

Crohn's & Colitis UK Research Awards Targeted Call 2024 - Guidance notes

Definition: The words 'the Charity' when used in this document mean Crohn's & Colitis UK

Information for Applicants

Please ensure you have read our <u>Terms and Conditions of Award</u> prior to applying. If successful these are the terms under which the grant will be awarded.

Application format

Applications to the 2024 grant round will be assessed via a two-stage process. Please note - this process has recently changed. If you have applied to us before, please ensure you have read the guidance fully so you are aware of the new process.

Stage 1: Submit an outline application form. You will need to email us at research@crohnsandcolitis.org.uk to get a copy of the form. The deadline for return of the form is 12noon, Friday 9 February 2024.

Stage 2: Shortlisted applicants will be invited to complete a full application via our online portal for peer review. You can find a Word version of the <u>full application form here</u>.

Applications will only be accepted in this form and must be submitted before the submissions deadline. Supplementary information cannot be added after the deadline and late applications will not be accepted.

If you are invited to submit a full application after shortlisting, this will be done through our online portal. We will share a link to the portal when we invite you through to stage two. The Principal Investigator will need to set up an account in order to sign in and create a new application.

Any queries about the preparation of your application should be directed to the Research Team, at Crohn's & Colitis UK (<u>research@crohnsandcolitis.org.uk</u>).

Guidance for the questions included in the stage two full application form can be found in Working Draft document (a Word version of the application form) on our website.

Area of Research

Applications may be submitted for research proposals which address one of the following James Lind Alliance Top 10 Priorities

- JLA Priority 2: What are the optimal markers/ combinations of markers (clinical, endoscopic, imaging, genetics, other biomarkers) for stratification of patients with regards to a) disease course and b) monitoring disease activity and c) treatment response?
- JLA Priority 5: What is an optimal treatment strategy for perianal Crohn's Disease and what individual factors determine this?
- JLA Priority 6: What is the best treatment for controlling diarrhoea and/or incontinence symptoms in people with IBD, including novel pharmacological and non-pharmacological options? Is high-dose Loperamide safe and effective in the treatment of diarrhoea in IBD?
- JLA Priority 8: What is the association between IBD and fatigue and how should it be managed?
- JLA Priority 9: Does early surgery or later surgery for terminal ileal Crohn's disease result in better outcomes (quality of life, cost-effectiveness)?

We encourage, where possible, studies that have the potential to realise rapid benefits for people living with Crohn's and Colitis, at the "bedside" end of the "bench to bedside" spectrum.

Applications that do not explicitly address one of the above priorities will not be considered.

The Charity can only accept applications from a UK-based university, research institute or NHS setting at this time and cannot accept applications from commercial organisations.

How our Research Awards are made

Applications are subjected to a rigorous peer review process for which the Charity has been awarded a "Best Practice in Peer Review Certificate" by the Association of Medical Research Charities (AMRC). The Charity operates a two-stage peer review process which is supported by its Research Awards Panel and its Research Strategy and Funding Committee (RSFC).

The Awards Panel shortlists outline applications at Stage One, and at Stage Two makes recommendations for funding to the RSFC. The RSFC makes funding decisions with delegated authority from the Board of Trustees.

The Awards Panel and Research Strategy and Funding Committee comprise expert medical, academic and people living with IBD. Each panel or committee operates under terms of reference which delineate their roles and responsibilities and address the issues of confidentiality and conflict of interest.

Outline applications are assessed against the following criteria:

CRITERIA FOR SCIENTIFIC/CLINICAL PANEL MEMBERS		
Originality	The proposed work is novel and important.	
Feasibility	The proposed approach(es) is realistic, well developed and is likely to achieve the aims within the timeframe set out	
Research Team	The research team has the necessary skills to carry out the proposed work.	
Benefit/Impact	 The proposed work is addressing an area of unmet need as outlined in the grant call, either in the field of IBD research or for people living with IBD. The proposed research will directly impact, or has the potential to directly impact people living with IBD and there is an achievable plan for evaluating impact. 	
Patient and Public Involvement and Engagement	• The applicant(s) have involved people living with IBD in the development of the proposal and have clear plans for involvement and engagement as the study progresses.	
Equality, Diversity and Inclusion	The applicant(s) have considered issues around health inequalities and equality, diversity and inclusion and have plans to embed EDI in their work, including in participant recruitment (if applicable).	

