

The conditions in this document should be viewed as an appendix to the **Conditions relating to a fellowship awarded by the Association of British Neurologists (ABN)** and are applicable to applicants for the Stroke Association and the Association of British Neurologists jointly funded Clinical Research Training Fellowship 2018.

1. The Fellowship is offered to applicants in the UK only (ABN conditions 2, 15, 20, 26).
2. Typically applicants will be pre-doctoral and will either already hold a UK specialist training post in a parent specialty relevant to stroke medicine i.e.: Neurology, Geriatric Medicine, Rehabilitation Medicine, Cardiology, Clinical Pharmacology & Therapeutics or General Internal Medicine, or be planning to start a specialist training post after completion of a PhD (ABN conditions 2).
3. The Supervisor of the Fellowship holder will hold a senior post in a UK Higher Education Institute or within the NHS (ABN conditions 4, 26).
4. Intellectual Property and Commercial Exploitation: The Stroke Association conditions relating to Intellectual Property and Commercial Exploitation (appendix 1) and its Revenue Sharing Policy (appendix 2) are applicable to this award (ABN condition 22).
5. Additional costs: Costs specified in [Annex A, Part B](#) of the guidelines for attributing the costs of health and social care research and development (AcoRD, appendix 3) will not be covered by this award (ABN conditions 16, 17, 21).
6. Unpaid leave: the fellow must notify the Stroke Association of any interruptions in the research programme so that payments may be held in abeyance, eg during a period of maternity/paternity or sick leave (ABN conditions 25).
7. Reporting: In addition to the standard reporting requested by the ABN, progress reports including all research outputs and outcomes should be submitted annually online through Researchfish.(ref ABN conditions 18).
8. Necessary approvals
 - a. Ethical Approval: An Award may not commence until all necessary Ethical Committee approvals have been obtained. A copy of all such approval(s) must be received by the Stroke Association Assistant Director of Research before any funds will be released. An exception may be made if the research requiring ethical approval will not begin in the first 6 months of the Award. In this instance, copies of ethical approval must be received by the Stroke Association prior to the commencement of this work before further funds will be released.
 - b. NHS Research Governance Framework for Health and Social Care: It is a requirement that all research carried out involving humans or human tissue must have a sponsor which accepts the sponsor responsibilities as defined by the above framework. The Stroke Association is not able to sponsor the work it funds. The appropriate NHS Trust or Host Institution must accept responsibility as sponsor of the research.
 - c. Research involving animals:
 - i. An award may not commence until approvals have been obtained for research involving animals from the Home Office, Animal Welfare or Ethical Review Body.
 - ii. All experimental programmes supported by Stroke Association must only use animals where there are no alternatives.
Experiments using animals funded by Stroke Association must:
 - use the simplest possible, or least sentient, species of animal
 - ensure that distress and suffering are avoided wherever possible
 - employ an appropriate design and use the minimum number of animals consistent with ensuring that the scientific objectives will be met.

- iii. All grant holders using animals must implement the principles in the cross-funder guidance [Responsibility in the Use of Animals in Bioscience Research](#).
- iv. Grant holders using non-human primates must comply with the NC3Rs guidelines [Primate Accommodation, Care and Use](#).
- v. Grant holders should make use of the [ARRIVE guidelines](#) when designing their experiments, and ensure that they report animal-based studies in accordance with the ARRIVE guidelines as far as possible, taking into account the specific editorial policies of the journal concerned.

NOTE: Please refer to the [NC3Rs website](#) for further information and guidance.

APPENDIX 1: Stroke Association Intellectual Property and Commercial Exploitation

APPENDIX 2: Stroke Association Revenue Sharing Policy

APPENDIX 3: Attributing the cost of health and social care Research & Development
[AcoRD](#)

