

Guidance for full application to the Treatment Subcommittee

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Applications are accepted from recognised UK academic organisations or NHS Trusts via the online system, Grant Tracker.

Specific guidance for Grant Tracker usage and additional guidance for applicants are available on the research website under [‘Applying for a grant’](#)

1 Introduction

At Versus Arthritis, we invest in breakthrough treatments, the best information and vital support for everyone affected by arthritis. We believe that by harnessing the power of exceptional science we can overcome the pain, isolation and fatigue arthritis causes, making everyday life better for all 10 million people with arthritis in the UK. Our remit covers all conditions which affect the joints, bones and muscles, including osteoarthritis, rheumatoid arthritis, back pain and osteoporosis. We fund research into the prevention, cause, treatment and cure of arthritis and we provide information on how to maintain healthy joints and bones, and how to live well with arthritis.

Arthritis (the term representing a range of conditions that affect muscles, bones and joints) affects approximately 10 million people across the UK.

- More than 1 in 6 people of all ages struggle with the pain and disability of arthritis every day
- Arthritis is the biggest cause of pain and disability in the UK
- Musculoskeletal conditions account for one in five GP consultations, rising to a third of all in the over 50s.

2 Application process

2.1 Signatories

Four signatories are required to submit an application. These are:

- Study Statistician
- CTU Representative
- Finance Officer
- Department Head

2.2 Submission

The main applicant, co-applicants and signatories must **all first register** for Grant Tracker access on an individual basis.

- Following registration, co-applicants and signatories are required to be available at certain time points to log on and complete tasks. All parties should be made aware of deadline dates. The co-applicants and signatories must all provide initial confirmation of their role on the study within Grant Tracker following receipt of the email from Grant Tracker notifying of their addition to the grant.
- Co-applicants must all provide electronic approval within Grant Tracker of the content of the application prior to submission.
- Main applicant must 'validate' the application content (this can be done as many times as required throughout completing the application).
- Main applicant must 'submit' the application content.
- Signatories must all in turn provide electronic approval within Grant Tracker of the submission of the application.
- Applications can be saved, closed and validated at any time as a work in progress.

2.3 Attachments in support of the application

Standard supporting documentation (see 'attachments' below, section 5.28, for more details)

3 General principles

3.1 Who can apply?

- Versus Arthritis research grants and research fellowships may only be held in universities, hospitals or recognised academic research institutes in the UK.
- Individuals who are employed by, or whose salary derives from, a commercial organisation are not normally eligible to apply for a Versus Arthritis grant.
- Employees based overseas are acceptable as co-applicants.
- All collaborators associated with an application who are not co-applicants are required to provide a letter of support with the application.
- Recruiting centres do not necessarily have to be co-applicants (can alternatively be collaborators or listed as a recruiting centre only).
- Employees of Versus Arthritis or previously Arthritis Care/Arthritis Research UK are not permitted to be named as co-applicants or collaborators and letters of support from this group will not be accepted.

3.2 Governance and study management in relation to clinical studies

Clinical studies are managed on the following basis and as applicable to the nature of the study and intervention under assessment.

- Versus Arthritis does not take on the role of Sponsor and should not be considered the Sponsor of the project.
- Versus Arthritis takes the role of Funder only; funding is conditional on the identified Sponsoring organisation confirming this role before the start of the project.
- Based on analysis of the trial risks (by either/or Chief Investigator / Clinical Trial Unit / Sponsor / NHS Trust / Data Monitoring Committee / Trial Steering Committee), adequate monitoring must be in place to fulfil the obligations of the Sponsor as per the relevant regulations.
- A Trial Management Group (TMG) must be set up to co-ordinate the daily activity of the project.
- An independent study/Trial Steering Committee (TSC) must be set up as per Versus Arthritis standards. Minutes should be forwarded to the Versus Arthritis head office within two weeks of finalisation.
- A Data Monitoring Committee (DMC) must be set up as per the assessment and requirements of the Sponsor.
- Versus Arthritis are not in a position to fund the project on a per patient payment basis, however it is expected that the study administration function will ensure that payment for patient related activities to investigators, networks, other units etc. will be linked to real-time recruitment.

3.3 Industrial support

Versus Arthritis will allow industrial support if it is directed towards our strategic goals and is based on genuine research collaboration with the industrial partner(s) or is an independent untied donation.

Any individual seeking support for any research activity with an industrial contribution must complete a disclosure form providing details of:

- The nature of the industrial support.
- Industrial links of relevance to the project either by the applicant(s) or their department or group. All such material received by Versus Arthritis will be treated in confidence.

3.4 Progress monitoring

Progress of studies will be monitored on a six monthly basis by submission of a report to Versus Arthritis. The timely submission of these reports will be a condition of any award granted. Additionally, successful applicants are required to register with Researchfish, the research outcomes system for researchers and funding organisations. This must be kept up to date throughout the life of the study.

