Project Grant Award
Guidance for Applicants

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This document is intended to be used in conjunction with the Conditions of Award to assist the completion of the Stroke Association Project Grant Award application form.

If you have any questions, please email research@stroke.org.uk and we will get back to you as soon as we can.

Contents

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Stroke Association Project Grants

There has been encouraging progress in stroke care driven by research over the last three decades, yet stroke remains a leading cause of death and complex disability. Through research we can improve treatment and care where people affected by stroke need it most. It will also tackle the need to reduce the impact of stroke on health and social services, and wider society. We know that uncertainties within the evidence base act as a road block to reducing the devastating effects of stroke.

In order to prioritise these research uncertainties, The James Lind Alliance (JLA) Stroke Priority Setting Partnership (Stroke PSP) led by the Stroke Association, brought stroke survivors and carers together with professionals across the stroke pathway, including GPs, neurologists, occupational therapists and physiotherapists. Together, they submitted and prioritised almost 4,000 questions about stroke. This process has given us two lists of 10 priority areas: the first in prevention and acute care, and the second in rehabilitation and long-term care, ranked in order of importance.

Award amount and duration

These awards are for up to **£250,000** over a period of up to 3 years.

In the application form you are asked to provide a proposed start and end date and project duration. The adjudication process of applications will not be completed until March 2023. We request that awards start within 6 months of the Stroke Association informing the applicant of the final decision.

Deadline for applications

Stage 1: 5pm 5th September 2022
Stage 2: 5pm 12th December 2022

Priorities for funding

The Stroke Association wishes to fund project grants which clearly address priorities for stroke research within the top ten topics from the 2021 PSP (Priority Setting Partnership) for either prevention and acute care, or rehabilitation and long-term care.

We wish to fund collaborative, multi-disciplinary projects for up to three years in duration. In order to be eligible, the pathway leading to impact upon one or more of the PSP priorities must be clearly and specifically demonstrated. We are seeking projects which have been developed by a multi-disciplinary team consisting of relevant expertise in clinical practice, methodology, statistics, and the lived experience. The project may or may not include a clinical trial, depending upon the research question being addressed.

The Application Process

The application process is in two stages, and will be administered via our online grant management system.

Stage 1

This an outline application, and will be reviewed by an expert panel regarding the following aspects:

- The research is novel and will make aan important contribution to the evidence base addressing research question(s) relevant to stroke survivors and the 2021 PSP
- The feasibility of a high quality stage 2 applicationThe appropriateness of the methodologies and outcomes measures. Will the proposed methods achieve the stated aims?
- The quality of the lay summary
- The proposed involvement of people affected by stroke

Applications will be shortlisted for invitation to Stage 2, and invitations to apply for Stage 2 will be sent on the week commencing 26th September 2022.

Stage 2

This is a full application which will undergo external peer review, followed by panel review regarding the following aspects:

- The scientific quality of the proposed research
- The likely impact on the 2021 PSP Prioties for Stroke Research
- The value for money and cost

Animal Research

Although projects involving the use of laboratory animals are eligible, we do not expect project grant applications to include animal research due to the budget envelope of this scheme. Please see the Stroke Association's Position Statement on Research Involving Animals.

We request anyone planning on including animal research in their application to discuss their proposed project with the Stroke Association Research Team prior to completion of their application form.

It is mandatory to complete all of the questions on the Research Involving Animals page if your proposal involves animals. Applications may be referred to the NC3Rs for review. Where animal work is sub-contracted, these questions must be completed by the organisation conducting the animal studies. Please note, we will also ask peer reviewers who will assess your application if there is appropriate justification for the use and number of animals.

Applicants should refer to the NC3Rs website for further information and guidance on the responsible and ethical use of animals in research.

If you are in doubt, please contact the Stroke Association Research Team.

Eligibility

- Primary organisation:
  Stroke Association Awards must be carried out at Universities, NHS Trusts, Statutory Social Care Organisations or other Research Institutions within Great Britain and Northern Ireland.

Your application's primary organisation should be the place where the award will be based. Usually, this refers to the organisation which holds the Lead applicant's employment contract and will administer invoicing for the award.

- The Lead applicant must be a senior researcher holding a PhD (or equivalent) with a track record of managing grants, delivering research studies and a strong publication record. Peer reviewers will judge the expertise and suitability of the applicant and co-applicant team.

- The salary of the Lead applicant has to be guaranteed for the duration of the proposed programme. Therefore the Lead applicant's salary cannot be requested in the budget.