APPENDIX 1

Stroke Association Intellectual Property and Commercial Exploitation

1. The Host Institution will notify the Stroke Association promptly (in any event no later than 30 days) in writing when Award Intellectual Property arises, and ensure that the Award Intellectual Property is not disclosed prior to Intellectual Property protection being sought.
2. The Host Institution must (if not already) develop and implement strategies and procedures for the identification, protection, management and exploitation of Award Intellectual Property. The Host Institution will own entirely any Intellectual Property generated using the Award.
3. No Award Intellectual Property may be exploited or disposed of in any way (by license, assignment, option or otherwise) without the prior written approval of the Stroke Association, such consent not to be reasonably withheld. The Host Institution will provide Stroke Association with details concerning the Host Institution plans for the exploitation of the Award Intellectual Property. As a condition of such consent, the Stroke Association will require the Host Institution to agree to a revenue sharing agreement, such agreement consistent with the provisions of this Clause 9 and the Stroke Association Revenue Sharing Policy (see Schedule 1), the provisions of which are hereby incorporated.
4. The Host Institution will provide Stroke Association with details of any agreements the Host Institution enters into in relation to the Award Intellectual Property. The Host Institution will provide Stroke Association with details of any Intellectual Property (including patent numbers, dates etc.) in relation to the Award Intellectual Property.
5. The Host Institution will ensure that separate and accurate reports are maintained of the commercial exploitation of Stroke Association funded IP and access for Stroke Association or its appointed representative to inspect and audit such records and take copies at the expense of the Stroke Association.
6. The Host Institution hereby grants to the Stroke Association a perpetual, sub-licensable (through one tier only), irrevocable, world-wide, non-exclusive royalty-free license to the Award Intellectual Property, for the purposes of academic/not-for-profit research (including in collaborations), teaching, and publicity purposes. The Host Institution and the Stroke Association will, if legally necessary or administratively convenient, execute such formal instruments as may be necessary to give full effect to this Clause 9.6. The Stroke Association will notify the Host Institution in the event that it sub-licenses the Award Intellectual Property. Further, in the event that the Stroke Association intends to exercise its right to sub-licence the Award Intellectual Property, it will notify the Host Institution in advance of doing so, in good time for the Host Institution to make representations regarding the proposed sub-licence, and the Stroke Association will consider those representations in good faith before finalising the terms of any sub-licence granted.
7. For the avoidance of doubt, if Host Institution requires permission or rights to exploit the Award Intellectual Property from any third party, this is the sole responsibility of the Host Institution, and not the Stroke Association. In addition, if the Host

Institution wishes to bundle other Intellectual Property rights together with the Award Intellectual Property for the purposes of exploitation, the Host Institution will secure any licences or permissions needed to use such IP. Where the Award Intellectual Property includes third party IP, the Host Institution will indemnify the Stroke Association in respect of any infringement of third party rights.

8. If the Host Institution fails to exploit the Award Intellectual Property which the Stroke Association reasonably considers should/can be exploited, then the Stroke Association will have the right but not the duty to seek to exploit the Award Intellectual Property. The Host Institution will provide all assistance reasonably requested by the Stroke Association. Such assistance will include licensing, assigning or otherwise transferring all rights in the Award Intellectual Property to the Stroke Association, provided always that the Stroke Association agree a revenue sharing arrangement with the Host Institution.
9. The Host Institution understands the Stroke Association may appoint a third party intellectual property or technology transfer agent. The Stroke Association may disclose information relating to the Award and the Award Intellectual Property to such third party provided always that such third party is bound by confidentiality. The Host Institution will co-operate fully with such agent, as the Host Institution would cooperate with the Stroke Association.
10. In the event that biological materials (such as genetically modified organisms, plasmids, virus particles, or cell lines) or software or designs (or other copyright protected matter) are generated using the Award, such materials or software will be made available to non-commercial third parties for academic or not-profit research. The Host Institution is encouraged to make use of public/not for profit repositories for the purposes of such dissemination, under an appropriate agreement with said repository. For clarity, Host Institution is also encouraged to make such materials, designs and software available to commercial third parties for appropriate consideration. For clarity, such consideration is also subject to the Stroke Association Revenue Sharing Policy (available in Annexe One).
11. The conditions in Appendix 1 will continue to apply after completion and termination of the Award.

APPENDIX 2

Stroke Association Revenue Sharing Policy

1. Definitions

1.1 The following words and phrases will have the following meanings unless the context requires otherwise:

"Award" means the award made by the Stroke Association to the Host Institution for the Principal Investigator/Lecturer/Fellow to undertake research.

"Business Day" will mean a day other than a day which is a Saturday, Sunday or public or bank holiday in England.

"Combination Package" will mean a package containing the Intellectual Property bundled together with any other intellectual property which the Host Institution owns or is the beneficial owner (or otherwise has access to).

"Combination Package Gross Revenue" will mean all consideration received by the Host Institution from the commercial exploitation of the Intellectual Property in a Combination Package including licence fees, option fees, up-front fees, royalties, minimum royalties or milestone payments, sub-licence initiation fees, or any other fixed sum payments received by the Host Institution from the licensing or other disposition of the Intellectual Property in a Combination Package.

"Combination Package Net Revenue" will mean Combination Package Gross Revenue multiplied by the WR, less Direct Costs and any taxes including, but not limited to, value added tax, sales, excise and withholding tax, imposed on the Host Institution in connection with Gross Revenue which the Host Institution is unable to offset or recover.

