

The Tuberous Sclerosis Association (TSA)

Guidance notes for applicants

1. Overview

The TSA is the only UK charity to fund research into Tuberous Sclerosis Complex (TSC). We hold a formal grant round every two-years, where we go through a rigorous decision-making process. This process ensures we fund the most appropriate and worthwhile projects, in line with our research strategy (see section 2) and in the best interests of individuals living with TSC and their families.

During award rounds, we ask potential applicants to complete the following documents:

- Application form
- Full proposal/protocol for the study
- Bio-sketch for each person who will work on the project
- Relevant ethical or other regulatory approval letters
- A use of animals in research form (if applicable)

Upon receipt of an application and all required documentation, the TSA will review the funding request to check its eligibility and to ensure that the research meets our own research strategy (see section 4).

2. TSA's Research Strategy

The TSA is committed to funding research in line with its six research priorities, which are consistent with the charity's five-year strategy to reach more people and drive more research. Our vision is a world where TSC and its effects are conquered.

Our research priorities from 2019-2023 are:

The Tuberous Sclerosis Association
research@tuberous-sclerosis.org
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Earlier diagnosis, including:

- Improving foetal ultrasound strategies
- Using neonatal EEG in those at risk to spot early signs of epilepsy
- Genetic testing through universal maternal blood tests and/or universal blood drop testing for neonates

Early risk assessment, including:

- Targeted genetic testing for families with known risks
- Genetic analysis combined with manifestations (genotype: phenotype correlations)
- Using natural history registers and databases to calculate predicted future severity of condition

Basic science and pre-clinical work, including:

- Lab-based research to understand molecular mechanisms
- Lab-based research to identify new therapeutic targets and establish effectiveness in a pre-clinical setting
- Stimulating initial stage research of TSC-gene modifying therapy in pre-clinical studies

Prevention, including:

- Trials of mTOR inhibitors and other therapies for newly diagnosed infants and older people aimed at preventing kidney damage, preventing lung damage (LAM) and earlier control of infantile spasms and other manifestations of TSC
- Diagnosis and early control of infantile spasms
- Tools to alert parents of infantile spasms and how to report them to TSC clinics
- Approaches to lowering the risk of developing neuropsychiatric disorders

Research into new and available therapies, including:

- Optimising therapy for kidney disease, skin disease, LAM and epilepsy (better and more tailored treatments)
- Promoting methods for the early identification of TSC-Associated Neuropsychiatric Disorders (TAND), measuring unmet need and improving treatments for each aspect of TAND.

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Social and service research, including:

- Looking at what is really affecting people's lives and how to support them (for example, isolation, inability to work, education)
- Understanding best practice in delivering support and care from the TSA

Every scientist and research project which the TSA funds must be focused on the potential benefits for people living with TSC, their families and carers. Applications should therefore familiarise themselves with the above research strategy.

3. Types of funding available

3.1. PhD Studentships

Our PhD studentship grants provide funding for students looking for a research career in TSC and its associated conditions.

Who can apply?

Studentships can be applied for by academics either intending to run an application process for PhD Studentships within usual University processes, or for postgraduates of high academic calibre already identified within their University.

Applicants must be associated with an established researcher/sponsor in a university department or similar research environment. Applications will be judged on the quality of the research proposal, the quality of the candidate (if already named), the sponsor, the supervisor and the training provided.

Value and length of award

The basic salary requested should be commensurate with the applicant's skills, responsibilities, expertise and experience, up to a maximum of £17,000 per annum. PhD fees should be charged at the applicant university's standard rate up to a maximum of £9,000 per annum. Research expenses will be funded, up to a maximum of £11,000 per year. Funding is for a maximum of 3 years.

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3.2. Fellowship Awards

Our fellowship awards provide funding for researchers planning to develop a track record in research into TSC and its associated conditions and seeking to transition into TSC research leadership.

Who can apply?

Applicants must be associated with an established researcher/sponsor in a university department or similar research environment. Applications will be judged on the quality of the research proposal, the quality of the candidate, the supervisor and the training provided.

Value and length of award

The basic salary requested should be commensurate with the applicant's skills, responsibilities, expertise and experience, up to a maximum of £40,000 (WTE) basic salary per annum.

Research expenses (travel, apparatus, consumables etc.) will be funded, up to a maximum of £11,000 per year. Funding is for a maximum of 3 years.

3.3. Project Grants

Our project grants are designed to be flexible enough to support a wide range of research. TSA project grants are suitable for focused research projects and can be awarded for any period of time up to three years.

Who can apply?