4 Resources and Costing

4.1 Versus Arthritis funding

In line with other UK medical research charities, we do not provide funds for administrative costs or overheads but fund **Directly Incurred Costs** only. Standardly, the elements of cost headings are:

- Directly Incurred Costs - the direct costs of research such as:
 - Staff (e.g. research assistant salaries).
 - Consumables and other costs directly attributable to the project.
 - Equipment.

4.2 Travel and subsistence.

- Directly Allocated Costs - shared costs, based on estimates and do not represent actual costs on a project-by-project basis such as:
 - Investigators: the time spent by tenured lead applicants and co-applicants.
 - Estates.
 - Other Directly Allocated - the costs of shared resources, such as staff and equipment.
- Indirect Costs - necessary for underpinning research but cannot be allocated to individual projects, and cover computing and information support, central services, general maintenance and other infrastructure costs.

In line with the new process for managing access to excess treatment costs, Versus Arthritis is requiring all clinical study applications that are eligible for adoption to the NIHR Clinical Research Network portfolio to complete the NIHRs Schedule of Events Costs Attribution Tool (SoECAT) and submit this alongside their full application. For more information on the new processes and access to the SoECAT please follow the following link:

<https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm>

The funding request of the full application should fall within +/- 20% of the estimated costs provided in the outline application, unless a change to the funding is specifically requested in the feedback provided.

4.3 Attributing the costs of health and social care Research & Development (AcoRD)

Costs for clinical studies eligible for Clinical Research Network adoption should be formulated in line with governmental guidance.

- Attributing the costs of health and social care Research & Development (AcoRD) – Published May 2012
- Responsibilities for meeting Patient Care Costs associated with R&D in the NHS - HSG(97)32.
- NHS England Guidance on Excess Treatment Costs and allied guidance from Health and Care Research Wales, Scotland's Chief Scientist Office or Northern Ireland Health and Social Care.

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 (AcoRD Annex A, Part A) that all funders should pay, the Department of Health has identified a subset of research costs (AcoRD Annex A, Part B) that are linked to research infrastructures, which the NIHR Clinical Research Network (NIHR CRN) or local Trusts will pay,

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 CRN or other organisations funded by the NHS to provide patient care services.

The research costs that Versus Arthritis, as an AMRC registered charity, will **not** be required to pay (detailed in AcoRD Annex 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.

Versus Arthritis will only fund **Directly Incurred Research Costs** and applicants should ensure that they have consulted their local NIHR CRN to discuss NHS Support Costs and NHS Trust Management to discuss Treatment Costs before submission.

4.4 Salaries

- Chief Investigator and Co-Investigator time is classed as Directly Allocated Costs and are not routinely funded.
- Investigators employed on a full time HEFCE basis for research cannot apply for their salaries.
- The potential for co-applicants to be employed on an 'awarded grants' basis (DI) rather than a permanent institutional contract (DA) basis is acknowledged, such co-applicants' salaries may be accommodated with appropriate justification.
- Main applicants on a grant proposal wishing to apply for his/her own salary must submit the application jointly with a tenured senior member (preferably the head) of the department in which he/she proposes to work.
- Clinical investigators employed on full time NHS contracts named as applicant or co-applicant can apply for payment of Programmed Activity (PA) sessions to allow for release of investigators to conduct their study duties by backfill payment (by locum or otherwise) to cover the released NHS clinical activity, the grant will accommodate application for such nominated salaries.
- Clinical investigators employed with both academic research (HEFCE) and clinical (NHS) commitments named as applicant or co-applicants cannot (other than in exceptional

circumstances) apply for payment of PA sessions to allow for release of investigators to conduct their study duties. Such activity is deemed to be conducted from within the nominated research time, the given study being considered a chosen research activity. Specifically, for co-funding there is no scope to apply for a Directly Incurred element of salary from Versus Arthritis and Directly Allocated element of salary from another funder.

- It is understood to be best practice for payment of locums to be facilitated as a Directly Incurred cost on a grant and thus is best handled such that backfill funding should be applied for on the basis of a salaried position 'to be confirmed', which can be notified to us in name when a locum is actually in post, this can be accommodated if it is facilitative to a given institution.
- Requested salary costs should be based on a recognised pay model or the host institution's local salary scale, including London weighting if appropriate. We must be advised of the pay model used and, where a local pay model is to be applied, a copy of the appropriate scale must be sent with the application.
- Annual increments must be included which should be based on the host institution's own salary scale, including London weighting if appropriate.
- London Weighting allowance will be payable at the rate appropriate to each host institution.
- Inflationary salary increases for funding in future years must be included in the costs requested. A compound allowance should be factored into the costing for this purpose. **The percentage used to calculate the compound inflationary allowance must be the same as the most recent pay award agreed by the institution and no more than 2%.**
- A "session" in respect of protected research time is such that 1 session = half a day.