"Direct Costs" will mean all external expenses incurred and paid by the Host Institution in connection with the filing, prosecution and maintenance of the Intellectual Property including, but not limited to, official filing fees, agent costs, and reasonable legal and other advisory and consultancy fees. To avoid doubt, Direct Costs will not include the Host Institution's internal costs relating to these activities, regardless of the legal constitution of the Host Institution's technology transfer office. For the avoidance of doubt, Organisation may not make deductions for salary or taxes in respect of the Organisation or the inventors or generators on the Intellectual Property.

"Gross Revenue" will mean all consideration received by Organisation from the commercial exploitation of the Intellectual Property pursuant to this Policy, including licence fees, option fees, up-front fees, royalties, minimum royalties or milestone payments, sub-licence initiation fees or any other fixed sum payments received by the Host Institution from the licensing or other disposition of the Intellectual Property in forms including but not limited to monies, shares or options.

"Intellectual Property" or **"IP"** will mean Materials, Patent Rights, Know-How, trademarks, service marks, registered designs, copyrights, database rights, design rights, confidential information, applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above.

"Know-How" will mean unpatented technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain.

"Materials" will mean the biological or biochemical matter generated in the course of the research project (whether living or not), for example (without limiting the foregoing), viruses, cell lines, plasmids, new varieties or genetically modified organisms, such as mice or bacteria.

"Net Revenue" will mean Gross Revenue less Direct Costs and any taxes including but not limited to value added tax, sales, excise and withholding tax, imposed on the Host Institution in connection with Gross Revenue which the Host Institution is unable to offset or recover.

"Organisation" will mean the Host Institution together with the TTO.

"Patent Rights" will mean the patent applications and any and all patent application(s) and patents deriving or claiming priority from any thereof or otherwise relating to the aforementioned patent application including all divisionals, continuations, reissues, extensions, registrations and supplementary protection certificates in relation to any thereof.

"TTO" will mean technology transfer office (or equivalent body).

"Weighting Ratio" or **"WR"** will mean the reasonable inventive relative weighting given by the Host Institution in good faith to each technology/intellectual property included in the Combination Package as a contribution to the whole.

2. Intellectual Property ownership

2.1 The Host Institution is responsible for ensuring that the Host Institution inventors or generators or authors of the Intellectual Property, who they control, assign their rights in the Intellectual Property to the Host Institution, in order to enable the Host Institution to exploit properly the Intellectual Property.

2.2 Subject to Clause 4.9, the Host Institution is responsible for ensuring that the Host Institution has all the necessary rights to comply with this Agreement and subject to third party rights, and is able to distribute the Materials (if any) for commercial and non-commercial purposes

2.3 The Host Institution hereby grants to the Stroke Association a non-exclusive, sub-licensable (through one tier only) license to use the Intellectual Property solely in academic or not-for-profit research.

2.4 For clarity, the Host Institution may transfer or assign or license the Intellectual Property to a technology transfer company for the purpose of distributing or commercialising this Intellectual Property. However, such transfer of rights must not be to the detriment of the Stroke Association's rights or the terms and conditions of the Award.

3. Intellectual Property and expenses

3.1 The Parties agree that the Host Institution will have sole responsibility and authority to manage and execute the duties required for the filing, prosecution and maintenance of the Intellectual Property, including the Patent Rights. The Host Institution will keep or will procure that their agents keep all notices, applications and correspondence filed in connection with the Intellectual Property, and will provide copies of such documents to the Stroke Association or their agent on reasonable request.

3.2 Direct Costs will be paid by the Host Institution and will then be deducted from Gross Revenue and/or Combination Package Gross Revenue.

3.3 If, at any time, the Host Institution decides to abandon in any territory any or all patent applications or patents included in the Patent Rights ("Patent Rights for Abandonment"), the Host Institution will notify the Stroke Association of its intention at least sixty (60) days prior to the date any Patent Office action concerning the Patent Rights for Abandonment is due and will offer to assign the Patent Rights for Abandonment to the Stroke Association. If the Stroke Association wishes to receive assignment of the Patent Rights for Abandonment, the Stroke Association will be responsible for all further costs arising from the Patent Rights for Abandonment and the Parties will negotiate a separate assignment and revenue sharing agreement that specifies the rights each Party will have in relation to the Patent Rights for Abandonment and any related data or information.

