patient samples/trial data will not be accepted.

In order to be within the remit of this funding call, your application must:

- Be led through a UK based academic institution (international collaborations are encouraged)
- Align with our research strategy: better diagnosis, better treatment and better prevention
- Be hypothesis driven, clearly outlining the new question(s) that this specific grant will aim to answer
- Identify appropriate existing datasets, images or patient samples to answer an innovative question that may impact the way prostate cancer is diagnosed or treated
- Have written agreed access to the data, samples or images from the relevant parties at the point of application.

This call is not solely restricted to the utilisation of UK samples/data. Applications intending to utilise/interrogate datasets, samples or images from international and/or industry partners are eligible and encouraged. However, proposals must be led by an individual(s) based at a UK academic institution (please refer to Lead Applicant eligibility criteria below for further details). Furthermore, the applicants must provide written evidence that they have guaranteed access to the necessary data/samples from the relevant parties at the point of application.

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

All proposals must align with our research strategy and the remit of this call (specified above). Applicants should clearly demonstrate the added value achieved through the proposed research and articulate how it will lead to improved health and wellbeing of men affected by, or at high risk of, prostate cancer.

The overall budget for this scheme is approximately £2m. There are no financial restrictions as to what you can request – you should simply apply for what you need. However, please note that value for money will be a consideration in making final funding decisions, and so we would advise applicants to ensure that the amount they are requesting is a realistic reflection of what is needed and that the likely impact of the proposal is commensurate with the funding requested. Whilst there is no financial restriction as to what you can request, proposals over £500,000 are unlikely to be supported unless an extremely compelling justification can be made. We would recommend that you speak with the Research Team at Prostate Cancer UK if you are intending to submit an application above this amount to discuss eligibility.

We would expect projects to be between 1 to 5 years in duration; However, again, you should apply for however long you need. Whilst projects over 5 years in length are still eligible, they are unlikely to be supported unless an extremely compelling justification can be made. 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.

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

- Awards are available to established researchers working within a recognised academic or clinical institution in the UK (including N. Ireland). Applicants should have a strong track record in their field, and we welcome proposals from academics not currently working on prostate cancer (however, in such cases an expert from the prostate cancer research community should be named as a Co-Applicant on the proposal).

- Lead Applicants will normally hold tenured or tenure-track academic appointments, or for clinical applicants, they should hold an honorary academic contract at a recognised academic institution.

- Lecturers on fixed term contracts or post-doctoral researchers holding competitively-awarded external fellowships can be Lead Applicants, as long as their contract extends at least 6 months beyond the duration of the project or the host institution has undertaken to award a permanent position at the end of the fixed term.

- Lead Applicants who are already in receipt of funding from Prostate Cancer UK are still eligible to apply to this scheme. Applicants should however make a clear case as to why they are the most appropriate person to lead the project and provide reassurance that they will have sufficient time to oversee the delivery of the project. We will check whether the proposed time commitments towards the project would be feasible (for example, a 0.5 FTE commitment from someone already committing 1.0 FTE on an existing grant would clearly not be feasible).
• Lead Applicants must have a minimum of 5 years’ post-doctoral experience. Lead Applicants with between 5 and 10 years’ post-doctoral experience must have a senior academic (usually the research group head) named on the proposal as a Joint Lead Applicant or Co-Applicant.

We are keen to grow good post-doctoral researchers towards independence, and we recognise that experienced post-doctoral researchers who have the expertise and experience required to lead a research project may not yet have their salary met by core institutional or fellowship funding. Therefore, it is permissible for a Lead Applicant with between 5 and 10 years’ post-doctoral experience to include their salary within the application budget. In this instance, they must truly be leading the research, and a detailed justification must be provided explaining how the salary support, and the research funding applied for, will support the individual in their career progression by achieving independence by the end of the project. A statement should also be provided by an appropriate authority at the host institution detailing how the individual will be supported by the institute at the end of the project (if awarded).

We will not be prepared to meet the salary of a post-doctoral Lead Applicant more than once and we would expect a post-doctoral Lead Applicant to spend a minimum of 80%FTE on the funded project. Any subsequent successful fellowship applications should result in their salary being removed from this grant at the point that the fellowship is taken up.

• Projects can include a period of research outside the UK where there is a Co-Applicant or Collaborator based overseas. However, research must be conducted predominantly in the UK and Prostate Cancer UK will not make any direct payments to non-UK institutions or pay invoices in any currency other than UK pounds.

• Funds requested in your proposal must be in accordance with our Finance Eligibility Guidelines.

Please note that we will NOT accept applications that:

• Do not fit the remit of this funding scheme
• Are intended solely or primarily to purchase substantial equipment and/or infrastructure
• Are solely seeking to collect or curate patient samples/trial data, without an underpinning hypothesis to the project.
• 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 and no later than 23rd September 2019 in order for you to submit by the 14th October 2019 deadline.
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 application and ensure that all online declarations and approvals have been completed by the relevant parties before 12pm (noon) on 14 October 2019.

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 06 January 2020, and responses must be submitted by 12pm (noon) on 20 January 2020. Further information about responding to the referees’ comments will be provided to applicants at the appropriate time.

The applications will then be further assessed by our Research Advisory Committee and final funding decisions will be made in late March 2019 and applicants will be informed of the outcome by email shortly afterwards.

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

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

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.

**Making your application**

The closing date for the receipt of applications is 12pm (noon) 14 October 2019.