4.5 Expenses

Please cross reference with section 5.23.

Costs must show sufficient detail (including numbers and the basis of estimation) to enable peer reviewers to make an informed decision.

4.6 Equipment

Applications for items of equipment greater than £5,000 must be supported by a written estimate. The following costs **will not** be accommodated within the application:

- Computers - there must be strong justification showing that computers will be used specifically for the project outlined in the application and would not normally be provided by the Institution.
- Mobile Phones.

4.7 Treatment costs

A breakdown of the treatment costs should be outlined on the SoECAT costing spreadsheet with the costs of the standard/usual care also provided. The treatments in the control and experimental arms of the study should be fully costed. If these costs are different from the normal/usual standard treatment for the condition, the difference between the costs should be highlighted as Excess Treatment Costs. If there are no Excess Treatment Cost implications linked to this study, then please explain the reasons behind this.

4.8 Research support costs

The identified NHS Support activities and costs should be outlined; investigators, coordinators and trial units should engage the relevant CRN at an early stage to secure commitment to these activities.

5 Guidance for completion of the Treatment application form

This section presents the screens to be completed in the online form for easy reference and preparation of content. In some instances, only the on-screen guidance is provided, in other instances additional details are included. Please reference the website pages highlighted at the start of the guidance.

5.1 Project Summary

5.1.1 Scientific title of research

The full title should be consistent with that on any documents submitted to Versus Arthritis.

5.1.2 Scientific synopsis

In no more than 300 words, summarise the research plan, including a summary of the question to be addressed, methodology, outcome measures and key goals.

5.1.3 Proposed start date

Sufficient time should be allowed to gain NHS or HSC management commission approval via the HRA (or equivalent for devolved nations), and all other necessary regulatory requirements such as Favorable Ethical Opinion and MHRA approval. This should not be underestimated and can take up to 12 months from the funding decision.

5.1.4 Proposed duration

The overall duration should include the startup time described above and a realistic estimate of how long the study will take, taking into account realistic and feasible recruitment estimates. It should also include sufficient time at the end of the study for full analysis of the data.

5.2 Key Characteristics

Please indicate estimates of the parameters of the study as requested. It is important at this stage to be realistic about estimates and the length of time it takes to reach the milestones so that these do not need to be changed at a later date.

5.3 Ancillary Parties

5.3.1 IMP Sponsor

Full details of IMP sponsor (if applicable) is to be provided.

5.3.2 Research Governance Sponsor

The Sponsor is the organisation that takes on responsibility for confirming that there are appropriate arrangements in place to initiate, manage and monitor, and finance a study.

For any research that takes place in the context of the NHS or Social Care services, it is necessary that a Sponsor is identified. The Sponsor is normally expected to be the lead employer of the research team, the lead health or social care organisation, or the main funder. Versus Arthritis does not take on the role of Sponsor. Full details of the Sponsor should be entered and a letter outlining intention to sponsor the study is required with submission of the application.

5.3.3 Clinical Research Network (CRN)

The NIHR CRN and devolved nation equivalent are funded to:

- Establish and fund an excellent clinical research infrastructure to support a high-quality portfolio of clinical research studies and facilitate patient participation in studies.
- Provide NHS Support Costs which were previously provided through other NHS R&D funding streams.
- Provide and deploy resources for research management in order to ensure that the research portfolio is delivered to the highest standards of research governance.

Applicants should ensure that they have identified the NHS Support costs in their application, in discussion with their local NIHR CRN (or equivalent in devolved nations). Versus Arthritis will not pay NHS Support Costs.

5.3.4 CTU Details

Acknowledging the complexity of running a clinical study and the input required from a multidisciplinary team with relevant expertise, it is expected that every study developed and delivered by a UKCRC-registered CTU or affiliated personnel <http://www.ukcrc-ctu.org.uk/>, or be engaged in a mentorship arrangement. This applies to non CTIMP as well as CTIMP studies. If it is considered that the study does not require the support of a CTU, because there is adequate equivalent expertise within the team in lieu of CTU engagement, applicants should contact the office to discuss and confirm that there are appropriate proposed arrangements.

CTUs should be contacted at least four months prior to submission and shown to have had an active collaborative involvement in the study design.

5.4 Lay Case for Support

The main purpose of the Lay Case for Support is to allow assessment of the application by representatives of Versus Arthritis stakeholders, patients and healthcare providers. Lay cases for all funded studies will be posted on the Versus Arthritis website and may form the basis of a press release or be used for fundraising and marketing activities.

