Form PG2 Clinical Trial Project Grant Guidance for Applicants

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If you are planning to apply for a Project Grant please register your interest with the Stroke Association Research Department by emailing research@stroke.org.uk. This will allow us to contact you in the event we need to notify applicants of any changes or clarifications to the guidance, forms and/ or deadlines. It will also assist the Research Department to plan the resources required to process all applications.

This document is intended to assist the completion of the Stroke Association Clinical Trial Project Grant Application Form (Form PG1) for project applications incorporating a clinical trial. The guidance is intended to be used in conjunction with the Conditions of Award (Form PG6).

The Stroke Association is the only medical charity working exclusively for stroke illness. The Stroke Association supports research directly related to stroke illness by means of project grants. These are awarded on the recommendation of the Research Awards Pool of the Stroke Association using the system of expert peer review and review by service users. Awards are made once a year in July, with the closing date in February. Applications are invited by means of advertisements in the medical press and the Stroke Association website (www.stroke.org.uk).

These awards are for up to £210,000 over a period of up to 3 years. In exceptional circumstances, awards may be granted for 5 years.

Eligibility

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.

Priorities for Funding

The purpose of the proposed research project must be directly related to stroke illness. Applications in the fields of epidemiology, prevention, diagnosis, imaging, childhood stroke, therapy both medical and surgical, assessment and rehabilitation are particularly welcome**.**

The Stroke Association's strategy is to increase the UK funding base and research capacity for stroke research. Priorities for funding therefore include research into the prevention, treatment, rehabilitation and long-term care of stroke patients. The majority of funded projects are patient-orientated.

Projects involving the use of laboratory animals will not be funded in this particular scheme. Please see the Stroke Association's Position Statement on Research Involving Animals at http://www.stroke.org.uk/research.

Types of funding application
There are two types of application under which project grant applications are welcomed:

- **Clinical Trial Project Grants:**
  Project grant applications incorporating a randomised controlled trial or other clinical trial of a device or an intervention. Projects which have a developmental and then a trial phase should be submitted in this category. Applications for Clinical Trials must be submitted on the Clinical Trials Project Grant Application form and **not** on the Developmental Research Project Grant Application form.

- **Developmental Research Project Grants**
  Project grant applications that are focused on areas which do not incorporate randomised controlled or other types of clinical trials.

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

When should you use the Clinical Trials application form?
The Clinical Trials application form should be used for project applications which incorporate the testing of a previously developed intervention on a population of people, whether stroke survivors or people unaffected by stroke.

The Clinical Trials funding stream is intended to:

- Support the early phases of trials with the intention that, if successful, they proceed to the full trial stage supported by a large funder such as the MRC or NIHR.
- Support the creation of UK centres for large international clinical trials in stroke medicine. Such applications will be in association with, and support the work of, the NIHR Clinical Research Network (NIHR CRN), or an equivalent regional research support network organisation before the application is submitted.

The form should not be used for study proposals in observational epidemiology, basic laboratory science and imaging studies, or early developmental/proof of concept studies.
If you are in doubt, please contact the Stroke Association Research Department for advice.

Application Procedure
An application for a Clinical Trial Project Grant must be submitted on the Stroke Association's **current** application form available from the Stroke Association website. The form must be completed in 11pt Arial typescript with 1.5 pt line spacing.

Please email an electronic Word version of the completed form to research@stroke.org.uk and send the original signed application form to the Stroke Association Research Department. **Please ensure that the original application form has wet signatures- electronic signatures**

will not be accepted on the original application form. The electronic copy must arrive by the deadline; hard copies can follow in the post within a few days of the deadline.

Please staple the pages together; please do not supply loose sheets or use paper clips. Plastic covers or heat/spiral binding should not be used since surplus papers will ultimately be shredded and recycled.

The application form and plain English summary form are supplied as form templates in Word, and **should be saved as Word documents**. Text entry fields will expand automatically as required. Text may be pasted into relevant fields, but please ensure it lies within the boxes provided.

Plain English Summary Form

Applications of sufficient quality are also reviewed by our Service User Review Panel. This Panel is made up of people affected by stroke, who will be sent the plain English summary form. The plain English summary form is available for download separately from the Stroke Association website, and should be completed in 12pt Arial typescript with 1.5pt line spacing.