- The salaries (whole or in part) of Senior Academic Researchers/Collaborators are not supported by these grants. This may be waived only in exceptional circumstances.

- For this funding call masters, PhD studentships, and clinical fellowships are not eligible to be included in the budget.

- Applications will not be accepted from investigators (whether applicants, sponsors or collaborators) who have an overdue report from a previous project funded by the Stroke Association at the time of submission (i.e. the deadline date). Applicants should consult with any sponsors and collaborators involved in their application to ensure that they have submitted their reports; otherwise the application will be rejected.

- You will be asked to give details of whether you have involved your local Research Design Service (RDS) or Clinical Trials Unit (CTU) in the development of the research proposal, including details of any discussions you have had with the RDS/CTU, improvements to the proposal as a result of the advice offered and their ongoing involvement in the project.
  Please note: involvement of a RDS (or equivalent) is **recommended for all** applications. Involvement of a CTU or a clinical statistics expert is **mandatory** for clinical trial applications. Your application may be excluded from shortlisting if this information is not included.

Guidance for detailing your proposed research project

The requirements for the Stage 1 and Stage 2 applications are detailed on the online application form.

Depending on the application Stage (see online form), the following areas should be considered, but not necessarily in the order listed below.

1. **The need for the study and how the research question is relevant to the needs of those affected by stroke**
   - What are the principle research questions the study will address?
   - Why is the study needed?

- Evidence from the medical literature should be provided, including discussion of the need for the study in light of any systematic reviews that have been completed.
- Are there any other studies that are currently underway (both nationally and internationally) which are relevant to the proposed study?
- How will the results of this study be used?

2. Proposed trial design

The adjudication panels have requested that as much detail as possible be given concerning the methodology of the proposed research.

2a. If your funding application is for a Clinical Trial Project Grant you trial design should include the following:

- Proposed trial design
  For example, Phase 1/Phase 2 randomised controlled trial (double or single blind).
- Planned trial interventions
  Please give details of both experimental and control interventions. Details should be given of the proposed arrangements for allocating participants to trial groups.
- Sample size
  Control and treatment group sizes should be defined, with a brief description of the power calculations detailing the outcome measures on which group sizes have been based. Event rates, means and medians etc should be included where possible. Justification for the size of difference the study is designed to detect should also be given. Details should include whether the sample size calculation takes into account any loss to follow-up or estimated rate of non-compliance.
- Details of the randomisation method
  If stratification or minimisation are to be used, please give reasons and factors to be included.
- Bias protection
  For example, masking or blinding. If this is not possible, please explain why and give details of any alternative methods proposed, or the implications for the interpretation of the results.
- Planned inclusion/exclusion criteria
  For example, if people with aphasia or cognitive impairment are to be excluded, please provide justification.
- Planned recruitment rate
  Details should be given of how recruitment will be organised and the time period over which recruitment will occur. Please give evidence that the planned recruitment rate is achievable.
- Proposed outcome measures
  The primary and secondary (if applicable) outcome measures, and how they will be measured at follow-up should be defined. Detail should be given of the proposed frequency and duration of follow-up.
- Complex interventions
  Applicants are encouraged to follow the MRC Framework for development and evaluation of RCTs for complex interventions in developing their study available from : https://www.journalslibrary.nihr.ac.uk/hta/hta25570/#/full-report

- MHRA approval
  Trials involving drugs and also some devices will require MHRA approval.
- Adverse effects
  Applicants should ensure that they have detailed the ways in which they will collate and report adverse effects.

3. Description of the research, its design and methods in the context of previous research/preliminary findings

Please detail how this project has been shaped and influenced by previous research. Please include any relevant data from preliminary or previous studies and a description of how this provides supportive evidence that your proposed study is needed.

3a. If your funding application is for a Clinical Trial Project Grant please upload the details/protocol of the main trial if your proposal is for an add-on study in the section below 'Please upload any figures referenced in the project overview.'

4. Feasibility and pilot studies

If your funding application is for a Clinical Trial and applicants are applying for a feasibility or pilot study they are required to detail how they propose to undertake the next stage of the research project.

5. Predicted outcomes of the research

Please describe what outcomes will be measured in the study.

We fully endorse the work of the Stroke Recovery and Rehabilitation Roundtable (SRRR) international taskforce and strongly advise adhering to recommendations of the SRRR in your application. The SRRR roundtables have led to a series of papers that can be found here: https://journals.sagepub.com/page/wso/srrr.