3.4 In the event the Intellectual Property rights are infringed by a third party, the Host Institution will have the right to defend the Intellectual Property rights and will do so at its own cost but will not be obliged to do so. If however, the Host Institution does not wish to defend the Intellectual Property rights, the Stroke Association will have the right (but not the obligation), and at the Stroke Association's own cost to defend the Intellectual Property rights. The Host Institution will give the Stroke Association all assistance, and carry out all such acts as reasonably necessary to allow the Stroke Association to defend the Intellectual Property rights.

4. Exploitation

4.1 Subject to Clause 2.4, prior to granting any rights over the Intellectual Property to any third party, the Host Institution will provide to the Stroke Association or its agent on a confidential basis in such reasonable detail as may be requested details of the proposals for the exploitation of the Intellectual Property including where applicable the identity of any proposed licensee or assignee of the Intellectual Property and the intended terms under which such rights will be granted.

4.2 The Host Institution will take into account in its negotiations with any such third party any representations made by the Stroke Association or its agent bearing in mind the legitimate interest of the Stroke Association in such negotiations as a potential recipient of a share of Net Revenue or of Combination Package Net Revenue.

4.3 Subject to the obligations in Clauses 4.1, 4.2 and 4.5, the Host Institution will have the sole responsibility to exploit the Intellectual Property commercially in any manner it decides including, but not limited to, licensing, selling and assigning in exchange for consideration. The decision whether or not to conclude any agreement in relation to such commercial exploitation will be matters for the sole discretion of the Host Institution.

4.4 The Host Institution will provide the Stroke Association or its agent on a confidential basis with copies of all agreements related to the Intellectual Property. For clarity, and without limiting the foregoing, this will include administration agreements, assignments, licenses, and sublicenses granted under the Intellectual Property.

4.5 If the Host Institution elects not to exploit the Intellectual Property commercially it will notify the Stroke Association (within a reasonable period of time) and the Stroke Association will inform the Host Institution of whether it, or a third party acting as the Stroke Association's agent, wishes to be granted the right of exploitation, and if so, the Parties will meet to agree upon the best way to proceed, and in accordance with the terms and conditions of the Award.

4.6 Subject to third party rights, the Host Institution agrees to make freely available the Materials and associated Know-How for academic or not-for-profit research, to the maximum extent possible. To that end, the Host Institution may deposit the Materials in an appropriate repository, for subsequent onward distribution.

4.7 The Host Institution agrees to use the Intellectual Property in a lawful manner according to applicable law and any associated guidelines and guidance. In relation to Materials, the Host Institution agrees to act (and will require that any assignee or licensee acts) with the utmost care in terms of human and animal health, wellbeing and ethics.

4.8 Where the Intellectual Property is to be licensed or assigned as part of a Combination package, the Host Institution will determine an appropriate and reasonable WR, in accordance with the custom and practice of reasonable technology transfer offices. The Host Institution will consult with the Stroke Association or its agent in making a determination of an appropriate WR.

4.9 The Parties recognise that in the case of jointly generated Intellectual Property (i.e. the Host Institution and a third party organisation) owns the Intellectual Property (at the point of generation); the Host Institution may not be the party exploiting the Intellectual Property. In such a situation, the Host Institution may assign or license its rights in the Intellectual Property to the joint owning organisation (in exchange for an appropriate and equitable revenue share). The Host Institution will notify the Stroke Association of such circumstances. Moreover, the provisions on revenue sharing in Clause 5 will apply only to the consideration actually received by the Host Institution. Moreover, the Host Institution will ensure that any agreement with a joint owning third party in respect of the Intellectual Property does not prejudice the rights of the Stroke Association in any way.

5. Revenue sharing

5.1 The Parties will share all Net Revenue received from the exploitation of the Intellectual Property, in the proportion of fifty percent (50%) to the Host Institution and fifty percent (50%) to the Stroke Association.

5.2 In the event that the Intellectual Property is exploited through a Combination Package, the Parties agree to share all Combination Package Net Revenue in the proportion of fifty percent (50%) to the Host Institution and fifty percent (50%) to the Stroke Association.

5.3 The Host Institution will be solely responsible for distributing its share of the Net Revenue or Combination Package Net Revenue to researchers who contributed to the Intellectual Property in accordance with any policy of the Host Institution, subject to the terms of this Contract.

6. Records and payments

6.1 The Host Institution will keep complete and accurate accounts of all Direct Costs plus Gross Revenue and/or Combination Package Gross Revenue. The Host Institution will make these accounts available on reasonable notice for inspection and verification during business hours by an independent professionally qualified accountant nominated by the Stroke Association and reasonably acceptable to the Host Institution. The Stroke Association will be responsible for the accountant's charges unless the accountant finds an underpayment of at least five percent (5%) between sums due and sums paid to the Stroke Association since the last most recent inspection.