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

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

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

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

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

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

When updating your personal details please note the following:

- You will need to include your **ORCID ID**, please add this to the corresponding section under 'Basic Information' via ‘Manage My Details’
- Your 10 most significant/relevant publications for this application must be entered in the ‘Publications’ section of the Lead Applicant Details page.

**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. If you are using data/images/samples from a previously completed or ongoing trail, please include a relevant party from the original trial on the proposal as a co-applicant (if applicable).

**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 they are unlikely to be supported unless an extremely compelling justification can be made. 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.).

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).

You must then select up to 6 keywords from the list provided which best describe the project.

Your scientific 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 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 National Cancer Research Institute (NCRI) and the International Cancer Research Partnership (ICRP) and any other organisation as specified in the grant terms and conditions.

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

**Key hypotheses, aims, objectives and milestones**

Please summarise the main aims of the project in no more than 100 words. 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 place it 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 will be rejected. 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

**Warning: 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 outline 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.

Do you have any preliminary data to share?
If you have relevant preliminary data to support your proposal, please select ‘Yes’ to this question and attach your data via the upload link. Depending on the nature of your proposal, it may be that you do not have any relevant preliminary data to support your hypothesis, in which case please select ‘No’ to this question.

Preliminary data (up to 500 words)
Please detail any preliminary/pilot data that supports and strengthens your application within this section and via the ‘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 ‘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).

Where will the proposed data/samples come from? Do you have approval from the relevant parties to access and utilise this resource? What are the practical considerations in order to access the relevant data/samples?
(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 approved your access to this resource. It is our expectation that all approvals are in place at the point of submission, and evidence of this should be provided within the ‘Approvals’ section of the application form.

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.

Please note that a letter of support from the relevant parties to confirm access to the data/samples must be uploaded in the approvals section.
Detailed plan of investigation (up to 1,200 words)

Please detail the proposed programme of work, broken into work packages where relevant. The focus here should be on the structure, timings and delivery of the programme of work etc. This section should give reviewers a clear understanding of the work proposed, along with planned timeframes and anticipated outputs, outcomes and impact.

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.

If applicable, please describe how you will make any data, cell lines, tissue samples, excess material etc. freely available to others in the research community.

We'd also like to know your plans for feeding back results to participants/ the general public at the end of the project. If this is not applicable to your project, please explain why.

Patient & Public Involvement
Will men with prostate cancer, or their relatives/partners etc., be involved in the planning or delivery 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 planning or delivery of this research, and if so, what their role will be. Please note, we do not consider the recruitment of patients to take part in a study as involvement in research.

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

What added value would the proposed research provide, over and above that of the original trial and/or other published data? *(up to 500 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.

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. Please mention what the potential impact/benefit to the research community would be.

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

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

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

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

Do you have approval from the relevant parties, to access the samples/data/images you intend to use?

If you have been granted approval from the relevant parties of the original trial/biobank, to access the samples/data/images you’re intending to use, please answer yes to this question. You will also be asked to attach your letter of approval here.

However, if you have yet to obtain approval from the relevant parties, please answer no and explain why approval has not yet been obtained.

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.

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 should clearly describe why an animal model is necessary and why this specific model was chosen. Carefully consider whether anyone else has already generated the model(s) required for this study and if so, please explain 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. In particular, considering:

- 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

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.

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 https://www.biobankinguk.org/

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
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.

Please also describe your proposed plans to suitably protect and utilise the IP, along with your institution’s current processes and available expertise in managing IP, including contact details of your IP/Tech Transfer Office.

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. We expect to be consulted on the exploitation of any new Foreground IP and for any net revenue generated from its commercial exploitation to be shared in accordance with our terms and conditions.

**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).

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

**Research expenses:**
Detail all expenses that will be directly incurred by the project, except for any animal costs (these should be included separately in the corresponding sections). If you are including fees for the use of any core research facilities – for example, DNA sequencing or flow cytometry – please state the cost per hour or per sample. These costs must be fully justified within the ‘Justification of Budget’ section.

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

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

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

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

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

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.
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 particular, you should justify the number and seniority of any staff to be employed on the project, and the inclusion of any costly equipment (or any other significant expenditure) deemed essential for the proposed project. If the project will include a clinical element, please also state whether the study is likely to receive support from a research network and, if so, the support that will be provided. If the amount requested does not cover the full study costs (e.g. where the work would be part funded by another grant) please also provide brief details as to how the remaining costs of the study will be met.

Declarations

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

Declaration – Candidate

Where did you hear about this funding opportunity?

Please indicate where you heard about the 2019 Major Awards Capitalising on existing clinical trial resources. Candidate Declaration Accept the terms and conditions by clicking the box marked ‘Candidate Acceptance’.

Declarations - Head of Department

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

Anti-Bullying Policy

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

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

**Head of Department Declaration**

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

**Declarations – Finance Officer**

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

Finance Officer Declaration.

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

**Submitting your application**

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

Please note that all mandatory sections of the form must be completed (within the stipulated word limits), and the Joint Lead Applicant (if applicable) and all Co-Applicants must confirm their involvement and approve the proposal before the application can be submitted. 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**

- **14 October 2019 (12pm noon):** Deadline for application submission
- **w/c 06 January 2020:** Applicants invited to submit a rebuttal to reviewer comments
- **20 January 2020 (12pm noon):** Deadline for rebuttal submission
- **w/c 17 February 2020:** Final funding decisions will be made
- **w/c 18 March 2020:** Notification of funding decisions

**Contact Us**

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

Email: research@prostatecanceruk.org