Clinical Research Fellowship Application Guidance

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I. 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.

We're committed to building a world-class workforce to continue the fight against arthritis through supporting research careers and ensuring there's sufficient capacity within the UK to translate ideas into benefit for people with arthritis. We aim to encourage the brightest and most committed researchers, from all relevant disciplines based in the UK and beyond, to become involved in research into musculoskeletal diseases.

Clinical research fellowships are our entry level scheme for talented medical and non-medical healthcare professionals. They provide clinically qualified professionals the opportunity to develop an academic research career in rheumatology or any related field concerned with the treatment of musculoskeletal conditions (including surgery and general practice). They aim to provide training in clinical and/or laboratory research techniques leading to a higher degree (usually a PhD) in a project that demonstrates clear relevance to the aims of Versus Arthritis in a university, hospital or other recognised research institution in the UK.

II. Eligibility

Versus Arthritis research awards may only be held in universities, hospitals or recognised academic research institutes in the UK.

Medical graduates are expected to apply usually during specialty training (including surgeons/surgical trainees), whilst non-medical healthcare professionals need to have at least 1 years' experience of clinical practice. Non-medical healthcare professions that are eligible to apply include: dentists, physiotherapists, nurses, occupational therapists, podiatrists, prosthetists, orthotists, psychologists, veterinary surgeons, radiographers and pharmacists. Salaries should be requested according to experience on the appropriate clinical salary scale, including London weighting if relevant. Consultant level salaries and NHS salaries above Band 7 will not be funded.

Projects must demonstrate a clear relevance to the aims of Versus Arthritis Before completing your application please ensure the proposal aligns with our current research priorities, by consulting the following:

- Our approach to research funding
- Scope of research

Multiple applications

We will not accept overlapping applications of the same research proposal to more than one Versus Arthritis funding scheme. We will accept an application that has been submitted to another funding body, however, please check the eligibility criteria of the other funding body before making an application.

III. Information on clinical trials within fellowships

- Versus Arthritis do not support the funding of a major or substantial clinical trial as a
 fellowship, trials should be funded through the appropriate Versus Arthritis grant scheme
 which has a reviewing subcommittee with the right expertise to assess clinical trial application
 content. It is not considered that running a trial from within a fellowship in a trial manager role
 represents good training.
- Trials are supported within fellowships in a junior principal investigator role only to support learning of methodology and recruitment and assist protocol development; there should be sufficient fellowship content that is non-trial.
- It is considered suitable for a fellowship to contain methodological development work or supplementary analysis as bolt on activity to an established or proposed trial.
- It is considered suitable to conduct a feasibility/pilot clinical study within a fellowship where studies are expected to be recruiting in small numbers.
- Versus Arthritis are supportive of fellowship applications as an add on to a clinical trial that has been supported by Versus Arthritis, or elsewhere, where the fellowship component is contributing to scientific training.

Standardly we do not support fellowships within clinical study grants. If data collection or review can only be done by clinically qualified personnel and such activities are core to the study proposal, then support for such activity as a fellowship post may be considered within a trial.

IV. Note on the language

The lay abstract should be written in appropriate non-technical language. For more information on how to write a clear and informative lay summary please use the following resources:

- INVOLVE plain English summaries
- The Plain English Campaign

If you have further enquiries on the use of appropriate language, please email the Patient Involvement Team at patientinsight@arthritisresearchuk.org.

V. How to apply

All applications for Versus Arthritis funding must be received through our online grant management system, Grant Tracker. The deadline for submission of applications is 16:00 on the stated deadline in the call document/webpage. No application will be accepted after this deadline. We strongly recommend that applicants allow sufficient time for submission before the deadline in order to obtain the necessary approvals from your research or finance office and head of department.

Specific information for the 2019 Clinical Research Fellowship round

In October 2018 we will be migrating our grant administration system over to the most up to date version of Grant Tracker. This is the final stage of work that has been ongoing throughout the year and which is an essential development to maintain and improve the efficiency of application and award management by the charity.

What this means for our award holders and applicants is that the system will not be available for a two-week period beginning **Monday 22 October 2018**. The system will be back on line on or before **Monday 5 November 2018**.