6. Difficulties that can be foreseen and plans for mitigation

Please detail any potential issues that may affect the project and cause the start to be delayed, or affect the smooth progress of the research (e.g. patient recruitment difficulties, access to scanning etc) should be outlined in as much detail as possible. Please outline any mitigation to address such issues. Views from the NIHR Clinical Research Network (NIHR CRN, or equivalent in Scotland, Northern Ireland or Wales) on the feasibility and proposed accrual targets of your study are especially relevant.

7. Team expertise

Applicants should outline the particular contribution each member of the project team will make towards the project. The team should include all the relevant expertise that will enable delivery of the proposed project.

8. Plans to manage and deliver the project

Please detail this. You may refer to a visual aid e.g. a Gantt Chart, but we require specific detail.

9. Collaboration with NHS research organisations

Support in developing studies is available from University Research Support Services, NIHR Research Design Services, UKCRC Registered Clinical Trials Units and the relevant research design and support services in the devolved nations Scotland – CSO; Wales – Health and Care Research Wales Support and Delivery Centre; Northern Ireland – HSC R&D Division). When preparing their proposal, applicants are encouraged to seek support from these organisations. If a project will involve the use of CRN resources, applicants are encouraged to contact their local research network to discuss support costs, feasibility and recruitment.

10. Impact of the research

Please describe the impact the proposal may have upon research and people affected by stroke, or any other impact that the study may have. A clear pathwaty to impact must be demonstrated, including detail about the mechanisms by which this impact will manifest.

Impact can occur in a number of ways, for example, changes in clinical practice, development of new products, new companies and job creation, skills development, changes in public services and policy. A clearly thought through and acceptable statement on pathways to impact should:

- be project-specific and not generalised;
- be flexible and focus on potential outcomes.

Applicants should:

- outline plans to identify and actively engage relevant users of your research,
- describe plans to disseminate findings to relevant stakeholders and how this will fit into the pathways to impact,
- articulate a clear understanding of the context and needs of users and consider ways the research findings can meet these needs,
- describe how findings will it be taken up/adopted in policy and/or practice. Include any barriers or challenges that may be encountered, and propose plans to mitigate these.
- explain how this has been taken into account in your approach to this project,
- outline how you will ensure the sustainability of any intervention beyond the life of this grant,
- outline the planning and management of associated activities including timing, personnel, skills, budget, deliverables and feasibility.

Top Tips for articulating potential impact (adapted from UKRI):

- Draft the pathways to impact very early in your preparation, so that it informs the design of your research. For example, this may include understanding challenges and barriers to adoption, or developing how an intervention can be sustainable beyond the grant.
- Remember to consider and include project specific costs relating to proposed impact activities e.g. engagement workshops, publication costs, etc.

11. Knowledge mobilisation/dissemination plan

Please outline how the applicants plan on disseminating the results of the study and outline their knowledge mobilisation plan.

Involvement of Industry

We recognise partnership with industry, such as parmacetutucal companes or technology compacies are vital to the development and deployment of new inteventions on the health and care system. Collaborations with industry partners, should clearly be described and contract arangements outlines within the IP and third party agreements section of the form. Where

proposed costs are budgeted in the grant for activity to be carried out by the industry partner or to cover costs f the partner, we would expect these to be matched by a financial contribution or an kind or by the partner.

Digital Technology

To ensure new digital technology has the greatest chance of being used routinesly in clinical practice and/or directly by stroke survivors partnership with a small and medium-sized enterprise (SME) is a mandatory requirement in all projects developing and/or evaluating digital technologies. This is so the interventions have a sustainable trajectory to end users, including navigating market analysis, business strategy and regulatory pathway. The appropriate section of the form should be completed, and we strongly recommend that any project using data adheres to the principles set out in the Department of Health & Social Care conduct for data-driven health and care technology code of conduct

Patient and Public Involvement

We expect that all applicants will have involved people affected by stroke in the planning and development stages of their funding application, and will continue to do so should their application be successful. This involvement should be meaningful, and people affected by stroke should have a real opportunity to contribute to your research.

In the application you will be asked how you have involved public and/or patients in this research and/or the application, how you will involve public and/or patients in this research going forward, what the impacts and benefits will be for them (short and/or longer term) and how you plan to disseminate this work to them.

We are able to offer you advice or answer questions you may have about involvement. If you would like to us to contact people affected by stroke to gain feedback on your proposal we can help, however please beware that we will not support any request made to us less than four weeks prior to the application deadline.

You can find out more about how we can help you to involve people affected by stroke in your work here.

Resubmission policy

Our policy permits you to resubmit previously unsuccessful applications to this call once. Should you choose to resubmit your unsuccessful application, we would ask that you take on board the comments of the reviewers and incorporate any suggestions accordingly, demonstrating this in the resubmission question in the application form.

