TRANSLATIONAL BIOMEDICAL RESEARCH AWARD

GUIDANCE NOTES

FOR SUBMISSION OF FULL APPLICATIONS

www.julesthorntrust.org.uk

Last updated: Oct 2021

These notes should be read in conjunction with the application form and Terms and Conditions for the grant programme; both of which are available on the Trust's website.

The deadline for Full applications is 10th June 2021

General information

The Trust is conscious of the disruption that the pandemic has caused to research across universities and the NHS, and the impact that the pandemic has had on other sources of research funding.

The Trust has therefore set up the Translational Biomedical award to provide a grant of up to £1 million to support a single outstanding research project, in any discipline or disease area, which is at an advanced stage of translation and demonstrates a clear pathway to benefit for patients.
The Applicant's team must have already generated data or samples to proceed to the next stage of their work and now be seeking funding to translate the research into clinical outcomes. This might include, for example, teams who have gathered Covid-related data and now require the funding for analysis. Alternatively, teams working in other fields may have data from previous studies but have been unable to progress their work during the pandemic and now find other charitable funding is unavailable.

There is no defined time period over which work must take place or funding should be drawn down. However, the Trustees wish to support work at an advanced stage of translation and expect this to be reflected in applicants' research plans

Eligibility

The proposed research must have a justifiable claim to be at the leading edge of international science and must be led by a clearly identified Principal Applicant. The Applicant may be at any stage of their research career but must be of outstanding quality and with a track record of peer-reviewed funding and publications which demonstrate their ability to deliver the proposed research project.

The work involved must be the major commitment of the Principal Applicant, comprising the majority of his/her research time.

The Award may not be used to meet the salary costs of the Principal Applicant. The Applicant will therefore need to hold an institutionally funded post for the duration of the project.

Applications will need to demonstrate the organisation's:

a) track record in international cutting edge clinical translational research,
b) adequate infrastructure support; and
c) commitment of internal resources for the synergy required.

The Trust's charitable status does not permit the provision of a grant which might, whether directly or indirectly, contribute to a commercial profit for a manufacturer. An application cannot therefore be considered where a manufacturer is supplying a cash grant or equipment, materials, drugs etc. at no cost, whether express or implied, for commercial use of the findings of the project.

Applications must cover the following points:

1. All research must be undertaken, and funding is restricted to work, including data collection, carried out in the United Kingdom.
2. Any co-applicants are expected to be actively involved in the work. Their precise role and time commitment must be stated.
3. The Award may not be used to meet the salary costs of the Principal Applicant(s) who should be in institutionally funded posts for the duration of the grant.
4. There must be visible strategic commitment to the research by the host institution.
5. All outcomes from the grant must be made freely available within three months of publication.

Please also note that the Trust will not support applications that are to supplement an existing project supported by other funding bodies, or to cover expenditure already incurred. Applications submitted concurrently to other funders will be accepted but subsequent short-listing would be conditional upon any such applications being withdrawn unless the Trust agrees otherwise. It is essential that any related applications are noted in the full application form.

Application Process

There is a three-stage application process for the award.

The key dates are as follows:

2020

•December	Call opens for initial applications

2021

•18th February	Closing date for submission of preliminary applications
•April	Long listed applicants invited to submit a full application
•10 June	Closing date for submission of full applications
•June-September	Peer review
•Early autumn	Presentation of short-listed applications to the Trust's Medical Advisory Committee
•End November	Announcement of the outcome of the competition.

How to Apply

Applications must be submitted using the application form in Word and accompanying financial tables. The Trust must receive an electronic copy of the application (PDF format preferred) attached to an email, sent to Donations@julesthorntrust.org.uk with a copy to director@julesthorntrust.org.uk.

The form must be accompanied by the following attachments:

a. Covering letter from the applicant addressing any specific questions contained in the invitation to submit a full application letter.

b. A letter of support from the Research Dean / Head of Department or equivalent indicating how and why the proposal was selected, including its relevance to the institution's research strategy,

c. A letter from the sponsor in accordance with question 15 of the application form and point Q15 on page 8 of these guidelines, confirming that it is willing and able to take on the responsibilities of the sponsor,

d. If the project proposes to use animals or animal tissue, a copy of the relevant Home Office Licence in accordance with question 16 of the application form and point Q16 on page 8 of these guidelines.

e. **Please provide the name, full postal address and email of scientific referees whom you feel would be suitable to comment on your application.** These must not include colleagues from your institution or those with whom you have collaborated in the last five years. Please note that the Trust may or may not choose to approach some or all of the individuals you have selected. It is the Trust's policy to seek opinions from whichever authorities it considers to be most appropriate, and it cannot accept requests from applicants to proscribe certain referees.