The lay case should be written at the level of a science feature in a broadsheet newspaper. It must specifically answer the questions set out, structured within each sub-heading. Minimal use of jargon or acronyms is important; where this is unavoidable, please provide explanations. Terms such as 'pathway', 'expression', and 'signalling' should be avoided or fully explained. There is no need to explain at length the generic importance or impact of the disease area you plan to investigate, or to summarise complex methodology. The use of non-scientific analogies to explain complex ideas is encouraged. Images and diagrams are also acceptable as an aid, not an alternative, to narrative explanation.

On screen instructions for each section of the Lay Case for Support should be followed.

5.5 Project Details

5.5.1 Describe the problem to be addressed

Describe carefully the extent of the problem in the current clinical environment. Include in this:

- Evidence from the medical literature, including discussion of the need for the trial in light of any systematic reviews or other studies that have been completed.
- Why this study is needed.
- Information about any other trials that are currently underway (both nationally and internationally) which are relevant to the proposed study.

5.5.2 Describe the principal research question/hypotheses to be addressed

Clinical studies by their nature must be hypothesis led and seek to answer a specific question. In this section please outline clearly the null and the alternative hypotheses and specifically the question being addressed.

5.5.3 Details of pilot or feasibility studies

Please indicate whether pilot or feasibility studies have been carried out in this area to explore specific study parameters, outcome measures, patient recruitment feasibility etc. Do not describe previous studies which have added to the body of clinical evidence in this section. These should be included when justifying the study as below.

5.5.4 Justification

Justify the need for the study in terms of previous studies coming to this point, systematic reviews showing lack of evidence/next steps recommendations.

5.5.5 How results will be used

Give details of how the results of the study will be used to improve patient care or change patient management. If the application is for a pilot or feasibility study, then please describe here how this will inform the definitive study.

5.5.6 Other research

Describe how the proposed study will differ from or complement any relevant planned, on-going or recently completed trials elsewhere in the UK or internationally

5.6 Additional Project Details

5.6.1 Facilities available to support the proposed project

Clearly state where the research and any procedures within it will be carried out and at which participating sites, if multi-centre. A list of brief details of the centres involved in the study must be provided together with a letter or fax stating the centres' willingness to participate in the project. Centres planning to be involved in the study must liaise with relevant parties at their institution to determine whether they would support any identified Excess Treatment Costs of the study. This issue is important to ensure that accrual into the trial is feasible. Evidence of Trust willingness to support such costs of the study must be provided.

5.6.2 Previously submitted

If, yes, please complete the box to state where else the application has been submitted and when you expect to hear the outcome.

5.6.3 Intellectual Property

Please consider carefully whether the nature of the product/treatment/approach to be tested in the research will have new intellectual property associated with it. If this is the case, intellectual property rights (IPR) should be considered at an early stage.

5.6.4 Industrial support

If the research is in collaboration with another industrial partner or is being supplemented by industrial support this must be declared in this section and detailed in the 'Industrial Details' subpage that appears below 'Additional Project Details' in the left-hand menu.

5.7 Lead Applicant

Details of the lead applicant will be pre-populated. To amend these, the application must be saved and closed and the “Manage my details” section opened.

5.8 Lead Applicant CV

Details stored in Grant Tracker will be displayed in this area. To amend them the application must be saved and closed and the “Manage my details” section opened.

5.9 Co-applicants

Individuals who will have had intellectual input into the application and who are expected to be involved in the project. If you wish to add a co-applicant that is based outside the UK, please contact the Versus Arthritis Research Department. You can attach signed letters of support in this section.

5.10 Collaborations

An individual named in the body of the application who will supply research materials, specific expertise or access to patients, but will not be involved in the day-to-day execution of the project. Please list all collaborators associated with the application who are not named as co-applicants. You can attach signed letters of support in this section.

All collaborators associated with an application who are not co-applicants are required to provide a letter of support with the application.

Recruiting sites should not be listed as collaborators.

5.11 Administrators

This page will display all of the Pre-award Administrators added for this grant.

Pre-award Administrators can access and edit the application form with the exception of the ‘Signatories’ page which must be completed by the lead applicant. However, their details will not appear explicitly on the completed form.

5.12 Signatories

Please add the details of the signatories required to sign-off the application. Once the application has been ‘submitted’ signatories will be asked to approve the application online, each in turn, one after the other. Full submission into the Versus Arthritis Grant Tracker system will not be complete until all signatures are in place so please ensure all signatory roles are allocated and that enough time is allowed for this final process.

If you do not have a CTU involved, the CI should add themselves to this signatory role.

Please note: We do not require paper copies containing signatures to be posted.

5.13 Study Design Part 1

5.13.1 Full details of the proposed study design

Please be explicit about the intended design of the study justifying timing of randomisation or why a randomisation is not being carried out in the study.