This has an impact on the 2019 Clinical Research Fellowship round as it means applications cannot be opened in the current version of Grant Tracker when the call launches in October 2018. At the opening of the call applicants will be asked to begin preparing their applications offline. We have developed tools and guidance to help you with this. Once Grant Tracker is available in early November, applicants will be contacted to then complete the online application form, using the information they have prepared offline. All applications should be completed in Grant Tracker by the deadline of 16:00, 16 January 2019. We regret that this is unavoidable for this year's round whilst the upgrade takes place, and we would like to reassure you that help and support will be available to all applicants through this process.

We thank you for your patience during this important system development.

Tools and guidance

We have prepared the following guidance and tools:

- This guidance document which contains information on how to complete the online application form.
- A copy of the application form in Word format, which will be editable. This can be used to prepare applications offline.

The Word application form must be requested from us directly, it is not publicly available. This is necessary so that we can understand who is working on applications in this round. It is very important we are aware of who is planning an application in order to provide them with the appropriate support to submit their grant during this software changeover period. If you would like a copy of the Word application form, please email Julie Marsden at i.marsden@versusarthritis.org. If you request this document there is no requirement to ultimately submit an application.

VI. Guidance for completion of the application form

The sections to be completed in the full application form are presented below. Please ensure you reference each section before completing the application form.

Project Summary

Scientific title of research: this should be descriptive. If relevant, please use PICO (Population, Intervention, Comparison, Outcome) principals and include a project acronym.

Scientific abstract of research including key goals (max 300 words): this should include the purpose, study design, the specific area of research interest for which this application is entered, and the potential application of results.

Host institution address where the project will be carried out

Proposed start date

Proposed duration (number of months)

Key Words that describe the application (max 6)

Project details

Please provide details on the proposed project under the following headings. **Please note the word limits for each of these sections.**

Background (max 850 words): Briefly and clearly explain the context of your research. This should include the disease/area and its clinical and/or patient impact, the particular area(s) that your research seeks to address, and the need for further understanding. Also include past and current research, including that funded by Versus Arthritis and include the applicant's own contribution to this.

Aims and Purpose (max 150 words): State the primary hypothesis and outline the aims and objectives of the research.

Detailed plan of investigation and scientific procedures (max 1400 words): Outline the proposed programme of work to include clear work packages, milestones and methodology. Please include a Gantt chart using the attachments section of the application form. Please include the following subheadings where applicable:

- Research design: Provide a detailed account of the research methodology. This should include a statistical plan, measures to reduce bias, justification for the proposed sampling strategies, sample size calculation, methods of data collection, analysis and outcome measures. The plan should be separated into work packages where appropriate
- Data management: Please describe the approach for data management to include making the data discoverable and the process for data sharing.

Candidates statement as to how the training fits in with his/her future career plans (max 350 words): Please detail why you would like to apply for a fellowship and how fellowship funding will help to further your research career.

Sponsors Statement as to the nature of the scientific training to be provided (max 300 words): We expect a strong commitment from the sponsors to provide the necessary training and support required to complete the aims of the project proposed within the fellowship and to the future career of the applicant.

Please provide a sponsor's statement including how you intend to address the following needs of the fellow (max 400 words):

- Induction, orientation and administrative support
- **Supervision** (giving an indication of the frequency of meetings, setting of timelines, and provision of verbal and written feedback)
- Training opportunities (eg, including both generic research and transferable skills)
- **Environment** (eg, group meetings, journal clubs, opportunities for ideas exchange)

Justification for support requested and relevance to the aims Versus Arthritis (max 300 words): Explain the relevance of your proposal to Versus Arthritis's purpose and strategic focus. Use this section to explain how this research will have an impact on and contribute to achieving the charity's mission and strategic focus. Please provide justification for the costs requested for the fellowship here.

Basic formatting can be applied to each section, but you cannot incorporate images or embed documents. Any additional documents or images can be attached in the Attachments section of the online application form. Please ensure any figure legends are included within the text.

Additional project details

Please outline the resources and facilities available to support the student (max 200 words): These should include access to libraries, online journals, generic and research specific software, appropriate work space and laboratory facilities (if relevant), and/or clinical facilities (if relevant).

Previously submitted: Please indicate if this or a related application has been submitted elsewhere, including Versus Arthritis. If a similar application has been submitted please provide details of the funder and name of scheme, as well as the outcome or expected date of outcome.