When received the application will be subject to the Trust's normal selection procedure and will be considered in competition with other applications for the Award. The final decision will be recommended to the Trustees by the Trust's Medical Advisory Committee after a review process aided, but not determined exclusively, by external referees. The Trust may seek further information during the process. There could be many reasons why an application is unsuccessful, and these will not necessarily be explained in full but the Trust may provide some feedback at the conclusion of this stage of the application process.

Grants are awarded entirely at the Trustees' discretion, and they reserve the right not to make the Award following completion of the review process.

Further questions about the award should be directed to the Trust team at donations@julesthorntrust.org.uk.

Definition of Terms

1. A Principal Applicant is the lead researcher who has the main intellectual input into, and ownership of, the research if the application is successful. This individual will be both responsible and accountable for the management of the research programme and will normally be considered by the Trust to be the "holder" of the grant.

2. A co-applicant is a researcher who will have significant intellectual input into, and part ownership of, the research if the application is successful.

3. A collaborator is an individual named in the body of the application who will supply technical advice or reagents, but who would not normally be involved in the day-to-day execution of the work.

Application Guidance

Applications must be completed in a typeface no smaller than 11 point Arial font. Abbreviations should not be used unless fully explained.

The application must be complete in itself. No additional pages will be accepted unless specific instructions are given.

Q1 Title of Project

Please input the title of the project.

Q2 Name and Address of Research Institution

Please input the name and full address of the research institution where the work will be undertaken.

Q3 Project Duration

Please state, in months, the period for which support is sought.

Q4 Proposed start date

Please take into account the timetable for the assessment of applications, and the expected lead-time for recruitment of staff who would be working on the project. Projects will not receive funding should they start later than 12 months from point of award.

Q5 Applicant(s) details

Please input the full details of the Principal Applicant, including address, email and phone number. Please also include the relevant details of any co-applicants.

Q6 Proportion of working time

Please detail for the Principal Applicant and each co-applicant the amount of time – expressed as full-time equivalent (FTE) - spent on research in general and on the project specifically. Please also outline how the time commitment from each applicant meets the requirements for the successful delivery of the project.

Q7 Summary of proposed research

Provide a concise scientific abstract and a lay summary for your project (in no more than 200 words each), outlining the background to the application, the proposed aims of the research to be undertaken and the expected outcomes. Please do not include any confidential or commercially sensitive information in this section.

Q8 Research question

Please summarise the main aims of the project and why they are important in no more than 300 words. Detail the main hypotheses to be investigated, along with a brief timetable of milestones. All proposals should articulate a strong, central research question and be placed in the context of current knowledge. This section is meant to provide an ‘at a glance’ summary of your project plan, so please keep it succinct and to the point.

Q9 Details of research project

(a) 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. You should also explain how your study will differ from or complement any planned, ongoing, or recently completed studies.

(b) Preliminary data (up to 500 words)

Please detail any preliminary/pilot data that support and strengthen your application within this section (in no more than 500 words). Manuscripts under review or in preparation should not be provided as additional information.

(c) Detailed plan of investigation (up to 2,500 words)

Graphs, figures and supporting unpublished data may be embedded in the text or included as an appendix (no greater than 2 A4 pages in file size). The data in this answer must not exceed the equivalent of 5 A4 pages in length. Applicants must provide all information pertinent to the grant proposal within the application form, unless directed otherwise.

Describe the experimental design and methodology you will use to address each hypothesis, along with the timescales for each section of the research, including any go/no-go points. Where there are multiple components to your proposal, please clarify who will be leading/delivering each component or sub-study. Sample sizes, power calculations and any assumptions must be clearly stated and justified.

If the project involves animals, the experimental design should include the case for the number of animals required to achieve significance and the factors that might affect this. The sample size calculations used to estimate the number of animals required in the proposed experimental design should be stated where appropriate.