A completed electronic copy of the plain English summary must be emailed to research@stroke.org.uk, and **one** double-sided copy sent accompanying the completed application form. The electronic copy must arrive by the deadline; hard copies can follow in the post within a few days of the deadline.

Completing the Plain English Summary – Form PG5

Please give a summary of the project title in plain English.

The form should be completed in plain English, and detail the proposed research, avoiding the use of complex medical terms and acronyms. Applicants should assume that readers have little or no detailed knowledge of science. However, please make sure that the summary contains enough detail so that the reviewer can make an informed decision about the project.

The Plain English Summary should accurately reflect what will be undertaken during the project and what research questions will be answered and not the applicants wider research interests.

The questions in sections A to D of the form (and listed below) have been identified and prioritised by a working group of stroke survivors and carers in consultation with other stroke survivors and carers in the community.

Applicants should address the questions within the text of the plain English summary.
A guide to completing a Plain English summary is available on the Stroke Association website: http://www.stroke.org.uk/research/how-write-lay-summary.

APPLICATIONS WITH MISSING OR INADEQUATE PLAIN ENGLISH SUMMARIES WILL BE REJECTED.

Please write your plain English summary **in no more than 1000 words** (in addition to the form questions).

A: About the Research

(i) What is the research about?
(ii) How will the research have an impact on stroke survivors?
(iii) How does the research build on research that has already been done?

B: About the researchers

(i) What is your experience in stroke research?

C: How will the research be carried out?

(i) What does the project involve for people taking part? Are there interviews, blood tests, a scan etc?
(ii) What information will you collect, and how will you use it?
(iii) Will people have to travel to take part? Will you refund their expenses?
(iv) How will you make sure no-one is out of pocket by participating?
(v) How will you keep the people who take part informed about progress and results?

D: What happens when the project is finished?

(i) What will you do with the information you collected about people who took part?

Glossary

Please use this section to define and explain any acronyms or medical terms you may have had to unavoidably use in the plain English summary.

Completing the Clinical Trials Application Form

1.0 Applicant details

The Principal Investigator (Award Holder) should be listed first. Please detail **all** individuals who will be involved with the project, and for whom a CV will be provided.

2.0 Trial title

A title must be provided. The title should not be generic, but should relate to the proposed research.

3.0 Trial acronym

The acronym for the trial (if applicable).

4.0 Abstract of research

A concise summary of the proposed research, including the aims, background, methods and expected outcomes of the project. Statistical predictions may be included. The abstract should be **no more than 200 words.**

5.0 Lay Title of Trial

A title for the proposed research project that is suitable for lay readers must be provided. The title should not be generic, but should relate to the proposed research.

6.0 Lay Abstract of Research

A concise summary of the proposed research suitable for lay readers. It should include the aims, background, methods and expected outcomes of the trial. Statistical predictions may be included. The Abstract should be no more than 300 words.

7.0 Research Awards Panel

Project grants are adjudicated by two Research Awards Panels made up of members of the Research Awards Pool depending on which Panel is most suitable to adjudicate a particular application. The preclinical, acute care and prevention Panel adjudicates on applications in the areas of prevention, acute care, medicine, statistics and epidemiology whilst the rehabilitation and long-term care Panel adjudicates applications focussed on stroke rehabilitation and long-term care. There are some applications that could be adjudicated by either Panel.

Please indicate which Panel you think your application should be adjudicated by. Please note 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.

8.0 Summary of Requested Support

Please summarise all requested amounts on a year by year basis, with totals. Please note this is the amount that the Stroke Association will provide, if the application is successful. The amount awarded will not be increased if there are errors in calculations so please ensure the total amount requested is correct. See section 21.1 for guidelines surrounding inflation.

Please include a proposed start date and project duration (in months).

9.0 Support from elsewhere

Please explain whether the proposed project is receiving support from elsewhere. The nature and tenure of the support should be disclosed.

10.0 Parallel submission

If this application has been submitted to another funding body for consideration, please give details and the date that a decision is expected.