Intellectual Property (IP): If appropriate, please provide the following information:

- Whether the proposal is likely to produce new IP (max 500 words)
- How the new IP will be managed (max 500 words)
- Whether there is existing IP associated with the proposal (max 500 words)

IP means patents, copyright, trademarks, trade names, service marks, domain names copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them. Where appropriate explain how you will engage with your Technology Transfer/Enterprise Office. For further enquiries on any aspect of IP, please email the Research & Programmes Directorate at research@versusarthritis.org.

Industrial Support: Indicate if the application involves any external commercial organisation (including collaborations and donations). If indicated that industrial support is associated with the project, an additional page will appear in the side menu of the application form for completion. Use the additional page to provide further details of the commercial partner including contact details, details of the support/collaboration and any conflicts of interest. Please refer to our <u>industrial support policy</u>.

Scientific Summary

All fellowship applicants are required to provide a scientific summary as part of their full application to be used for the initial triage assessment. The format of the scientific summary is at the discretion of the candidate and it is not essential to use the items in the list below as headers, as long as the required information is provided. You may supplement the scientific summary with one scientific summary supporting diagram (JPEG, GIF or Word documents (.doc.)).

- 1. Introduction to include the background to the project, the candidate's preliminary work in the area and the objectives of the current proposal
- 2. Methods to include details of the techniques to be used, the candidate's personal experience with these techniques and/or the institutional support available in these techniques
- 3. Predicted outcome/wider impact of research
- 4. Relevance to Versus Arthritis
- 5. Training/facilities

The scientific summary has a maximum word count of **600 words** with an additional **300 words** permitted for candidates to include selected publications (including published abstracts) which are relevant to the application.

Publications

Please enter a complete list of the fellowship applicants research publications to-date (full citations including title and all authors). These should be separated into

- Original peer reviewed papers
- Reviews
- Books or book chapters

Editorials, letters or case reports

Clinical information

Applicants will be asked to provide details on their clinical commitments during the fellowship.

Lay Case for Support

Please complete this section in a lay language. Each question has a word limit of 100 words. Further guidance on writing for a lay audience is provided above.

Lay Title: The title should be descriptive and in a lay language.

Lay Abstract: Provide one or two sentences which summarise your research proposal. This should be succinct and contain top level information only

Background: Briefly and clearly explain the context of your research, the particular area(s) that your proposal seeks to address and the need for further understanding or treatment options. Please avoid going into great detail of the condition in question unless it is rare.

Questions: What questions do you hope to answer and what will this tell you?

Experimental plan: Give a brief overview of how you intend to answer your research question(s), including details of what experimental models you will use (e.g. human cells, animal models, clinical samples, patient and/or education research studies).

Importance: Explain why this particular study is important and how this research is different to what has been done before by your research group and others? For example, why have you chosen to investigate this molecule, gene, therapy or aspect of disease, education or health promotion over others

Relevance: Explain the relevance of your proposal to Versus Arthritis's purpose and strategic focus. Use this section to explain how this research will have an impact on and contribute to achieving the charity's mission and strategic focus

Novelty: How is this research different to what has been done before by your research group and others?

Impact (potential for benefit): How will the outcomes of your research lead to clinical, patient and/or societal benefits, and what are the likely timescales to benefit? We recognise that, depending on the nature of the research, the applications that we receive can have immediate patient benefit and others increase the knowledge basis for future interventions. In applications where the outcomes directly impact on the quality of life of people with arthritis, this should be clearly detailed in this section. Where benefit is less obvious, for example in basic laboratory research, explain:

- why this study is necessary to inform a gap in knowledge that will be useful for subsequent translational research?
- how future research can be built on the findings toward benefit?
- what are the potential next steps that would be required to get your research findings to clinical intervention?
- when the benefit might be achieved, with realistic justification of these timelines?

Lead Applicant details and Lead Applicant CV

For fellowship applications, the lead applicant is the researcher who is applying for the fellowship. They are the individual who will lead the work and must be based in a UK university, hospital or recognised academic research institute in the UK.

The Lead Applicant details in these sections of the application form will be populated automatically based on the information that is stored in GrantTracker. To amend these details, please save and close the application form and visit the 'Manage My Details' section on the GrantTracker Versus Arthritis homepage.

Pre-Award administrators

Please add a pre-award administrator to your application in this section if required. Pre-award administrators can access and edit the application form however their details will not appear explicitly on the completed form.