5.13.2 Full details of the study interventions

Describe all protocol treatments and schedules for each therapeutic arm. Clearly identify the standard (control) therapeutic arm for randomised trials.

5.13.3 Methods for protecting against bias

Discuss what methods will be used to protect against bias in the study, for example blinding and justify these methods. If the study is not to be blinded, please explain the exact rationale behind this.

5.13.4 Contribution of patients and their carers

Outline what steps have been taken to ensure involvement of patients and carers in the study design and what role they took. If there has been no patient or carer involvement, please explain why this decision was made.

5.14 Study Design Part 2

5.14.1 Potential risks and hazards to participants

Explain any potential risks and hazard to participants and describe how these have been minimised.

5.14.2 Early stopping

Describe (1) stopping rules for efficacy (2) stopping rules for futility (3) stopping rules for safety, as appropriate.

5.14.3 Methods of allocating participants to study groups

Outline what methods will be used to allocate participants to respective study arms.

5.14.4 Planned inclusion and exclusion criteria

List the inclusion and exclusion criteria for the study justifying in each instance why this is.

5.15 Study Design Part 3

5.15.1 Proposed duration of treatment

Give the total length of time each participant will be treated.

5.15.2 Proposed frequency and duration of follow up

Provide details of the anticipated long-term follow up need of the proposed trial. Please provide details of the number of years and frequency of the follow up and justify why. List the data elements/tests that are needed for the long-term follow up and justify why these have been chosen and how they will be measured.

5.15.3 Planned recruitment rate

Describe how recruitment will be organised and over what time period. Include evidence that the planned recruitment rate is achievable and from where the potential pool of patients is to be taken. Also provide evidence showing how the disease and non-disease characteristics of the patients will affect the size of this pool in relation to inclusion and exclusion criteria and for the number of patients at each centre who would have fulfilled entry criteria in the previous six months, including how this evidence was collected.

5.15.4 Compliance and loss to follow up

Please provide the anticipated compliance rate and explain on what evidence this is based, taking into account issues such as toxicity, cross-over and co-morbidities. Explain how the number of clinic visits,

duration of visits and demands of each visit will affect recruitment and dropout rates, providing the evidence on which this loss to follow up is based.

5.16 Study Design Part 4

5.16.1 Primary outcome measure

Please give details of outcome measures including justification of the outcome measures used where a legitimate alternative exists. A decision not to use established validated outcome measures must be explained.

5.16.2 Secondary outcome measure

See above for guidance.

5.16.3 Sample size and sample size calculation

Please state the sample size for the study, providing a detailed description of how the sample size has been calculated, including details of which outcome measure this has been based on and give the event rates, means and standard deviations as appropriate.

5.16.4 Statistical analysis

Please summarise the statistical analysis plan for the chosen design highlighting statistical technique to be used, sub-group analysis if appropriate and proposed frequency of analysis.

5.17 Study Design Part 5

5.17.1 Economic evaluation

Does the study include a health economic component? If so, please describe from which perspective the costs and benefits will be considered and how these will be collected.

5.17.2 Economic evaluation methodology

Please provide details about the economic evaluation methodology, for any proposed health economic component of the study.

5.17.3 Quality of Life

Please provide details of how quality of life will be measured in the Economic Evaluation.

5.18 Ethics

Please indicate if a favourable ethical opinion is required for this research.

5.19 Participating Centres

5.19.1 Number and origin of centres

List the number of centres to be involved in the study and indicate whether any of these are outside the UK. If so, please clarify the position of this application in the wider context, indicating if the study is co-ordinated from a lead site in the EU/US or if there is a UK lead site

Our policy regarding provision of support to studies of an international nature is in line with other major funders in that we do not provide funding to non-UK sites, it is up to the individual who has agreed to run the study in that country to secure funding locally. We will support overseas costs to facilitate central co-ordination, setup and some monitoring activities but not for local data collection and pharmacy activity.

5.19.2 Adding centres

To add a centre, select the link “Add Participating Centre”. Enter the details of each centre in the pop-up box.

Note that the centres planning to be involved in the study must liaise with relevant parties to determine whether they would support the Treatment and ETCs of this study. This issue is important to ensure that accrual into this trial is feasible. Specifically:

The application will not be valid if a letter of support from each centre is not included at submission

The lead at each centre must have discussed treatment and ETCs with their institution to answer the treatment costs question. This should be confirmed in the letter of support.

5.20 Study Management

5.20.1 Add a team member

Provide brief details of the responsibilities of the team including those who have developed the study and will be responsible for running and contributing to it. Include co-investigators, named research staff and other collaborators.

5.20.2 Outline the arrangements for the day to day management of the study

Provide details of who will carry out specific duties such as randomisation, data handling and co-ordination.