11.0 Resubmission

The Stroke Association allows resubmission of rejected applications only if they scored above threshold after peer review and were discussed at the Research Awards Adjudication Panel meeting upon previous submission. Applicants must demonstrate how feedback from peer reviewers and the adjudication panel has been addressed in the revised application. If unsure whether you can resubmit an application please contact the Research Department with the month and year you applied and the reference number of your application which can be found on your rejection letter.

12.0 Intellectual Property

Please advise whether the research could give rise to a new product or process, and whether Intellectual Property will be generated. Please see section 9 of the Conditions of Award (Form PG6).

13.0 Involvement of a Research Design Service or Clinical Trials Unit in the design of the application and/or research project

Please give details of whether you have involved your local Research Design Service or Clinical Trials Unit 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 Research Design Service (or equivalent) is recommended. **Involvement of a CTU is mandatory for a clinical trial application.**

14.0 Public and/or Patient Benefit and Involvement

The funded activity should have a focus on patient outcomes. Please outline 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.

15.0 Background Research- List of databases checked

You must establish whether there are on-going or completed trials similar or the same as the trial detailed in the application. Please tick the databases that have been checked and detail any others not included on the application form.

16.0 Guidelines used in the development of the study design

It is **mandatory** that you use guidelines in the design of your study. Please detail which guidelines have been used, e.g. CONSORT (http://www.consort-statement.org/); SPIRIT (http://www.spirit-statement.org/); tidier (http://www.consort-statement.org/resources/tidier-2); CASP (http://www.casp-uk.net/). If you have not consulted guidelines during the design of your trial, your application will not proceed to peer review.

17.0 Addresses and signatures

Please ensure that the full postal addresses and contact details of the lead applicant and the administering department are given. All signatures and dates should be present. At least one hard-copy application form will need to have **wet** signatures- electronic signatures will not be accepted on the original form. ***Unsigned or incompletely signed forms will be rejected.***

18.0 Proposed research programme

Your proposal statement should not exceed 9 single-sided pages in length. References (one page maximum) can be listed on an extra page. The Gantt chart/timeline can also be included as a separate page or document. The following areas should all be incorporated, but not necessarily in the order listed below.

18.1 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 trial in light of any systematic reviews that have been completed.
- Are there any other trials that are currently underway (both nationally and internationally) which are relevant to the proposed study?

- How will the results of this trial be used?

18.2 Pilot Study or Feasibility/Supporting Data

Please include any relevant data from pilot or feasibility studies and a description of how this provides supportive evidence that this proposed trial will build upon.

18.3 Proposed Trial Design

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

- 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 :

http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372

- 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.

18.4 Description of the research, its design and methods in the context of previous research

Please detail how this project has been shaped and influenced by previous research.

18.5 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.

18.6 Feasibility and pilot studies

If 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.

18.7 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.

18.8 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.

18.9 Service user involvement

Details should be given of how service users will be involved in the proposed research. Participant recruitment should be detailed under methodology and not user involvement.

Further details of how service users can be involved in research can be obtained from the Involve website at http://www.invo.org.uk. Service user involvement is defined by Involve as 'An active partnership between the public and researchers in the research process, rather than the use of people as the 'subjects' of research. Active involvement may take the form of consultation, collaboration or user control. Many people define public involvement in research as doing research 'with' or 'by' the public, rather than 'to', 'about' or 'for' the public. This

would include, for example, public involvement in advising on a research project, assisting in the design of a project, or in carrying out the research'.

18.10 Justification for the support requested

Detailed justification for the support/resources requested should be given. This should include justification for staff, proposed expenses and equipment.

18.11 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 devolved stroke research specialties. 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.

18.12 Impact of the research

Please describe the impact the proposal may potentially have upon research and patient care, or any other impact that the study may have.

18.13 Knowledge Mobilisation/ Dissemination Plan

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

19.0 Research purpose

Please tick **one** box which most appropriately fits the nature of the proposed research.

Prevention – research investigating how the occurrence of stroke can be reduced.

Acute Stroke Service – research exploring how hospitals diagnose and treat stroke patients immediately following stroke onset.