Clinical studies must include additional information via the 'Clinical Research' section to describe the number of people to be recruited, the recruitment strategy, feasibility of full recruitment etc. Clinical trials must describe how the study is statistically powered and for what endpoint.

Projects using human or animal tissue samples should state the source and indicate the availability of tissue.

Q10 Please detail the translational aspects of the research and the timescale for impact in a clinical setting (no more than 500 words)

We want to see translational research, at an advanced stage, which has high potential to make a real impact in the short term. You should therefore make a clear case as to how your proposal is translational, explaining how it will differ from or complement any planned, ongoing, or recently completed studies. You must clearly define how your research will translate into benefit for patients and the timescale within which this will take place.

Q11 Risks and contingency plans

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.

Q12 Please detail the potential impact and outcome for the project, including dissemination and sharing plans (no more than 300 words).

We wish to understand the potential outcome you seek to deliver as well as any impacts of your research both in the short and longer term, and how you intend to disseminate any outcomes of your research (if applicable; describing how you will make any data cell lines, tissue samples, excess material etc. freely available to others in the academic community). We look to aid delivery of clinical impact as quickly as possible rather than solely academic outputs. However, we also understand that several additional steps may be required in order to deliver longer term impacts. Please provide brief details of those subsequent steps and how you intend to fund them and any plans for commercial licencing or exploitation (if applicable).

Q13 Clinical Research

Please use this section to provide further details of your proposed clinical study (no more than 600 words)

Please detail the following in this section:

(a) State the phase of trial.

(b) Power calculations and statistical analysis
You should provide a clear justification for your power calculations, sample sizes, stratification factors, randomisation ratio etc. to provide the reviewers with sufficient reassurance that the study has been suitably powered. Studies which are underpowered and unlikely to answer the research hypothesis will not be considered favourably.

(c) Primary and Secondary end points, interim analysis and early stopping rules
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. 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.

(d) Inclusion and exclusion criteria for patient recruitment
What will be your inclusion and exclusion criteria for recruiting patients? Please specify who will and won't be eligible to enrol in the study and why.

(e) Patient recruitment strategy and contingency
You should describe your planned recruitment strategy and your anticipated rate/timescale of recruitment. If available, please provide any pilot evidence to demonstrate feasibility of recruitment. Please specify the number of sites to be involved in the study (and where they are located), and the timeframes in which you anticipate them to be set up and begin recruitment. If patient samples are to be collected, please specify the type of tissue that will be obtained and how many samples will be required.
Recruitment contingency.
We appreciate that recruitment of patients to a trial may not always go to plan. Please provide further detail as to the likely challenges you may experience with patient recruitment/sample collection and what steps you will take to mitigate the risk of not recruiting a sufficient number of patients and/or the loss of patients during follow-up.

(f) Experience of running clinical trials
Please specify your past experience of delivering studies of this nature.

(g) Please state what would be expected of patients involved in this study
Please describe the level of commitment, number of visits etc., expected of those recruited to the study, and how you have considered the trial protocol to ensure that it will be acceptable and sensitive to the situations of potential research participants.

Q14 Research on human participants or human tissue

Approval from the appropriate research ethics committee is required for all research involving human participants or biological samples. Approval from other regulatory bodies should also be sought where necessary. For research carried out at multiple sites, ethics committee approval must cover each site.

Q15 Research using NHS facilities or patients

If the research is covered by the UK Policy Framework for Health and Social Care Research, a letter from the intended sponsor, if identified, should be included, confirming that the research proposal is consistent with the Framework and that the sponsor is willing to undertake the responsibilities stated in the Framework and applicable clinical trial regulations. The Trust is unable to fund any research which does not have such sponsorship. The Trust does not cover costs incurred by the sponsoring organisation in discharging its sponsorship obligations.

Q16 Experiments on animals

It is the Trust's policy only to support the use of animals where no viable alternative exists. Applicants must have regard to animal welfare and to advances in the refinement, replacement, and reduction of animal use. The institution must ensure that research involving the use of animals complies with relevant laws and regulations. Copies of relevant licences should be included. While the Trust will consider proposals awaiting Home Office authorisation, no award may be activated, and no animal experiments may commence until the appropriate licences have been granted. The following questions should be addressed specifically: -

(a) **Does the work proposed involve the use of protected animals in regulated procedures under the Animals (Scientific Procedures) Act 1986?**

(b) **If so, what species, and how many animals?**

(c) **Are any of the procedures of substantial severity?**

(d) **Why is animal use necessary: are there any other possible approaches**

Please justify why animal use necessary and if there are there any other possible approaches.