6.2 The Host Institution, within thirty (30) days after 31 March each year, will provide the Stroke Association with a statement setting out Gross Revenue or Combination Package Gross Revenue received and Direct Costs incurred during the previous twelve (12) month period, together with the value of the Net Revenue or Combination Package Net Revenue arising therefrom. If no revenue will be due to the Stroke Association, the Host Institution will so report. On receipt of such statement from the Host Institution the Stroke Association will issue the Host Institution with an invoice for any payment due to the Stroke Association, which will be paid by the Host Institution in accordance with the instructions set out in the Stroke Association's invoice.

6.3 In the event that the Host Institution is obliged by law to deduct tax from any payment to the Stroke Association under this Policy, it will provide the Stroke Association with documentary evidence of such deduction and will assist the Stroke Association to seek relief under a double taxation agreement or other applicable agreements.

7. Confidentiality

7.1 The Stroke Association will use all reasonable endeavours to keep confidential all information relevant to the Intellectual Property and all information provided under Clause 4 which is in the Stroke Association's possession, and which is not disclosed by the Host Institution.

7.2 The Stroke Association may disclose the information referred to in Clause 7.1 to a third party which is acting as its agent provided that such third party is bound by obligations of confidentiality no less protective of the Host Institution's rights than this Policy.

7.3 Each Party agrees not to use the names or marks of the other Party without the prior written consent of the other Party.

8. Indemnification

The Host Institution will indemnify and hold harmless the Stroke Association and its employees and agents against all liability, loss, damage, cost or expense which may result directly from the use or commercialisation of the Intellectual Property.

APPENDIX 3

Attributing the cost of health and social care Research & Development ([AcoRD](#))

[Annex A](#)

List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs

Activities that are attributed to Research Costs include:

The costs of activities listed in Part A should be funded in full by all grant funders. The costs of activities listed in Part B will also need to be funded in full by grant funders except where 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 or other organisations funded by the NHS to provide patient care services. Under these circumstances, the cost of the activities in Part B will be met by the Department of Health.

Part A

1. Any screening tests/assessments, to determine whether a patient is eligible to participate in a study, performed after the patient has been approached to ask if they wish to participate in the study, but before they are accepted onto the study.
2. Study specific central trial co-ordination and management.
3. Patient randomization.
4. Investigations, assessments and tests relating to if, how, why and when an intervention/procedure works - in other words, activity which is intended to answer the research question.
5. Investigations, assessments and tests where the results are anonymous and unlinked to a patient identifier, or where the individual results will not be reported back to study participants or their clinicians, since such information is collected primarily for the purpose of answering the research question. However, exceptional circumstances may arise where there is an overwhelming clinical need to convey results to the clinician providing care. The possibility of such exceptional circumstances does not change the primary purpose.
6. Patient follow-up where the follow-up is not a part of individual patient clinical management.
7. Cash reimbursements or payments to volunteers to participate in the study.
8. All costs associated with placebos including but not limited to producing, formulating, disguising, shipping, storing and dispensing placebos, including administering sham treatments, since these costs do not form part of the patient's care and would not continue to be incurred once the study is finished.
9. Registration of trials, including MHRA clinical trial authorisation fees.
10. Data storage archiving of clinical research records.

11. Costs associated with making the results accessible.
 12. Training where new skills are required to carry out the R&D activity, but not training in obtaining informed consent, or training to deliver the treatment under investigation.
 13. Data analysis needed to answer the questions that the research study is addressing.
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Part B

14. Local study trial co-ordination and management.
15. Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).
16. Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.
17. 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.

Activities that are attributed to NHS Treatment Costs include:

1. Supplying and administering the medicine/device/therapy being studied.
2. Supplying and administering any active comparators - including medicines, devices or therapies, but not placebo or sham treatments.
3. Training of clinicians to deliver the treatment.
4. Investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the R&D study has stopped.
5. Patient follow-up where this is required as part of the clinical management of a patient. If the primary purpose of the follow up is to inform the long-term evaluation of an experimental treatment, the activity should be attributed as a Research Cost. If the primary purpose of the follow-up is to monitor patient safety rather than efficacy, the activity should be attributed as an NHS Support cost.

Activities that are attributed to NHS Support Costs include:

1. The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project.
2. Obtaining informed consent from patients where the study is a health research study, taking place within the NHS.
3. Additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.