Any researcher based within an established university department or similar research environment.

Value and length of award

The total value of a project grant will not exceed £200,000 over 3 years.

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The TSA fully supports the AMRC statement on supporting research in universities. Charitable funding of research relies on public donation and philanthropy. As funders, we only support directly incurred costs of research and therefore will not pay indirect or directly allocated costs. The statement can be found [here](#).

3.4 Co-funding

The TSA's research strategy for 2019-2023 encourages us to work closer with other groups who share the same goals that we do in researching TSC. Instead of enabling research as a sole funder, we try to share the cost of a study with other groups. This involves contributing funding to a call for research applications; either an open, restricted or commissioned. How we select who we partner with depends on the reputation, credibility and track record of the partner, the size of the grant monies being offered in relation to what TSA is being asked to contribute, the potential impact of co-branding, whether or not the funding being offered is dependent on TSA contributing a proportion, and whether or not the research area under investigation fits into the categories identified as a research priority and aligns with TSA's research strategy.

Examples of other funders include (but is not limited to):

- Autistica
- Epilepsy Research UK
- Kidney Research UK
- The LAM Foundation
- TS Alliance (USA)

If you would like to apply for co-funding, please contact the TSA's research team in advance of submitting your application. It is important to approach us as early as possible, so that we can consider the request, approach the other funder(s) and review our processes. If a co-funding application is agreed, we or the other funder(s) will manage the application review process. This will be discussed by all under and a suitable approach will be agreed.

4. Assessment criteria

Our research strategy sets out the key areas of research with unmet need that we need to focus on. Research projects are selected through a two-fold peer review process, as this is recognised as best practice in awarding research grants, with each application subject to review by independent experts in the field*.

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All applications will be initially triaged by TSA's research team to ensure the completeness of the paperwork and compliance with the application process, funding thresholds, application guidance and T&Cs.

Where applications do not comply with such requirements and require some minimal quality adjustments, applications will be contacted and asked to make the necessary amendments within an agreed timeframe. The TSA reserves the right to reject the application at this stage if the applicant is unable or unwilling to make the necessary amendments within the required timescale.

Where applications are significantly short of these requirements, TSA's research team will consult with two scientific members of our research committee for advice. Again, amendments may be required, but the TSA reserves the right to reject the application at this stage if advised by scientific members of our research committee.

After passing through the initial triage stage, all applications will be subject to external peer review. All comments from external reviewers will be anonymised and sent to applicants. Applicants are then expected to reply to these comments and make any necessary changes to their application during an agreed timeframe.

All applications are then subject to internal review and consideration by the TSA's research committee, consisting of both scientific and lay members.

This two-fold peer review process allows a rigorous and effective assessment of the quality, scientific merit, and the likely benefit and impact of the work on the TSC community. Your application will be assessed, by all reviewers, against the following criteria:

- The overall potential for impact that will improve the lives of people living with TSC; those affected directly, along with their family members and carers
- Impact leading to wider research, including social, economic and health sector benefits
- The quality of the application and study protocol
- The level of innovation in the study
- The strength and track record of the researchers
- The clarity and strength of the multi-disciplinary collaboration to deliver the proposed study, and additionally the impact moving forward
- Value for money
- Plans to ensure that people living with TSC; those affected directly including their family members and carers are at the centre of the study, throughout the duration of the study

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- The strength of plans to communicate and disseminate the findings of research to other research professionals, as well as the lay TSC community

**Please note: independent reviewers make decisions on the scientific quality of applications, not the charities administrative staff.*

5. Before you start

Before preparing your application, you must read and consult the following documents, available from our webpages.

- These guidance notes (including TSA's research strategy 2019-2023)
- TSA's Terms and Conditions

Please contact a member of TSA's research team if you have any problems in locating or accessing any of these documents. Contact details can be found on the TSA's website.

6. Eligibility

Submission and review

- Each applicant must not submit more than one application for project funding
- Applicants must include, alongside their application form:
 - A full research proposal document (max 1,500 words)
 - Bio-sketches for each named person involved
- The research committee (RESCOM) will not reconsider unrevised applications that have previously been rejected by the committee under another TSA grant award round.
- Applicants should not approach the Chair or members of RESCOM about the research application either before or after the decision on the awards. Applicants may seek advice on the application process from the TSA before applications are submitted.
- Once the application has been submitted, no additional unsolicited information intended to support the application will be accepted unless related to new legislative or regulatory change that will have a significant impact on the work undertaken.
- Applications will not be accepted from investigators (applicants, sponsors or collaborators) who have an overdue final report from a previous project funded by the TSA at the time of submission.