(e) Is the species to be used the most appropriate? This is especially important when an animal is being used as a model for a human physiological or pathological condition.

Please justify why the species used is the most appropriate.

Q17 Financial details of support requested

The excel spreadsheet (Annex A) should be completed to detail the full costs of the project up to the maximum award amount of £1 million. Justification of the costs input into the excel spreadsheet should be detailed in the word application form.

Q18 Justification of support requested (max 200 words per section)

Please note that the Trust will only pay relevant research costs as defined by AcoRD and applicants must consult with their institution to ensure that other clinical costs will be covered from other sources.

(a) Please justify the support requested for staff, specifying their roles and responsibilities with respect to the proposed project.

The Award may not be used to meet the salary costs of the applicant(s) who should be in institutionally funded posts for the duration of the grant.

Please detail salaries requested for all staff, along with their roles and responsibilities to be funded on the grant within the excel spreadsheet (Annex A)

i. Salary support will be cash limited at the point of the award. The institution should factor in a compound inflationary allowance for each post to cover the cost of future pay awards. The percentage used for the calculation must be the same as the most recent pay award agreed by the institution for the grade on which the individual is to be employed. Please confirm the percentage figure in the appropriate box.

ii. Salary costs should include any London/Regional weighting allowances, contributions towards an institutional pension scheme, and employer's national insurance payments. The Trust is not able to provide funding for personal pension schemes held by the individual.

(b) Please justify the support requested for materials and consumables

i. The Trust will only provide the direct costs of the research proposal. It does not meet the overhead costs of the host institution, the cost of NHS service support, or sponsorship costs (see Q15). The Trust is an NIHR Non-commercial Partner, which ensures that NHS service support costs incurred in the research will be met. Please note applicants must consult with their institution to ensure that other clinical costs will be covered from other sources.

ii. Requests for publication costs may not be included.

iii. Expenses for travel which is to be undertaken for the immediate purposes of the project may be included for consideration. They will not normally be paid where the person is already eligible to claim them by reason of his or her office.

(c) **Please justify the support requested for miscellaneous costs**

Please detail any other miscellaneous costs not detailed in the above points

(d) Please justify the support requested for animal costs, if relevant.

Where animal experimentation costs are involved, applicants should complete this after reference to their animal house or biological services manager. The justification for the use of animals should cover:-

i. How the benefits outweigh the costs.

ii. Why animals are necessary, and why non-animal alternatives are not possible.

iii. How the experimental and statistical design has been used to optimise/minimise the number of animals used.

iv. What steps have been taken to refine procedures to reduce discomfort?

(e) Please justify the support requested for equipment and equipment maintenance.

An Award may include the cost of equipment, but it must satisfy the following criteria:-

a) The equipment must be essential to the research.
b) The reason for using the equipment must be justified.
c) Equivalent equipment must not be available to the applicant elsewhere in the institution.
d) The cost should exclude VAT where exemption is applicable.
e) No equipment is purchased within the last six months of the grant.

Q19 Commercial Exploitation

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 the Trust 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 Trust'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 will be utilised with this proposed study (upload all letters as a single MS Word or PDF only).

Q20 Related applications

Applications submitted concurrently to other funders will be accepted but subsequent short-listing would be conditional upon any such applications being withdrawn unless the Trust agrees otherwise.

Q21 References

Reference may be made to papers "in press". Copies of referenced papers that have been accepted for publication but are awaiting distribution in paper or online should also be submitted. Manuscripts which are "in preparation" or "submitted for publication" must not be included.

Q22 Curriculum Vitae of applicant(s)

Please ensure you summarise what you consider to be your key scientific achievements and state to which periods of your career they relate. You do not need to list all of your positions. If the source of personal salary support is indicated as “other”, please provide details.

Q23 Curriculum Vitae of named research assistant(s)

Please complete the C.V form for each research assistant that is named on the project.

Q24 Collaborators Forms

Please complete the form for any collaborators on the project. One form must be completed per collaborator.