Sponsor(s)

A Host Institution sponsor guarantees facilities and resources for the tenure of an award. The sponsor must have a contract of employment with the institution or, in the case of an NHS employee, an honorary academic appointment, with tenure beyond the duration of the proposed fellowship. Sponsors are encouraged to view their support and mentorship of you as part of the longer-term committee to assist you to realise your future career aspirations in research.

You will be asked to provide the name of sponsors(s) associated with the fellowship, if the sponsor is already on our GrantTracker system, their contact details will appear and an automatic message will be generated to allow you to notify the sponsor and provide a link to the application form for them to provide their details.

Signatories

Enter the details of the signatories required to sign-off the application. The head of department and finance office details should be completed. Before submitting your application to Versus Arthritis, you must obtain the necessary signatories prior to the deadline. A workflow diagram can be found here.

Scientific References

Please detail all references (citing all authors) that are referenced in the application. Please include full title and all authors.

Research Students

Please provide details of research students supervised by any of the Sponsor(s) over the last 5 years – please give the names of all supervisors, source of funding, degree registered for, start date and date of award of degree:

Recent Grants

Please provide details of all current grants held by the fellowship applicant (excluding any from Versus Arthritis). Those on the fellowship applicant's CV will be added automatically, but this page can be used to add any additional grants if necessary. Please ensure that sponsor(s) also provide details of all current grants.

Versus Arthritis Grants

Please provide details of all Versus Arthritis grants held by the fellowship applicant within the past five years. Those on the fellowship applicant's CV will be added automatically in the PDF of your application, but this page can be used to add any additional grants if necessary. Please ensure that sponsor(s) also provide details of all Versus Arthritis grants held within the past five years.

Finance and Costs

The finances requested for the grant should be entered in this section under the following headings:

Staff members (salaries)

For a Clinical Research Fellowship application, the only staff member salary included should be that of the fellow. No other salaries will be accepted in this section. Please provide the following information for your salary:

- Name
- Salary scale and grade
- Increment Date
- Percentage inflation rate used
- Staff type (to select from a list)
- Basic salary for each year of the fellowship,
- Employer contributions for each year of the fellowship
- London weighting (if applicable) for each year of the fellowship

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).

Animals

We require the costs associated with animal use to be separated by species and strain. Please provide the following information (multiple can be added):

- Animal species
- Animal strain
- Whether they are genetically modified
- Source of supply
- Number of animals to be purchased for each year of the fellowship
- Purchase price per animal
- Number of animals to be maintained for each year of the fellowship
- Number of weeks maintenance required for each year of the fellowship
- Weekly maintenance cost

Expenses/Consumables

Items and their cost should be listed.

Apparatus/Equipment

Small item(s) of essential equipment (costing less than £30,000 in total) which are needed for the fellowship can be detailed here. Requests for individual items of equipment costing more than £5,000 must be supported by a quote.

Full economic costing

In line with other UK medical charities, Versus Arthritis does not provide funds for administrative costs or overheads, and funds directly incurred costs only. Ineligible costs include directly allocated costs and indirect costs:

Directly Allocated Costs – shared costs, based on estimates and do not represent actual costs on a project-by-project basis, such as:

- estates
- 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.

Eligible costs within a clinical research fellowship application:

- London weighting applies to any applicant applying from an institution in London and will be payable at the rate appropriate to each host institution
- Any additional salaries/staff time (e.g. statistician/data manager/trial manager) should be costed as a consultancy under expenses and not as a salary. These costs will be considered by the panel
- 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 proposal
- Costs to cover travel and accommodation (if required) to a collaborating institution can be requested
- Training courses for the professional development of the fellow can be applied for. These should be relevant to the aims of the fellowship and justified within the application
- Costs associated with patient and public involvement/engagement can be applied for. Please see our <u>Research Involvement Handbook</u> for guidance on how to cost these activities appropriately
- Reasonable costs associated with carrying out a pilot clinical or feasibility study can be applied for

Ineligible costs within a clinical research fellowship application:

- Relocation costs
- Student tuition fees
- Home office license fees (personal and project)
- Good clinical practice (GCP) training
- Funding to provide maintenance of equipment
- Office stationery costs unless required for the project and justified accordingly
- Indemnity insurance
- Publication costs

• 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

Time allocation

Please provide information on

- How many hours per week the fellowship applicant spends on research
- How many hours per week the fellowship applicant will spend on this project

Ethics

The Department of Health requires that research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently by a Research Ethics Committee (REC) to ensure it meets ethical standards (Favourable Ethical Opinion).