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- For any applicants who have held a TSA grant that is ongoing or has finished in the last 5 years, applications will not be funded until the relevant data is entered onto Researchfish.
- Please complete and return your application form in Word format so that the information can be easily analysed.
- Supporting documents can be returned in either Word or PDF format.

Lay Reviewers

- Lay reviewers will be involved in reviewing and scoring your application. These are people affected by TSC daily, for example a person with TSC or a parent or carer of a person with TSC. They may not have any scientific knowledge of TSC.
- Their scores will be used to rank your application, alongside scores from scientific reviewers. You must therefore give sufficient attention to the 'lay summary' section of the application form.
- The lay summary must be clear and understandable to the lay reviewers. It must not be just a lay translation of the scientific abstract. The lay summary should be an overall summary of the entire project. For further guidance and useful resources, visit the INVOLVE website: <https://www.invo.org.uk/makeitclear/support-and-resources/>

Lead Applicants

- Researchers should be able to demonstrate evidence of a strong research record and should display evidence of leadership.
- All lead applicants must be willing and able to agree to the current Terms and Conditions if their application is successful.

Staff Members / Employees

- Any individual whose salary, or proportion of salary, is going to be paid using the grant, must be named as a staff member on the application form. This may include post-doctorial researchers, research technicians, PhD students, etc.
- If the staff member who will be employed by the grant has not yet been recruited or is unknown at this stage, please provide the title of the position to be filled. Further information must be provided to the TSA as soon as possible after the award letter is issued.
- There is no limit to the number of staff members that can be involved in the application, provided their salary costs can be accommodated within the grant.

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Collaborators

- There is no limit to the number of collaborators that can be involved in an application, but for each collaborator there must be a signed declaration letter on official letter headed paper which confirms they have consented to co-operate in the programme of research. It should also outline the reasons for collaborating and explain their role in the project.

Ethics

- All appropriate regulatory approvals must be in place before the work on the research commences.
- The TSA is a member of the Association of Medical Research Charities (AMRC) and we fully support the AMRC position statement on the use of animals in research. This position statement can be found [here](#).
- The TSA also supports the Home Office's commitment to the '3Rs' which serves to refine experimental techniques and procedures, reduce the number of animals involved in research and replace animals in research wherever possible.
- If your project involves the use of animals, the TSA requires a copy of the front sheet of the licence or licence number of the personal licence as confirmation before the project commences; and a copy of the 'Use of Animals' Questionnaire should be submitted alongside the application form.
- All UK research involving embryonic stem cells is strictly regulated by the Human Fertilisation and Embryology Authority (HFEA). The TSA supports the view of the AMRC that the particularly important ethical issues must be considered when funding research that involves embryonic stem cells.

Finances

- For academic institutions: the TSA does not pay for the salary of the lead applicant as they are expected to hold a secure or tenured position within their institution. If applicants are to employ staff (including post-doctoral researchers, research technicians, PhD students) then the salaries for these members can be applied for.
- Any individual whose salary, or proportion of salary, is going to be paid using TSA funding must be entered as a staff member in the salaries section.
- There is no limit to the number of staff members that can be included on an application, provided their salary costs can be accommodated within the award.
- Staff costs should include any anticipated (and realistic) nationally agreed pay awards.

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- Staff names and CVs will need to be provided at the time of application.
- The TSA does not build inflation into contractual grant commitments and all costs expected to be claimed for must be quoted in the application. This should include inflation projections more than the current market rate.

Funding information

- The TSA funds PhD Studentships, Fellowship Awards and Project Grants.
- Once the final award amount has been agreed by the TSA's Board of Trustees, this cannot and will not, be amended at a later date.
- The TSA depends on income from voluntary sources, e.g. donations, and funding will be subject to the availability of the necessary funds.
- The TSA will fund:
 - Academic costs*
 - PhD studentship fees and a stipend.
 - Other directly incurred costs associated with the delivery of the research as outlined in the application form. These include the familiar direct costs of research such as staff (e.g. research assistant salaries), consumables and other costs directly attributable to the project equipment, and animal costs.

If you are unsure whether your application meets the above eligibility criteria, please contact the TSA's Research Team by emailing research@tuberous-sclerosis.org or by calling the main switchboard on 0300 222 5737.

7. Application form

Overview

Please complete all sections of the application form.

For most questions, you can expand the boxes to include more information.

Please keep the application form as one whole document as it stands, rather than inserting supplementary enclosures in the middle of the form. These should be submitted as separate files.

Please see section 13 for electronic submission and mailing instructions.