5.20.3 Trial steering committee

Applicants should propose a TSC, including potential membership. The membership should include an independent chair, other independent members and principal investigators or applicants (see appendix 1). We would only like you to list suggestions of members, please do not invite these people, Versus Arthritis will confirm to the chief investigator that they may proceed to invite the proposed members if the study is awarded.

5.20.4 Data monitoring committee

Applicants should propose a DMC, including potential membership. We would only like you to list suggestions of members, the study sponsor should confirm DMC membership if the study is awarded.

5.21 Time Allocation

As indicated input how many hours each applicant spends on research per week and how many hours will be spent on the study being applied for.

5.22 Research Network Support

Indicate that the lead CRN or equivalent has been notified of the study and detail what NHS Support Costs they have either undertaken to provide or been made aware are required, if the Research Costs are funded.

In line with the new process for managing access to excess treatment costs, Versus Arthritis is requiring all clinical study applications that are eligible for adoption to the NIHR Clinical Research Network portfolio to complete the NIHRs Schedule of Events Costs Attribution Tool (SoECAT) and submit this alongside their full application. For more information on the new processes and access to the SoECAT please follow the following link:

<https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm>

5.23 Treatment Costs

Please provide a breakdown of the Treatment Costs and Excess Treatment Costs for this study.

In line with the new process for managing access to excess treatment costs, Versus Arthritis is requiring all clinical study applications that are eligible for adoption to the NIHR Clinical Research Network portfolio to complete the NIHRs Schedule of Events Costs Attribution Tool (SoECAT) and submit this alongside their full application. For more information on the new processes and access to the SoECAT please follow the following link:

<https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm>

5.24 Finance

Please cross reference to section 4.3.

NHS Support Costs, Treatment Costs, Standard Treatment and the study Visit Schedule **must** be detailed in the mandatory SoECAT costing spreadsheet.

Due to a system constraint, costs beyond year five must be rolled up and included for presentation with the year 5 costs on the application form screen. Additional years beyond five years **must** be detailed **individually** in the costing spreadsheet.

On the application form please complete the details related to the cost of the study as directed, ensuring that 'staff type' is selected.

Requested salary costs should be based on a recognised pay model or the host institution's local salary scale, including London weighting if appropriate. We must be advised of the pay model used and, where a local pay model is to be applied, a copy of the appropriate scale must be attached. A maximum of spine point 43 on the National Scale is allowed for postdoctoral research staff and special justification will be required for funding senior postdoctoral research staff between points 37 and 42 (RA2 equivalent).

Eligible costs within an application:

- The percentage of inflation used must be included in the application and be in line with the most recent pay award agreed by the Institution and no more than 2% (as at May 2015 and this will be periodically reviewed)
- London weighting applies to any applicant applying from an institution in London and will be payable at the rate appropriate to each host institution
- A maximum spine point 43 on the national scale is allowed for postdoctoral research staff, special justification is required for funding senior postdoctoral research staff above point 37
- Requests for external consultancy costs should be included in expenses
- The stipend for a PhD studentship can be applied for within schemes where stated in the call document
- Training and supervision of staff costs by non-tenured applicants within the project must be justified

- Fully justified items of equipment of up to £30,000 can be requested, requests for items of equipment included in applications with a cost greater than £5,000 must be supported by an estimate at full application stage
- Access charges for use of specialist equipment may be applied for within expenses
- Any requests for computers must be fully justified and integral to the success of the research

Ineligible costs within an application:

- Costs relating to staff recruitment and relocation costs
- Student tuition fees aren't provided on grants unless it's specifically stated that these can be applied for in the call document
- Good clinical practice (GCP) training
- Funding to provide maintenance of equipment
- Office stationery costs unless required for the project and justified accordingly
- Indemnity insurance
- Travel support and open access are not to be included within standard grant applications, these are additional awards that can be applied for by a Versus Arthritis grant holder

5.25 Scientific References

Please use this page to list the details of all References that you feel will aid your application. Include full title and all authors. Failure to cite a reference in full may impede processing of your application.

5.26 Grant information

All grants currently entered into lead applicant's CV (excluding Arthritis Research UK and Versus Arthritis grants) will automatically be listed in this section. If there are more to be added please edit "Manage my details" as above.

Click the "Add Grant" link to add grants for co-applicants.

5.27 Arthritis Research UK Grants

All Arthritis Research UK and Versus Arthritis grants currently held by the lead applicant will be automatically listed in the PDF of the application form.

Click the "Add Arthritis Research UK Grant" link to add Arthritis Research UK and Versus Arthritis grants for co-applicants.

5.28 Attachments

Please refer to the items listed below to ensure you have attached all required documents (as the link within the application form no longer works).

Failure to upload the required documents will delay processing of the application and may impact on its timely review.