Community Care – research looking at how the long term care of stroke patients in the community can be improved.

Rehabilitation – research aimed at identifying ways in which a stroke patient's independence and quality of life may be improved after stroke.

Applied Neuroscience – research aimed at furthering the understanding of how the brain and nervous system work in relation to stroke.

20.0 Research type

Please tick **one** box which most appropriately fits the type of the proposed research.

Carers and Patients – identifying ways in which the well being of stroke patients and their carers might be improved, as well as the interaction between patients and carers.

Clinical Pharmacology – investigating how drugs (including their properties and effects), might be used to prevent and treat stroke.

Clinical Psychology – investigating how the diagnosis and treatment of psychological disorders in stroke patients can be improved.

Epidemiology – furthering our understanding of stroke by studying the causes, distribution and control of stroke in populations.

Genetics - identifying the role of genetics as biomarkers, risk or predictive/prognostic factors for different aspects of stroke.

Ethnic factors – identifying how ethnic factors (factors that are particular to a group sharing a common origin, culture or language), might act as risk factors for stroke.
Imaging – improving our understanding of the cause and effect of stroke by using imaging techniques that produce pictures of the inside of the brain.
Information, education – researching the ways in which the public may be better informed and educated about stroke, its prevention, identification and treatment.
Neuropathology – identifying changes in the brain and nervous system that may be the cause or effect of stroke.
Neuroprotection – improving our understanding of how damage to the brain and nervous system following stroke can be minimised and prevented.
Neurorehabilitation – exploring techniques in which the brain and nervous system may be rehabilitated after stroke so that partial or total function is restored**.**
Primary care – exploring how the medical care received by a stroke patient on first contact with the medical system can be improved.
Quality of life (including communication) – investigating how stroke patients' level of independence, comfort, enjoyment and ability to pursue daily activities of living can be improved.
Stroke Unit Care – investigating how the functions of specialised stroke units in hospitals can be improved.
Surgical Treatment – exploring the potentials of surgery in the prevention and treatment of stroke.
Vascular Pathology – furthering our understanding of how structural and functional changes in blood vessels may be the cause or effect of stroke.

21.0 Research Keywords

Please provide **five** keywords to specifically describe the research in this application.

22.0 Details of Support Requested

Please refer to the Conditions of Award for further details of support.

22.1 Support may be sought for the following items:

Salaries of research staff. The salaries (whole or in part) of Senior Academic Supervisors/Staff or Award holders are <u>not</u> supported by Project Grants

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.

Travel expenses, which are integral to the project as, for example, when patients have to be visited in their homes. Up to £2,000 over the duration of the award will be allowed for attendance at meetings and conferences. This amount must be included in the original award application.

Expenses for bringing together representatives from participating trial centres will be considered, but must be included in the original application.

When a MRI scan is integral to the research programme and would not otherwise be carried out, (i.e. does not qualify as an excess treatment cost), the Stroke Association will pay up to £300. Likewise for CT scans the Stroke Association will pay up to £100. The Stroke Association will contribute towards the cost of research PET scans, but applicants should discuss the potential cost of such PET scans with the Research Department before applying.

Up to £2000 for open access publishing costs may be incorporated into the original application.

Please note the Stroke Association does not pay inflation on grants. Applicants will need to request all costs, including salary increases, in the original grant application. Salary increases need to be in line with the host institution policy.

23.0 NHS Costs/NHS Treatment Costs

These costs are defined in section 6 of the Conditions of Award.

23.1 Clinical research in the NHS incurs research, support and treatment costs, which are defined under the 1997 Health Service Guidelines (HSG (97)32).[1]

23.1.1 Research costs – costs of the research itself, which will end when the research ends. These are paid by research funders. For example – tests to show the effect of the drug/device that are not part of the patient's care.

23.1.2 Treatment costs – patient care costs, which would continue to be incurred if the service were continued after the research project ends. For example – supplying and administering the drug/device.

23.1.3 Support costs – patient care costs which would end once the research had stopped, even if the service continued to be provided. For example – tests to ensure the patient is safe while taking the drug/device, or which are used by clinicians treating the patient.

