Connect Immune Research/ Chernajovsky Foundation

Targeting shared mechanisms in immune mediated inflammatory diseases

Guidance for funding applications





















Contents

I. Introduction

There are more than 80 autoimmune conditions, affecting over four million people in the UK.

Research into immune-mediated inflammatory conditions is often pursued in a disease-specific manner, according to clinical presentation, and focusing on later stages of disease. Emerging evidence suggests there are similarities across immune diseases in risk factors, immunological and mechanistic features, suggesting there are significant opportunities to drive forward our understanding of the root causes of individual diseases by encouraging research that works across, or learns from, other autoimmune conditions.

Connect Immune Research members, in partnership with the Chernajovsky Foundation, now call for applications to target shared mechanisms of autoimmunity towards developing new treatments for people affected by autoimmune conditions.

Applications should be highly innovative and have a translational focus, defined as "Research that seeks to advance and apply discoveries from basic discovery research and/or clinical findings, through preclinical studies and towards clinical studies and trials".

Applications must show how the outputs from the award could lead to benefit for patients from more than one autoimmune condition. Projects are limited to 12 months and up to £100,000 in value

II. Eligibility criteria

Connect Immune Research and the Chernajovsky Foundation awards may only be held in universities, hospitals or recognised academic research institutes in the UK. Any academic, clinician or allied health care professional at an eligible UK institution can apply. The lead applicant must be based at an eligible UK institution. Individuals who are employed by, or whose salary derives from, a commercial organisation are not eligible to apply but may be included as a co-applicant.

Please note all applications must have a lead applicant or another co-applicant that is tenured.

III. How to apply

All applications for the Connect Immune Research/Chernajovsky Foundation Targeting Shared Mechanisms in Immune Mediated Inflammatory diseases funding must be received through the Versus Arthritis online grant management system Grant Tracker. Versus Arthritis (a Connect Immune Research member) is acting as the single point of application (and application system advice) on behalf of all Connect Immune Research members and the Chernajovsky Foundation. Further details on how to apply can be found on the <u>Versus Arthritis website</u>.

The deadline for submission of applications is 16:00 on the stated deadline in the call document. 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, such as from your research or finance office and head of department.

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

IV. Note on the language

We recognise that specialist language will be required to accurately convey the detail of your proposal and, as such, sections that require technical detail will be labelled accordingly. In addition to scientific review, applications will also be reviewed by people living with multiple autoimmune conditions. They assess the quality of the public involvement, the relevance to the funders and potential for benefit for people with autoimmune conditions. The abstract, application summary and involvement & engagement sections should be written in appropriate non-technical language, these are important parts of the application and require careful consideration.

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@versusarthritis.org.

V. Guidance for completion of the full application form

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

Help icon @

Additional information and guidance is also provided within the form for specific questions, this can be accessed by clicking on

Application summary

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

Organisation: Insert the name of the lead applicant's host organisation

Proposed start date: Sufficient time should be allowed to gain NHS approval, if relevant, and all other necessary regulatory requirements such as Health Research Authority, if applicable.

Proposed duration: The overall duration is up to 12 months and should include time at the end of the study for full analysis and reporting of the data.

Key words: Please enter up to six key words that describe your application.

Previously submitted: Please indicate here if this or a related proposal has currently or previously been submitted elsewhere, including any of the Connect Immune Research members and the Chernajovsky Foundation. If a similar application has been submitted, please provide further details about the application, where it has been submitted and the outcome or date of expected outcome.

Abstract: Provide a brief account of the proposed activity in non-technical language including background to the problem; the aims and purposes of your proposal and why they are important; a brief experimental plan; the relevance to the requirements of the call for applications and potential patient benefit. This information may be used in public summaries of the Connect Immune Research members' and Chernajovsky Foundation's funded research, and therefore must be accessible by a wide audience. This section has a limit of 500 words.

Description of how the proposed research is innovative, translational and relevant to multiple autoimmune conditions: Highlight briefly how the application fits the three key elements of the call remit of being: highly innovative; translational (defined as "Research that seeks to advance and apply

discoveries from basic discovery research and/or clinical findings, through preclinical studies and towards clinical studies and trials"); and relevant to multiple autoimmune conditions. This section has a limit of 300 words.

What impact and potential benefits will the research have on those living with autoimmune conditions? Answer within 300 words.

How is this research relevant to more than one autoimmune condition? Answer within 300 words.

Involvement and engagement

Meaningful involvement and engagement of people with autoimmune conditions could include activities such as:

- identifying and prioritising the project question
- helping design study protocols and patient information
- inputting into the application and/or ethics approval
- helping carry out elements of the study, rather than simply participating as a subject
- evaluating the project findings
- dissemination and implementation of outputs and outcomes.

To find out more on how to plan and carry out meaningful patient involvement please use the links below or contact patientinsight@versusarthritis.org.

http://www.invo.org.uk/find-out-more/how-to-involve-people/

http://www.invo.org.uk/resource-centre/plain-english-summaries/

http://www.invo.org.uk/posttyperesource/where-and-how-to-involve-in-the-research-cycle/

Please note that applications must clearly show how the award could lead to benefit for patients from more than one autoimmune condition.