SoECAT Costing Spreadsheet

You must complete all relevant worksheets within the costing spreadsheet.

Institutional pay scales

Where a staff member will receive salary from grant funding, include pay scales for the relevant institution.

Centre/Site(s) Letter(s) of Support

Provide a letter of support from a representative of each centre involved in the study. Include details of the nature of their involvement and number of participants to be recruited, where applicable. **Upload centre letters together as a single PDF document.**

Collaborator(s) Letter(s) of Support

Provide a letter from each collaborator confirming their involvement on the study and the nature of their involvement. **Upload collaborator letters together as a single PDF document.**

Sponsor Letter

Provide a letter of intention to act as sponsor from the host institution. Include a clear statement of intention to sponsor the study and should be directed from a member of Trust management.

Cover Letter

Please provide a cover letter with the submission of the full application that outlines how you have addressed the feedback and comments from the subcommittee notification/feedback letter.

Treatment costs and excess treatment costs letter

Provide a letter of intention to support treatment and excess treatment costs on the study from the lead Trust. This should be directed from a senior Trust manager.

Evidence of LCRN willingness to provide Service Support Costs

Provide a letter of intention to provide Service Support costs on the study from the LCRN. This should be directed from a senior LCRN manager.

Written Estimates (ALL items of equipment over £5,000)

Provide estimates for all items of equipment costing £5,000 or more.

Document naming conventions that should be used for attached documents are provided below. All documents, with the exception of the Costing Spreadsheet, **must be uploaded in PDF format.**

Document	Naming Convention
SoECAT Costing Spreadsheet	SoECAT Costing Spreadsheet <i>mm.yyyy</i>
Institutional pay scales	Pay Scales <i>Institution mm.yyyy</i>
Centre/Site(s) Letter(s) of Support	Recruiting Centre(s) Letter(s) of Support
Collaborator(s) Letter(s) of Support	Collaborator(s) Letter(s) of Support
Sponsor Letter	Sponsor Letter_ <i>Institution_dd.mm.yyyy</i>
Treatment costs and excess treatment costs letter	Treatment Cost Letter_ <i>Trust_dd.mm.yyyy</i>
Evidence of LCRN willingness to provide Service Support Costs	Service Support Letter_ <i>LCRN_dd.mm.yyyy</i>

Written Estimates (ALL items of equipment over £5,000)	Equipment Quote_ <i>Supplier_dd.mm.yyyy</i>
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The following sections are used to gather research classification information on your application. This will be used by Versus Arthritis to categorise the applications it receives and the work that it funds.

5.29 Disease category

5.30 Research focus

5.31 Research category

5.32 Methods used

5.33 Validation Summary

This section provides guidance on the required actions to submit the application, including a list of outstanding required actions from the incomplete sections of the application form.

Appendix 1. Clinical studies steering committee guidance

Contents

1. Terms of Reference
2. Progress Review Committee approval of membership
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11. Consideration of New Information
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It is Versus Arthritis policy that a study steering committee should be set up for each of its clinical studies with the following terms of reference:

1 Terms of Reference

1. To monitor and supervise the progress of the study towards its interim and overall objectives
2. To review at regular intervals (annual/bi-annual/quarterly) relevant information from other sources (e.g. other related studies)
3. To consider the recommendations of the Data Monitoring Committee (DMC) where one exists as defined by the Sponsor organisation based on an assessment of risk
4. In the light of 1, 2 & 3 to be sure Versus Arthritis are well informed, via Chief Investigator (CI) reporting, on the progress of the study
5. To advise Versus Arthritis on publicity and presentation of all aspects of the study

2. Progress Review Committee approval of membership

The Progress Review Committee (PRC) must approve the Chair of the Steering Committee and two independent members; no approval of the remaining Steering Committee composition is required.

Proposals for Steering Committee Chair and members may be made within the relevant section of the

application form. For successful applications, where the grant holder has been unsuccessful in identifying a chair, the PRC will propose a chair whom the CI should invite.

3. Steering Committee Membership

The membership should be limited and include:

- an **independent** Chairperson (not involved directly with the study other than as a member of the Steering Committee)
- two or more other independent expert members (clinical and/or methodological)
- the Chief Investigator
- where possible a lay/consumer representative

A Versus Arthritis observer should be included as advised by the PRC and/or Treatment subcommittee.

The study manager, study statistician etc. should attend meetings as appropriate. Observers from the Sponsor and/or Host Institution should be invited to all meetings.

4. Steering Committee Meetings

Before the study starts, the CI (or Study Co-ordinator or Manager) should organise a meeting of the Steering Committee to finalise the protocol, which should then be sent to Versus Arthritis. The Steering Committee should then meet at least annually but possibly bi-annually or quarterly, although there may be periods when more frequent meetings are necessary. Meetings should be organised by the CI. Papers for the meeting should be circulated in advance. An accurate minute should be prepared by the CI and agreed by all the members and a copy sent to Versus Arthritis.