CRITERIA FOR LIVED EXPERIENCE PANEL MEMBERS		
Benefit/Impact	 The proposed work is addressing an area of unmet need or is of importance for people living with IBD. The proposed research will directly impact, or has the potential to directly impact people living with IBD and there is an achievable plan for evaluating impact. 	
Patient and Public Involvement and Engagement	• The applicant(s) have involved people living with IBD in the development of the proposal and have clear plans for involvement and engagement as the study progresses.	
Equality, Diversity and Inclusion	• The applicant(s) have considered issues around health inequalities and equality, diversity and inclusion and have plans to embed EDI in their work, including in participant recruitment (if applicable).	
Clarity	The project overview section of the application is written clearly in Plain English and the applicants have avoided the use of technical jargon or explained any terms or abbreviations where necessary.	

At the Outline stage, we are only looking for summarised, top line costings. We anticipate there may be some changes to budget lines between Stages One and Two but would not expect to see the budget completely change without prior discussion with the charity. In addition, there is no requirement for supporting letters at the outline stage, we only require you to submit the application form, the PIs CV and the scientific proposal. Details of what is required for each of these are set out in the outline application form.

If you are successfully shortlisted by the Awards Panel, you will be invited to submit a full application for Stage 2. The Stage 2 deadline will be 12noon, Wednesday 5 June 2024. The Awards Panel may provide feedback that they wish you to take into account while developing your full application. Once you have submitted your full application, this will be sent for external peer review. You will be given the opportunity to respond to the peer reviewers' anonymised comments. The Awards Panel meets in late September/early October and will produce a recommendation for funding that will then be considered by our Research Strategy and Funding Committee.

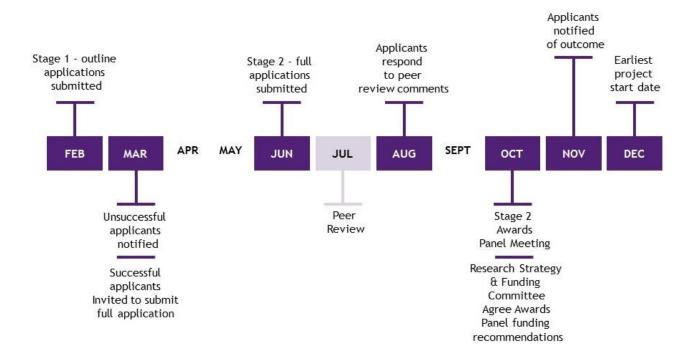
The Committee then makes the final funding decisions with delegated authority from the Board of Trustees based on the available research budget for the year.

Full applications are assessed using the following criteria:

• •	IFIC/CLINICAL PEER REVIEWERS AND PANEL MEMBERS
Scientific/Academic Merit	 The research proposal is novel and important. The proposed work is particularly creative or innovative in the solution /intervention it is proposing. The proposal is of high quality and will add significantly to the scientific body of knowledge.
Methodology	 The methods are clearly explained and appropriate and there is a clear rationale for the patient population being targeted in the study. If relevant, there are no ethical concerns raised in the proposed work. If the application involves the use of animals, is this appropriate and in line with the 3Rs principles.
Feasibility	 The proposed approaches are realistic, well developed and likely to achieve the aims within the timeframe set out. The research team has the necessary skills and access to required infrastructure to carry out the proposed work. The budget is sensible and adequate to carry out the proposed work.
Benefit/Impact	 The research will directly impact people living with IBD or has the potential to impact people living with IBD in the future. The work will provide clinicians and/or patients with the tools and resources to manage the disease. There is an achievable plan for evaluating impact.
Patient and Public Involvement and Engagement (PPIE)	The applicant(s) have involved people living with IBD in the development of the proposal and have clear plans for involvement and engagement as the study progresses.
Equality, Diversity and Inclusion (EDI)	 The applicant(s) have considered issues around health inequalities and equality, diversity and inclusion and have described the specific activities they will undertake to embed EDI in their work. If participants are to be recruited to the study, the applicant(s) have considered issues around health inequalities and EDI? The applicant(s) have considered how the results of their study could be widened so they are representative of the IBD population.