Many activities – such as taking blood for a test – could be a research, treatment or support cost, depending on the context in which the activity happens and how the resulting information will be used.

23.2 From 1 October 2012, Department of Health has adopted revised guidance for attributing research costs – AcoRD. AcoRD reflects changes to clinical research infrastructure, and will apply to all applications submitted after 1 October 2012. It now relates to clinical research in England, Wales, Scotland and Northern Ireland.

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[1] Department of Health, 1997. HSG (97)32: *Responsibilities for meeting patient care costs associated with research and development in the NHS.* Available at: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353

23.3 What's changed under AcoRD?

Charity law dictates that charities can only fund costs within their charitable objectives. The Department of Health recognises that medical research charities should fund direct research costs and not institutional overheads.

As well as a set of direct research costs (Part A) that all funders should pay, the Department of Health has identified a subset of research costs (Part B) that are linked to research infrastructures, that the National Institute of Health Research Clinical Research Network (NIHR CRN) - in England, Scottish Stroke Research Network (SSRN) – in Scotland, Northern Ireland Clinical Research Network (NICRN) - in Northern Ireland, Health and Care Research Wales (formerly NISCHR) - in Wales or local trusts will pay, when:

- the funder is a medical research charity that is a member of the Association of Medical Research Charities (AMRC); and

- the activity is undertaken by existing staff employed by the NHS, NIHR Clinical Research Network (NIHR CRN) or other organisations funded by the NHS to provide patient care services.

The research costs that the Stroke Association, as an AMRC registered charity, will **not** be required to pay (detailed in AcoRD Appendix A, Part B) are as follows:

- Local study trial co-ordination and management.

- Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).

- Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.

- The time taken by Chief and Principal Investigators (CI and PI) to explain the study to professional colleagues, and to understand, the research elements of a study. For example the time taken to explain the criteria for patient eligibility or to explain the randomisation protocol.

- Sponsorship fees such as MHRA fees, and CTA annual renewal fees.

23.4 This costing model is analogous to the system of classifying research costs in universities as directly incurred, directly allocated and indirect costs. Universities receive charity support funding through the relevant funding councils in England, Scotland, Wales and Northern Ireland to support the indirect costs of charity-sponsored research. These include things like over heads such as lighting, heating and maintaining labs. More information can be found here:

http://www.amrc.org.uk/our-work/working-with-others/working-with-universities/charity-research-support-fund.

23.5 AcoRD: Further Information

https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

23.6 AcoRD – Further details and completing the form

Please give details of any anticipated NHS Support Costs or NHS Treatment Costs in the table. Please also give details of any discussions you have had concerning funding these costs with your local NHS Trust or NHS Research Office. It would be helpful if you could provide the contact details of the person(s) you have spoken to. If there is an undertaking by a relevant authority to finance these costs or offer support should the application be funded, please give details.
It is important that the NHS Support Costs and Excess Treatment Costs provided by applicants are as robust as possible, and should be discussed with both the relevant Research Network(s) and NHS Trust(s) to ensure they are aware of all initial cost and resource implications should your application be successful. The Stroke Association will ultimately require proof that the appropriate NHS institution R&D Manager has approved and signed off the costs.

The National Institute for Health Research Clinical Research Network (NIHR-CRN) provides support for studies that are included in the NIHR-CRN Portfolio or relevant CRN portfolio in Scotland, Wales and Northern Ireland. The Stroke Association is a National Institute for Health Research non-commercial partner and funds research through open national competition with a full peer review process. All funded projects with an element of clinical research are, therefore, likely to meet the eligibility criteria for automatic inclusion in the NIHR-CRN portfolio (which can be found at: http://www.crn.nihr.ac.uk) and will consequently have support from the Clinical Research Network Specialties (namely the Stroke Specialty) in the form of NHS service support costs, for example access to dedicated skilled research support staff including research nurses and other allied health professionals, support to ensure your study can be successfully undertaken in the NHS, and access to experienced Research Management and Governance staff. Automatic adoption does not imply that the CRN will offer unlimited support, or that CRN will agree that target enrolment is realistic. Instead, the CRN Portfolio Management Committee will review your application for adoption to determine the type of support and target enrolment numbers that would be realistic for the CRN. You are strongly recommended to have your application reviewed by the relevant Clinical Studies Group of the CRN before it is submitted, and that you take into account CRN views on feasibility and accrual targets when planning your research.
It is a condition of award that Award Holders of relevant awards funded by the Stroke Association apply to have their study adopted and included in the relevant section of one of the NIHR-CRN, SSRN or Health and Care Research Wales study portfolios. By accepting the Conditions of Award, applicants also agree to provide information on their study to the relevant Portfolio, and if support from the