1. TYPE AND TITLE OF PROJECT

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1.1. Please state (by deleting as appropriate) the type of award that is being sought. This may be a PhD studentship, a Junior Fellowship or a Project Grant (please see section 3 of this document: *Types of funding available*).

1.2. Please state the full project title.

1.3. Please state the short project title, if applicable. Please detail any abbreviated title for the project.

2. APPLICANT

The applicant is the grant holder of the project and to whom all correspondence will be addressed.

2.1 Please provide the applicants title (delete as appropriate). This could be Prof, Dr, Mr, Mrs, Ms, or Other.

2.2. Please provide the full name (forename, middle name and surname) of the applicant.

2.3. Please provide the applicants post or role at the institution or organisation in which they are based.

2.4. Please provide the applicants email address. This is where all correspondence will be sent.

2.5. Please provide the applicants telephone number.

2.6. Please provide the applicants postal address. This is where hard copies of all correspondence will be sent.

3. ADDRESS WHERE RESEARCH WILL BE CONDUCTED

3.1. Please provide the name of the institution

3.2. Please provide the name of the department

3.3. Please provide the postal address of the department where the research will be conducted.

3.4. Please provide the telephone number for the department.

3.5. Please provide the fax number for the department.

4. STUDY DURATION

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4.1. Please state the proposed duration of the project.

4.2. Please state the proposed start date of the project.

5. SHORT ABSTRACT OF RESEARCH PROPOSAL

Please provide a short abstract of the research proposal, maximum 500 words.

The abstract on the application form should include:

- Background – please detail brief background information that is needed to understand the wider context of your application and accompanying documents.
- Hypothesis and objectives
- Methodology

Please note: You are also expected to provide a full research proposal alongside the application form (see section 8 of this guide).

6. LAY SUMMARY

Research projects funded by the TSA must have a significant focus on the potential benefit for people living with TSC. Applicants should bear this in mind when preparing their application, especially when writing the lay summary.

The lay summary should clearly demonstrate how your application fits in with the TSA's current research strategy and must clearly state the outcome that people with TSC can expect from the research. The lay summary should not exceed 500 words.

Please provide a structured and detailed lay summary, **written in plain English**. In other words, it must be understandable to a non-scientific person. This summary will be used by lay reviewers – people living with TSC or their parents and/or carers – when assessing and scoring your application to ensure it is relevant to people with TSC. These people have little to no scientific background. It is very important therefore, that the lay summary is accessible and provides enough information for lay reviewers to make informed decisions during the review process.

INVOLVE have useful resources, information and guidance on writing an effective lay summary; which can be found [here](#).

Here are some of the things you should include in your lay summary:

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- clearly state the aims and objectives of the project – the problem you are trying to address and how relevant it is to TSC and its associated conditions
- clearly describe what you are going to do in the project, without using scientific jargon
- explain how the findings of your research will be of benefit to people living with TSC and their families and carers
- provide details of how your project will involve people living with TSC and their families, both as participants and by providing input into the design and delivery of the research
- describe what steps you would take to disseminate the results of the research
- outline the timescale to impact and reasons why

Lay reviewers do not comment on the science of the project - this is the role of the external and internal peer reviews. Lay reviewers will play an important role in answering other questions, such as:

- is the research question important to people living with TSC?
- will the results of the research be of benefit to people living with TSC?
- will participants actually be willing to take part in the study? Or will it be an inconvenience to them meaning they are unlikely to take part?
- did the researchers seek the advice of people living with TSC when they planned their research? Did this make a difference to the design of the research proposal?
- is the information clear and easy to understand?

Applicants should keep the above questions in mind when writing the lay summary. We recommend your lay summary is read by people living with TSC and their families for their comments before submission. Please visit the TSA's [**TSC Research Volunteer Network page**](#) for more information.

Please ensure that your lay summary does not contain any confidential or sensitive information as this section will be used to publicise your project should it be funded.

7. PROJECT STAFFING

- 7.1. Please outline the extent of the applicant's (as listed in item 2) engagement in research project (e.g. grant holder/supervisor/actively engaged in research, etc)
- 7.2. Please list all others involved in the project. Please give names (if known) and role (for example PhD student, fellow, co-applicant)

Please include CV's for the applicant and all others named.