Relevance	The research proposed is addressing an area of unmet need or is
	of importance for people living with IBD.
Benefit/Impact	• The research will directly impact people living with IBD or has the
	potential to impact people living with IBD in the future.
	The work will provide clinicians and/or patients with the tools and
	resources to manage the disease.
	There is an achievable plan for evaluating impact.
Feasibility	• If relevant, any barriers concerning recruitment of people to the
	study have been identified and addressed.
	• If relevant, there are no ethical concerns raised in the proposed work.
Patient and Public	The applicant(s) have involved people living with IBD in the
Involvement and	development of the proposal and have clear plans for involvement
Engagement (PPIE)	and engagement as the study progresses.
	The level of PPIE for the project is appropriate for the type of
	work e.g. there is a steering committee/working group for large,
	clinical projects.
	The plan for providing feedback to participants or people who
	have been involved in shaping the research is well thought-out and appropriate.
	• There is a wider engagement plan to communicate results to people affected by IBD and/or the general public.
Equality, Diversity and	The applicant(s) have considered issues around health inequalities
Inclusion (EDI)	and equality, diversity and inclusion and have described the specific
	activities they will undertake to embed EDI in their work.
	• If participants are to be recruited to the study, the applicant(s)
	have considered issues around health inequalities and EDI?
Clarity	The project overview section of the application is written clearly
	in Plain English and the applicants have avoided the use of technical
	jargon or explained any terms or abbreviations where necessary.

Timeline



What costs can be covered

Crohn's & Colitis UK awards can cover any direct costs of the research. This includes the costs of materials, laboratory services, expenses and staff specifically employed in the research. PhD stipends and fees may also be included. Any salary costs for the Principal Investigator, or other directly allocated salary costs, must be fully justified within the application.

You can apply for funds to cover the cost of purchasing equipment (but not the costs associated with maintenance of equipment), but these must be specific to the project. We will not, for example, cover the costs of generic lab equipment such as fridges or freezers unless required specifically for the purposes of the project being applied for - this must be clearly justified in the grant application. In addition, we will not consider grants where the item of equipment represents a significant portion of the grant costs.

All budget requests must be fully justified in the full application.

You may include any consumables and laboratory materials directly attributable to the project including animal costs and access charges to shared equipment facilities (e.g. microscopes, flow cytometers, mass spectrometers). You can also include costs for consultancy and statistician advice.

The Charity will not pay for:

- Estates costs
- Equipment maintenance or running costs.
- Staff recruitment costs
- Standard office equipment (e.g. laptops, printers etc.)
- Apprenticeship levy
- Organisational overheads (e.g. rent, heating, administrative support etc.) and other indirect costs

We expect applicants to have allowed for any salary increments due and for any Employers' National Insurance or Pension Scheme costs. They should include an estimate for pay awards in second or subsequent years, stating the percentage increase.

The Charity understands that the budget we offer for research grants will often not cover the full direct costs of a project. You will be asked at full application stage to be clear where any additional funding is coming from and what it will cover.

Please make sure that your application focusses on what the Crohn's & Colitis UK grant will help you to deliver. If this is unclear at outline application stage, you may be asked to clarify it at full application stage.

Staff costs

In calculating staff costs, please ensure that you have allowed the appropriate amounts for any increments due and for any Employers' National Insurance or Pension Scheme costs. You should include an estimate for pay awards in second or subsequent years and state the percentage increase you have assumed in the item description. Pay awards cannot be added to the budget once the award has been made.

Please take into account the proposed start date of the project when calculating staff costs, particularly if ethics approval is required which can cause significant delay to start dates.

Drug costs

If drugs are needed for the research for direct use in humans or animals, the Charity expects the applicant to approach the manufacturer or supplier to seek their support in providing these for the research. Your application should include an explanation if you consider it inappropriate or impracticable to make such an approach. This does not apply to in vitro cell culture studies.

Duration of Awards

Awards can be for up to three years. Payment of invoices is dependent on receipt of timely reports as set out in our Terms and Conditions.

Required Supporting Documents

The only supporting documents required at Stage One with your outline application are a short CV for the Principal Investigator and a short scientific proposal. Full details are in the outline application form.

At Stage Two, when submitting a full application form you you will be asked to upload the following documents to our online portal:

- CVs for the Principal Investigator and any Co-Investigators. Each CV should be no more than 2 pages long, and all CVs should be combined into one PDF document for upload.
- Signed Stakeholder Declaration forms for all stakeholders involved in the project. All Stakeholder Declaration forms should be combined into one PDF document for upload.
- Any relevant letters of support including from collaborators. All letters of support should be combined into one PDF document for upload.
- Detailed proposal document and reference list
- Proof of ethics approval if available. Studies that have not yet received ethics approval
 will be considered, provided the reason for this and expected timescales are made clear
 in the application. Please note that the grant cannot start before ethics approval is in
 place. If ethics approval is not yet in place, please ensure the start date of the proposed
 work is realistic and reflects this.