CRN will be received, to comply with the relevant Portfolio requirements for reporting study recruitment. Applicants also agree that the Stroke Association may receive copies of reports and correspondence concerning feasibility and recruitment to your study.

24.0 Ethical approval

If the proposed research requires approval from a Research Ethics Committee please give details of the anticipated time for approval to be gained, and the Research Ethics Committee from which approval is, or will be, sought. Please note that a copy of the ethical approval must be submitted to the Stroke Association before the first invoice will be paid.

25.0 Curriculum Vitae of applicants

Please include a CV for each person who is named in section one of the form. The CV for the lead applicant should be given first. CVs for named research staff (if applicable) should also be supplied.

26.0 General information

26.1 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.

The Stroke Association will be polite and courteous in its dealings with you. We will acknowledge your application within five working days of submission, and will respond to any queries within five working days.

26.2 What happens to your application?

Once your application is received by the Stroke Association Research Department, the details are entered onto the research database.

The application form is then reviewed by two members of the relevant adjudication panel (made up of members of our Research Awards Pool). The lowest scoring applications (depending on numbers) will be removed from further assessment and rejected at this stage. The remaining applications will be sent for expert peer review to at least two relevant external peer reviewers. Reviewers complete an external review form assessing the quality of the science, value for money, feasibility and the potential impact of the proposed research. Reviewers also score the research on a scale of 1 to 6, where 1 is poor and 6 is excellent. Applications that score above threshold will then be discussed by the relevant Research Awards Adjudication Panel. The threshold is usually an average of 4, this may be variable depending on the number of applications and a final decision will be taken by the Chairs of the relevant adjudication panels of where the threshold will lie in each application round. Those applications that do not score

above threshold after internal and external peer review will be rejected at this stage.

Applications of sufficient quality will also be reviewed by the Stroke Association's Service User Review Panel who are sent the plain English summaries. The service users are asked to comment and score the applications.

Applications are discussed, scored and ranked at the relevant Research Awards Adjudication Panel meeting. The Research Awards Panel then recommend to the Stroke Association which applications they recommend for funding. Successful applications need to be signed off by the Stroke Association's Council of Trustees.

26.3 When will you hear the outcome of your application?

The closing date (8 February 2017) is approximately four months prior to the adjudication panel meeting at which your application will be considered (June 2017). Following the closing date, applications are allocated to internal and then external reviewers if appropriate (see above). The entire review process usually takes around 10-12 weeks.

Recommendations as to which applications should be funded will be made by the adjudication panel meeting, based on the highest scoring applications. The recommendations must then be ratified by the Stroke Association Council of Trustees.

Letters to unsuccessful applications are sent out at various stages depending at what stage the application is rejected i.e. after triage (within 2 months of the deadline), after external peer review (within 3 months of the deadline) or after the Stroke Association's Council of Trustees' meeting (within five months of the deadline).

Letters to successful applicants are sent immediately following the next Council of Trustees' meeting, which may be up to one month after the adjudication panel meeting.

26.4 Feedback

The lead applicants of all applications will receive copies of the anonymised reviewers' comments as well as a summary of the Research Awards Panel feedback where applicable. In some cases you will only receive one set of comments as reviewers may request that their comments are kept confidential.

26.5 Complaints

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.

26.6 Confidentiality

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 Data Protection Act 1998. 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.

Application Checklist:

Have you sent via email to research@stroke.org.uk:

- Electronic copy of the completed application form?
- Electronic copy of the completed plain English summary form?

Have you sent to the Research Department via post:

- Signed single-sided original copy of the application form with original, **wet** signatures?
- One doubled-sided copy of the plain English summary form?