How have people living with autoimmune conditions inputted into the design of the research? Please explain how people with autoimmune conditions have inputted to and informed this application. This could include: identifying and prioritising the research question, helping to design the study protocol and patient information, inputting into the application and ethics approvals (up to 300 words).

How will people living with autoimmune conditions be involved in the conduct of the research? Please explain how people with autoimmune conditions will input into the conduct of the research. This could include: helping to carry out elements of the research, evaluation of research findings, disseminating and implementing outputs and outcomes (up to 300 words).

Describe how the outcome measures of the research are relevant to people with autoimmune conditions? Please explain how people with autoimmune conditions have been consulted on the relevance of the outcome measures (up to 300 words).

How will results of the research be fed back to those participating and other people living with autoimmune conditions? Outline plans to disseminate the results of the research to participants of the research and the wider population of people with the conditions being researched (up to 300 words).

Project Details

Background: Provide a technical summary of background information and research in support of the application, demonstrating how the proposed research is relevant to the call for applications (up to 2000 words).

Hypothesis: The proposed research should be hypothesis-led and seek to answer a specific question. Outline clearly the full and null hypotheses and specifically the question to be addressed (up to 100 words).

Milestones: Describe up to 4 milestones for the delivery of the proposed research (up to 100 words each). Clearly explain the rationale for each milestone and provide estimated start and end dates.

Outcomes: Describe up to 6 outcome measures for the proposed research (up to 100 words each). Clearly explain the 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.

Impacts: Describe up to 6 anticipated impacts (up to 100 words each). Clearly explain the link between the outcome measures and the impacts.

Statistical Analysis Plan: Detail the statistical analysis plan for the chosen design, highlighting statistical technique to be used, sub-group analysis if appropriate, proposed frequency of analysis and power assumptions (up to 300 words).

Project Plan: Outline the arrangements for the management of the research, paying attention to the Study Design Principals outlined in the Call for Applications. This could include a project timeline including any individual workstreams, plus arrangement for the day-to-day management of the research including details of who will carry out specific duties such as co-ordination, randomisation, recruitment, data handling and statistical analyses (up to 1000 words).

Facilities: Describe the facilities available to support delivery of the research (up to 300 words).

Risks/ migration strategies: Discuss any potential risks to the success of the research and highlight mitigation strategies. Please consider all types of risk – commercial, technical, financial, and organisational (up to 300 words)

Gantt chart: Please attach a Gantt chart to illustrate the work package and deliverables.

Research types

Research involving humans -

Please only complete this section if applicable to your application.

The <u>Department of Health</u> requires that work 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 project 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 attachment section.

Research involving animals -

Please only complete this section if applicable to your application.

The Funders are committed to the principles of reduction, replacement and refinement in animal studies.

Versus Arthritis, JDRF and the MS Society are members of the Association of Medical Research Charities and sign up to their <u>position on animal research</u>.

Before completing this section please read the AMRC guidance 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.
- Select the maximum severity of the procedures involved.
- Indicate if the project involves a protected species (non-human primate, cats, dogs or equine).
- Indicate if the relevant Home Office project and personal licences have been obtained

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 National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) http://www.nc3rs.org.uk/responsibility-use-animals-bioscience-research, including an online experimental design assistant to guide researchers through the design of animal experiments: http://www.nc3rs.org.uk/experimental-design-assistant-eda.

Replacement, reduction and refinement (3Rs) of animal experiments: Indicate if the proposed research will lead to the advancement of the 3Rs (replacement, refinement or reduction in the use of animals) and how it will do this. Further information on the 3Rs is available from the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) https://www.nc3rs.org.uk/the-3rs.

Intellectual property (IP)

Please indicate whether the proposal is likely to produce new IP*

*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.

Please indicate whether there is existing IP associated with the research

Scientific references

Detail all references (citing all authors) that are of interest for this application.

Additional support

Indicate here if there is any additional financial support for the application including any of the following: from the applying institution, from another funder, from the Clinical Research Network (CRN), in the form of treatment costs and excess treatment costs, industrial support (including collaborations and donations) or any other type of support.

Finance and costs

Finance summary: Please complete the relevant financial detail within each of the following categories:

- Staff members (salaries)
- Animals (total)
- Expenses/consumables (total)
- Apparatus/Equipment (total)

Full economic costing

In line with other UK medical charities, the funders do 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:
 - Investigators: the time spent by tenured lead applicants (Chief Investigators) and coapplicants.
 - o Estates
 - o 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.

Lead applicants and co-applicants can apply for their salaries if they don't hold a tenured position. Please note all applications must have a lead applicant or another co-applicant that holds a tenured position. Lead applicants and co-applicants that are employed on full time NHS contracts can apply for funding to release them from clinical commitments to conduct project activities.