If you have any questions regarding a resubmission, please contact the Research Team with with the month and year you applied and the reference number of your application which can be found on your rejection letter.

Details of support requested

In the main budget table of the Stage 2 application form we would like you to include all the funding you are requesting from the Stroke Association. You will also be required to fully justify all the funding you are requesting.

Please note that if your application is successful, the funding provided will be the figure that you have requested (unless this is queried by the panel). After the Award Acceptance form is signed, the amount awarded will not be increased if there are errors in your calculations so please ensure that the total amount requested is correct.

If you have financial support from other sources, the nature and tenure of the support should be disclosed in either the project proposal section of the application form, or in the justification textbox underneath the budget table.

Support may be sought for the following items:

- Salaries of research workers and technical assistants. Salaries should be calculated with assistance from your institution's finance team to ensure that they are in line with your institution's policy/based on National payscales or recognised local pay models. We do not require a breakdown (ie: take home salary, National Insurance, pension contribution) – only the total figure per year per staff member, but please include the salary grade in the job role title section.
- Please account for inflation and salary increases in the costings in the application form. Salary increases need to be in line with the host institution policy. We are not able to increase the award amount over the course of the award from what is requested in your original budget.
- Equipment to be used exclusively in the research project.
- Consumables that are specific to the research project should be itemised and costed individually over the duration of the award.
- There is no maximum limit for imaging costs. However you will have to justify your request and ensure that costings are in line with institutional and national practices.
- Consultancy or commercial development costs, for example digital app development, should be appropriately costed and clearly justified.
- Travel expenses which are integral to the project, for example, when patients have to be visited in their homes. Please ensure these are costed appropriately.
- Expenses of attendance at meetings and conferences must be justified as part of a necessary expenditure to deliver this work, for example, if overseas collaborations and visits for exchange of skills/knowledge are necessary.
- Open access publishing costs may be incorporated into the budget.
- Patient and Public Involvement: you should ensure you budget for all involvement activities you plan to hold as part of this research; such as as venue hire, catering and travel expenses.

Support may <u>not</u> be sought for the following items:

- The salaries (whole or in part) of the Lead Applicant/Principal Investigator and other Senior Academic Staff are <u>not</u> supported by these grants. This may be waived only in exceptional circumstances.
- Stipends and tuition fees for studentships. For this funding call masters, PhD studentships, and clinical fellowships are <u>not</u> eligible to be included in the budget.
- The Stroke Association considers the Apprenticeship Levy as an indirect cost of research, therefore we will <u>not</u> pay this.

Where the study takes places within the NHS, we ask you to outline any associated NHS costs in the supplementary spreadsheet on the budget page and not in the main budget table:

We are a partnership funder of the NIHR, who have developed the new process to address the continued frustration about the complexity and variation in processes for commissioners and providers agreeing excess treatment costs (ETCs). In Wales studies will automatically be adopted onto the Health and Care Research Wales Research Portfolio, in Scotland the Scottish Stroke Research Network may adopt the study and in Northern Ireland the NICRN and in Wales the HSC R&D Division may provide support.

Researchers are required to complete the **Schedule of Events Cost Attribution Tool (SoECAT)** at the point of submission of their application. This is designed to capture the different costs associated with clinical research and attribute them according to whether they are research costs, service support costs, treatment costs, and excess treatment costs/treatment cost savings. The SoECAT will be used by funders and the HRA, and is intended to standardise the way in which the different costs categories will be calculated and attributed.

The impact of this work will:

- Enable the 15 NIHR Local Clinical Research Networks (LCRNs) to help manage the excess treatment costs process on behalf of their local Clinical Commissioning Groups (CCGs) and in collaboration with NHS England Specialised Commissioning. This single point of access for all proposals for which excess treatment costs may be applicable is designed to make the process much simpler for researchers to navigate.
- Establish a more rapid, standardised and consistent process for the management of excess treatment costs to avoid delays during study set up and to maximise patient recruitment.
- Set a threshold under which excess treatment costs will need to be absorbed by non-primary care providers participating in studies.

Defining ETC values for each study

To underpin the new arrangements, a cost attribution tool has been created in partnership with charity funders and research sponsors. This tool provides a standardised approach for attributing the costs of health and social care research and development (AcoRD) across England. As part of their funding applications, researchers will be required to complete this new tool, known as a Schedule of Events Cost Attribution Tool (SoECAT) for clinical research, which has been developed from the current HRA Schedule of Events. This tool is designed to capture the different costs associated with clinical research and attribute them accordingly.