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8. REGULATORY APPROVAL

- 8.1. Please detail, if relevant, whether ethical or other regulatory approval been sought/granted for this proposal? Please delete as appropriate. **Please include a copy of any approval letters.**
- 8.2. If required ethical or other regulatory approval is not yet confirmed, please describe the steps and timetable required before the project can commence. **Please note the TSA will not release funds without all necessary approvals in place**
- 8.3. Does the proposed project involve the use of live animals (either protected by UK law or not). **If yes, please complete the 'Proposed use of animals' questionnaire'**

9. FINANCIAL SUPPORT REQUIRED

- 9.1. Please provide a brief description and justification of all the resources (including staffing) required for the proposed project.
- 9.2. Summary of resources sought as part of this award:
 - Please note that in accordance with AMRC policy, TSA only funds the direct costs of the research. Please include present incremental salary increases.
 - Please consult the financial limits for the type of grant you are applying for, outlined in the guidance for applicants.
 - Additional lines can be added within subheadings.

10. OTHER SOURCES OF FUNDING

- 10.1. Please detail whether this proposal is receiving confirmed funding from another source/s. Please delete as appropriate.
- 10.2. If yes, please provide details of the other funder/s and an outline of the financial support received.
- 10.3. Other than that mentioned in 10.1 and 10.2, please detail whether you have you applied for funding for this application from other sources.
- 10.4. If yes, please provide details of the other funder/s and an outline of the financial support sought and the process/timetable for any decisions on this funding.

11. DECLARATION TO BE COMPLETED BY APPLICANT

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Please read the statements in each of the three boxes, and initial in the corresponding box to the right. Then sign, print and date in the relevant boxes below.

12. CHECKLIST FOR APPLICANTS

Please ensure you have completed the steps below before submitting your application and provide your initials in the corresponding box to the right of each point.

	Please initial
• Check all relevant sections of the form are complete	
• Include full scientific proposal/protocol for the study	
• Include relevant ethical or other regulatory approval letters	
• Include all CV for applicants of those already identified as working on the project	
• If applicable, complete and include the 'Use of Animals Questionnaire'	

13. ELECTRONIC SUBMISSION AND MAILING INSTRUCTIONS

Please send both a Word version and a signed PDF copy of the application form to:

research@tuberous-sclerosis.org

All accompanying documents must be sent as PDF files.

Electronic applications should be received no later than: **SEE DATE ON APPLICATION FORM**

Please send signed, hard copies of this form (and all accompanying documents) to:

Bethan Vaughan, Research and Evidence Officer, The Tuberous Sclerosis Association, Unit 56, Containerville, 1 Emma Street, London, E2 9FP.

Hard copies should be received no later than: **SEE DATE ON APPLICATION FORM**

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If you have any queries or concerns, or if you need any further information or guidance, please contact Bethan Vaughan, Research and Evidence Officer, by emailing bethan.vaughan@tuberous-sclerosis.org

8. Full research proposal (max. 1,500 words)

You are expected to provide a full research proposal alongside the application form. This should include:

- Detailed information of the summarised short abstract of research proposal on the application form.
- Full references (Harvard style): author(s) of journal article, year of publication, title of journal, volume, issue or number, page numbers (start – end).
- Any figures, tables and pictures should be saved as a Microsoft Word document or PDF and submitted alongside the application form and accompanying documents.

Please note: The word limit for the detailed proposal is 1,500 words excluding references.

The detailed proposal for the research programme should include the following information:

- a) Background:** detail the relevant background information that is needed to understand the wider context of your application.
- b) Hypothesis and objectives:** describe the main hypothesis to be investigated, details of the objective and how they will be achieved.
- c) Study design:** describe the methodology for the research in detail (for example giving and explaining sample sizes, methods of recruitment and trial designs)
- d) Timelines and milestones:** give timelines for the research with major milestones and deliverables
- e) Potential problems and contingency plans:** highlight any potential risks and identify procedures that can be put in place to deal with them.
- f) Dissemination plans:** describe how you plan to disseminate the findings of the research, in particular to lay members of the TSC community and the wider public
- g) Future plans for the research:** give any plans for further subsequent work

The full proposal should describe the proposed work including clearly defined and measurable research objectives. You must justify why the chosen experimental design is suitable, and both acknowledge and address where there may be difficulties. You should reference established

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protocols where possible and provide justification for any unusual or novel techniques. The purpose of any proposed statistical analysis should be clearly stated, rather than simply giving the name of a statistical test or software package. You may also wish to give details of the expertise and prior knowledge contained within your project team, and highlight why you are ideally placed to carry out the proposed research, for example successful pilot studies, adequate patient numbers, facilities in place, etc.

If you require any further information or guidance, please contact the TSA's Research Team by emailing research@tuberous-sclerosis.org or by calling the main switchboard on 0300 222 5737.

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