Eligible costs within an 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
- 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
- Costs for the purchase and maintenance of laboratory animals can be applied for. Studies
 involving animals must provide adequate details on the number, species, strain and associated
 costs of animals to be used
- Access charges for use of specialist equipment may be applied for within expenses

Ineligible costs within an application

- Costs relating to staff recruitment and relocation costs
- Personal license fees and home office license
- · Good clinical practice (GCP) training
- Funding to provide maintenance of equipment
- Office stationery costs unless required for the project and justified accordingly
- Indemnity insurance

AcoRD: Applications that propose activities conducted with human subjects within a health or social care setting should be formulated in line with Department of Health Guidance "Attributing the costs of health and social care Research & Development (AcoRD)" The Funders will only fund Directly Incurred Project Costs and applicants should ensure that they have consulted their local NIHR CRN, where appropriate, to discuss NHS Support Costs and NHS Trust Management to discuss Treatment Costs before submission.

Lead Applicant details

The lead applicant is the individual who will lead the work on the grant and be responsible to the Funders to ensure the conditions of award are met. They must be based in a UK university, hospital or recognised academic research institute in the UK.

The principal/lead applicant must open the application form on grant tracker and add the other key personnel who can then add information.

The details displayed in the application form for the lead applicant are those that are stored on Grant Tracker. To amend them, please save and close the application form and visit the 'Manage My Details' section on the GrantTracker Versus Arthritis homepage.

Basic information: Please ensure all fields marked with a red dot are completed (these are compulsory fields).

Update CV: Degree/Qualification - please add any degrees or professional qualifications that you hold and feel would aid your application. Employment – Please list your present and last position held as a minimum. Please list any further positions that feel would aid your application. Publications. Please list your most important research publications up to a maximum to 10 that you feel would aid your application. Full author citations are required. Grants – Please list all current grants held.

Other roles in the application

Co-applicants: Co-applicants are individuals who will have had intellectual input into the application and are expected to be involved in the project. All co-applicants are expected to make a substantive contribution to the delivery and management of the activities described in the application. For further details on how to enter a co-applicant see Versusarthritis.org).

If you wish to add a co-applicant that is based outside the UK please contact the Versus Arthritis research department.

Recruiting centres do not necessarily have to be co-applicants they can alternatively be collaborators or listed as a recruiting centre only.

People with autoimmune conditions or service users who are named co-applicants should include in their CV a summary of any knowledge, skills and experience relevant to their role in the application.

Please add details of all co-applicants involved with the project. You will be able to select individuals who already have an account with us. Individuals who do not have an account with us will be asked to register and will be sent details via an automated email.

Collaborations: Please list any collaborations that are not listed as co-applicants. Collaborators are individuals who are named in the body of the application who supply project materials, specific expertise or access to patients, but will not be involved in the day-to-day execution of the project.

To enter a collaborator select add collaboration and enter the name of the collaborator, their institution and details of the collaboration into the box.

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

Pre-award administrators: Please enter all of the administrators required for this application. Administrators can access and edit the application form, however, their details will not appear explicitly on the completed form.

Time Allocation: Enter the amount of time, in hours per week, intended to be spent by each applicant on the project being applied for.

Relevant grants and publications

All participants listed below must log in separately, select up to a maximum of ten of their grants and ten of their publications that are most relevant to the application. Each participant will only see their own information.

- Lead applicant
- Co-applicant(s)

To add a grant

Use the button to add a new field then select a grant from the drop-down menu. If the grant you wish to add is not listed in the drop-down menu, you can add it to your CV in the Manage My Details section of grant tracker.

To add a publication

Use the Dutton to add a new field then select a publication from the drop-down menu. If the publication you wish to add is not listed in the drop-down menu, you can add it to your CV in the Manage My Details section of grant tracker.

Signatories

Enter the details of the signatories required to sign-off the application. The head of department and finance officer OR research officer details should be completed. Before submitting your application, you must obtain the necessary signatories prior to the deadline.

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 size per attachment is 10 MB.

The following documents should be included as attachments where relevant:

- 1. Scientific summary supporting diagram
- 2. Letters of collaboration / support
- 3. Ethical approval
- 4. Animal licence(s)
- 5. Gantt chart
- 6. Additional figures / data referenced in the project details section
- 7. If the application is a resubmission, a cover letter should be attached detailing how the application has been altered in response to the feedback received from the original submission.

UKCRC HRCS

We subscribe to the use of the UK Clinical Research Collaboration's Health Research Classification System, more information and guidance can be found at Home-HRCS Online.

Please select up to 5 of the UKCRC Health category classifications that you feel best fits your proposal using the drop down list.

 Please select up to 5 of the UKCRC Research activities classifications that you feel best fits your proposal using the drop down list

Suggested Reviewers

Here you may add names of potential reviewers (not connected with you or your proposal) or any reviewers that you do not wish to be approached. Please note, these will be treated confidentially.

End – Submitting your application

To complete the application process, the final steps are listed below.

1. Select Validate form

This will check that you have completed all sections within the application. Also, that your coapplicants have confirmed and approved their role(s).

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 research or 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. **This must be completed by 16:00**.

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.