5. Study Management

The role of the Steering Committee is to provide overall supervision of the study on behalf of Versus Arthritis and the Sponsor. In particular, the Steering Committee should concentrate on the progress of the study, adherence to the protocol, patient safety and consideration of new information. It is the role of the Steering Committee to monitor the progress of the study and to maximise the chances of completing the study within the agreed time scale and allocated budget.

Day to day management of the study is the responsibility of the CI. The CI may wish to set up a separate Study Management Group to assist with this function.

6. Data Monitoring Committee

The Sponsor should complete a risk assessment to determine the need for a DMC; if required this should be constituted. The Steering Committee should establish the reporting logistics between itself and the DMC which should meet regularly to review the data and results of any interim analyses. Members of the DMC should be independent of both the Study Management and Steering Committee.

It is the responsibility of the CI to notify the Steering Committee, DMC, Sponsor and relevant regulatory authority (if applicable) immediately of any unexpected serious adverse events occurring during the course of the study.

7. Patient Safety

In all of the deliberations of the Steering Committee the rights, safety and wellbeing of

the study participants are the most important considerations. The Steering Committee should advise the investigators on the completeness and suitability of the patient information provided as part of the process of obtaining freely given informed consent from each subject.

8. Good Clinical Practice

The Steering Committee should endeavour to ensure that the study is conducted at all times to the standards set out in Guidelines for Good Clinical Practice (GCP) e.g. MRC GCP, ICH GCP.

9. Adherence to Protocol

The full protocol should be presented and agreed at the first Steering Committee meeting. Any subsequent substantial amendments to the protocol must be approved by the Steering Committee and ethics, be notified to Versus Arthritis and the revised protocol submitted for reference.

10. Progress of the Study

At the first Steering Committee meeting, targets for recruitment, data collection, compliance etc. should be agreed with the CI. Based on these targets, the Steering Committee should agree a set of data that should be presented at each meeting.

The CI is required to submit status reports, to a defined template, to Versus Arthritis at defined timelines issued with the Letter of Award. The status report does not have to be endorsed by the Steering Committee but should be submitted with their awareness. The report should stand alone and contain sufficient information to enable Versus Arthritis to assess the progress of the study without the need to refer back to the original grant application. The Progress Report should not be a tool for reporting recruitment status only, it is imperative that progress in attaining relevant regulatory approvals is stated in the initial reports. The Progress Report should inform Versus Arthritis of any new information that has a bearing on safety or ethical acceptability of the study or any significant complaints arising, with a justification of the decisions taken.

11. Consideration of New Information

The Steering Committee should consider new information relevant to the study including reports from the DMC. It is the responsibility of the CI, the Chair and other independent members to bring results from other studies that may have a direct bearing on future conduct of the study to the attention of the Steering Committee. On consideration of this information the Steering Committee should recommend appropriate action, such as changes to the protocol, additional patient information, or stopping the study. The rights, safety and well-being of the study participants should be the most important consideration.

12. Timeline Extensions

Versus Arthritis will consider proposals for no cost extensions of grants for clinical studies. If progress on the study suggests that additional time may be necessary, under Steering Committee agreement and direction, the CI should submit such requests via the online application system. Extension of funding duration will be made with reference to the PRC which in turn will require evidence of support from the Steering Committee that all practicable steps have been taken e.g. to improve recruitment and keep within the agreed duration of the grant.

The DMC, where in existence, should be asked to advise the Steering Committee, and

may be required to provide information on the availability of data collected to date (from this and other studies) and advise on the likelihood that continuation of the study will allow detection of an important effect. This should be done using methods that do not unblind the study.

13. Supplementary Funding

In exceptional circumstances Versus Arthritis will consider proposals for supplementary funding to clinical studies grants. If progress on the study suggests that additional funding may be necessary, the CI should seek Steering Committee opinion on the suitability to request additional funding from Versus Arthritis. Requests for additional funding must be made via the online application system to the Versus Arthritis funding committee. Extension funding adjudication will be made with reference to a report from the PRC which in turn will require evidence from the Steering Committee that all practicable steps have been taken e.g. to improve recruitment and keep within the agreed duration of the grant.

The DMC, where in existence, should be asked to advise the Steering Committee, and may be required to provide information on the availability of data collected to date (from this and other studies) and advise on the likelihood that continuation of the study will allow detection of an important effect. This should be done using methods that do not unblind the study.

14. Failing Studies

Notably in the case of failing studies, particularly those requiring requests for additional funding, Steering Committee, DMC and PRC opinion will inform the decision making regarding appropriate remedial action or otherwise.