Please tick the box if Favourable Ethical Opinion is required for this research from an NHS Research Ethics Committee

If Favourable Ethical Opinion is not required, please enter justification for not needing it.

If Favourable Ethical Opinion is required, please tick the box if it is already in place for this research and attach the final letter from the REC in the attachments section.

If Favourable Ethical Opinion is required but not yet in place, please provide the approximate date this will be applied for.

Animal ethics

Versus Arthritis is committed to the principles of reduction, refinement and replacement in animal studies. Before completing this section please read our policy on <u>animal research</u>.

Versus Arthritis is a member of the Association of Medical Research Charities and signs up to their position on animal research.

Please tick the box if the project involves the use of experimental animals or other organisms covered by the Animals (Scientific Procedures) Act

You will be required to indicate:

- The maximum severity of the procedures involved
- Whether the proposed research involved a protected species (non-human primates, cats, dogs or equidae)
- Whether the relevant Home Office project and personal licences been obtained

If you do not hold the relevant Home Office licence, please state when you expect to obtain them.

Justification for the use of animals: Please justify the use of animals, the species and techniques proposed and the number of animals to be used per experiment. Please include details of sample size calculations and statistical advice sought for the number of animals required to reach statistical significance.

There should be sufficient information to allow for a robust review of any applications involving animals. Further guidance is available from the <u>National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs</u>), including an online <u>experimental design assistant</u> to guide researcher through the design of animal experiments.

Replacement, reduction and refinement (3Rs) of animal experiments: Indicate whether the proposed research lead to the advancement of the 3Rs and how it will do this. Further information on the 3Rs is available from the NC3Rs.

Referees

Please provide contact details for two nominated referees, who should not be your sponsor(s). They should know you both personally and in a professional capacity and be able to write a letter of reference for you as a candidate, in the same manner as if you were applying for a job. The referee is not asked to write in support of the project (or to review the project) but rather to write in support of you and why you are a suitable candidate for the scheme and should in their opinion be given the opportunity to hold the fellowship. Please ensure you have obtained prior permission from the referee.

Attachments

Only text can be added to the fields of the online application form. Where additional files are required they can be uploaded in this section.

The maximum combined file size cannot be more than 7MB.

Attachments will either be appended to the PDF or they will be referenced from the PDF and included for reviewers as separate files according to the following rules:

- Image files (JPG and GIF format) will be appended within the PDF.
- For Microsoft Word files you have the option to either append them or include them as separate files, by default they will be appended. (Please note: Docx files are not currently supported for embedding and will be included as separate files).
- Excel and other file types (e.g. PDF, PPT) will be included as separate files and listed in an appendix.

The following documents should be uploaded using the naming conventions below. Please upload documents separately in the formats specified against each one.

Items 3 to 5 should be submitted as separate documents not combined.

- 1. Letters of collaboration (e.g Prof Smith_letters of collaboration) (combined PDF)
- 2. Letters of support (combined PDF)
- 3. Ethical approval
- 4. Animal licence(s)
- 5. Salary scales
- 6. Other (to include Gantt chart and Public and Patient Involvement annex)

Disease category, Research focus, Research category and Methods used

In these sections, we ask you to provide some research classification information on your application. You will be asked to select a number of classifications from a standard list in each section.

End – submitting your application

To complete the application process, the final steps are as follows:

1. Select Validate form

This will check that you have completed all of the sections within the application.

2. Click Save then close

After completing these steps, you will be taken to the details page of your application. The submit application button on the right-hand side of the page should be available.

3. Click Submit

Once you have submitted your application an automated email will be sent firstly to your finance officer, once they have approved the application a second email will be sent to your Head of Department. It is only upon your Head of Department's approval that the application is finally submitted to Versus Arthritis. This must be completed by 4pm on the deadline day.

You will receive an automated email containing an acknowledgement that we have received your application. If you are experiencing difficulties submitting your application, please contact us on 0300 7900 403, allowing for sufficient time prior to the deadline.

Finally, please email suggested names of potential reviewers of your application (not connected with you or your proposal) or the names of any reviewers that you do not wish to be approached to mailto:research@versusarthritis.org. Please note, these will be treated confidentially.

Contact

For further enquiries on any aspect of your application, or any issues relating to the submission of your application, please email the Research & Programmes Directorate at research@versusarthritis.org or phone us on 0300 7900 403.