Supporting guidance for researchers, study teams and sponsors to complete the SoECAT can be found here.

Non-commercial research sponsors have a responsibility to ensure the study is appropriately costed and attributed

Attribution support is available for investigators, study teams and their R&D offices through AcoRD specialists in the NIHR Local Clinical Research Network. Find out more about how to access this support via the Study Support Service.

Under the new arrangements, sign off via the tool is required to confirm the study attribution complies with the Department of Health and Social Care AcoRD guidance. This early attribution support will underpin the excess treatment cost management process by providing formal sign off, supporting the role of the research sponsor and lead R&D office or Clinical Trial Unit. Completion of the Schedule of Events Cost Attribution Template will be required for studies eligible for the NIHR portfolio and the support this provides, which will include access to excess treatment cost payments under the new arrangements. This ETC value, alongside recruitment activity in the NIHR Central Portfolio Management System, will then be utilised to inform the payments to NHS providers.

Application checklist

- You are required to submit your Stage 1 application online, via our award management system, before the deadline (5pm 5th September 2022): https://strokeassociation.flexigrant.com
- We will not accept paper/Word/PDF copies of the application form.
- For the Stage 2 application, The **Head of Department** and the **Finance/Research Administration Officer** from your primary organisation, and (if applicable) **Research Sponsor** must provide their approval of your application in order to allow you to submit the application. This is done by you inviting them to your application form via the 'Participants' tab in the system and them typing their details into the corresponding declaration page. This acts as their signature. If your application is funded, wet copies of their signatures will be required.
  Please see in the **Eligibility** section above defining 'primary organisation'.
- You are not required to have the necessary ethical approval at the time of application. If successful, ethical approval for your study will have to be gained before you can begin your award. You are required to send us a copy of the ethical approval when it is gained.

Adjudication procedure

What happens to your application?

Once your application is received by the Stroke Association Research Department, the applications will be read to ensure that they are eligible and that all the mandatory questions have been answered appropriately. Stage 1 applications will be shortlisted at the first panel meeting. The **Pre-clinical, acute care and prevention panel** adjudicates on applications in the areas of prevention, acute care, medicine, statistics and epidemiology. The **Rehabilitation and long-term care panel** adjudicates applications focused on stroke rehabilitation and long-term care.

The panels will consist of international and UK experts in the field as well as members of our Stroke Voices in Research group (made up of people affected by stroke). The panels will review applications and recommend the applications to be shortlisted for Stage 2.

If shortlisted for Stage 2, you will be invited to submit a full application online. This application will then undergo external peer review prior to the second adjudication panel from which funding recommendations will be agreed upon. projects will be confirmed.

You will be asked in the form which panel you think would be best suited to adjudicate your application. We appreciate that there are some applications that could be adjudicated by either

panel. Please note that the Stroke Association's Research Team and the Chair of the Research Awards Pool will make a final decision on which panel adjudicates your application.

Stroke Association Standards of Adjudication and Peer Review

The Stroke Association is a member of the Association of Medical Research Charities (AMRC), and meets all membership criteria. The research awards adjudication process aligns to AMRC guidelines, and the Stroke Association holds an AMRC Certificate of Best Practice in Medical and Health Research Peer Review.

When you submit an application, the Stroke Association will use the information provided on the form to process the application, which may involve revealing details of the application to peer reviewers outside the Stroke Association. All personal data will be processed in accordance with the General Data Protection Regulation (GDPR). If your award is funded, then details of the award may be used for dissemination and will be made publicly available. All reviewers and Research Awards Pool members must sign and abide by our Confidentiality and Conflicts of Interest Policy.

When will you hear the outcome of your application?

Letters to unsuccessful applications are sent out at various stages depending at what stage the application is rejected i.e. after Stage 1 shortlisting (26th September 2022) or after the second panel meeting (March 2023).

The Research Awards Panel will decide which applications they recommend for funding at the panel meeting. Successful applications need to be signed off by the Stroke Association's Trustees. The panel meeting will take place in February 2023, and you will be informed of the outcome in March 2023.

Feedback

The Lead applicants of all applications will receive copies of the anonymised reviewers' comments as well as a summary of the panel's deliberations if the application was shortlisted for discussion at the panel meeting.

The Stroke Association is fully committed to ensuring that the process by which applications are adjudicated and funding decisions are made is as fair and transparent as possible. We will not enter into any discussion or debate over applications that are unsuccessful. The application process is reviewed after each round. Where improvement has been identified, changes are made and implemented before the next round of applications commence.