Justification for the use of live animals

Crohn's & Colitis UK will not support the use of live animals unless there is no alternative. The numbers of animals requested must be optimised and fully justified, and we emphasise the importance of refinements of procedures to minimise any pain or distress.

If you propose to use live animals in this research, you must include the following information:

- i. Why the use of live animals is necessary and what other possible approaches have been considered.
- **ii.** Why the species requested is the most appropriate, especially if the animals are being used as a model for a human physiological or pathological condition.
- **iii.** The experimental design should include the case for the numbers of animals required to achieve statistical significance and the factors that might affect this.

Crohn's & Colitis UK Research Awards Panels will pay particular attention to the above issues in assessing applications.

You are required to provide written confirmation of the following points:

- iv. That the institution which will hold the Award holds (or is not required to hold) a Certificate of Designation under the Animals (Scientific Procedures) Act 1986.
- v. That the Home Secretary has granted a Project Licence under the above Act (Please give the name of the licensee, the Home Office reference and the date of issue).
- vi. That the necessary personal licences are held, or, if not, have been applied for.

As a member of the AMRC, the Charity supports the AMRC position statement on the use of animals in research which can be found at:

https://www.amrc.org.uk/position-statement-on-the-use-of-animals-in-research

What happens if you are offered an Award?

You will sent an award letter and a set of Terms and Conditions to sign and return. Please make sure you (or an appropriate person at the Host Institute) have read these in advance of applying and are confident that your Host Institution will be able to accept the grant under these Terms. We may get in contact to ask for additional information from you or the Host Institute to allow us to prepare the Terms.

The principal investigator and an authorised signatory for the Host Institution will be required to sign this the Terms and Conditions by a set deadline which will be detailed in the award letter.

Details of the project in respect of which an Award is made may be shared in confidence with potential funders of the Charity to raise funding for the Award.

The grant start date will need to be agreed in writing (by email) once any conditions set out in the award letter have been met and ethical approvals (if required) are in place.

Payment of Awards

Awards are paid on receipt of a valid invoice (detailing approved costs incurred during a defined period) from the department administering your research funds. The Host Institute should invoice quarterly, in arrears for actual expenses incurred.

Host institutions must invoice any final costs within six months of completion of the award. Any invoices received after this time will not be paid.

Supervision

The Charity Commission places a duty on the trustees of charities which fund research to ensure that adequate arrangements are made for the proper supervision of the research that is being undertaken. The Charity does not have any permanent staff who are able to undertake a supervisory role directly and, therefore, the Charity requires that Host Institutions have in place policies and procedures to protect against scientific fraud.

The AMRC suggests that a procedure for dealing with accusations of scientific fraud would cover the following elements:

- a guidance document or code of practice on standards of professional behaviour
- provisions for induction and training of staff
- monitoring
- regulations and procedures for handling allegations
- fair procedures and appropriate protection for both the accused and the 'whistleblower'.

The Charity requires Principal Investigators and Host Institutions to supervise the research undertaken in line with the Universities UK's Concordat to Support Research Integrity.

Reports Required

A full report is required within three months of the completion of the research project. If you are unable to report within the required timescale, you are required to request a no cost extension providing a justification for the additional time required. Payment of the last 10% of the grant funds will be held until such time as the report is received. In the case of two-or three-year awards, an interim report is also required at the end of each year of the project for review by a member of the Awards Panel.

Both interim and final reports must be submitted in prescribed form and should include a short report of the progress or outcome in language understandable to the general public. This may be published on the Crohn's & Colitis UK website. Reports may also be shared with third party funders who have contributed to the funding of Awards.

Reports on the impact of the research undertaken are also required by way of annual submission through Researchfish in addition to the interim and final reports.

Acknowledgement of Crohn's & Colitis UK funding

It is expected that all publications or presentations arising from Crohn's & Colitis UK funded projects should acknowledge the funding given by the Charity. Greater public and professional recognition of the Charity's role will help us in the task of raising more research funds.

A copy of any publication based on or arising from the research should be sent to research@crohnsandcolitis.org.uk

Branding and logos

The Principal Investigator and Host Institution are responsible for ensuring that the Charity's full name (not CCUK or any other abbreviation) is used in all publications or presentations.

For these purposes only, the official logo for the Charity is provided at: http://s3-eu-west-

1.amazonaws.com/files.crohnsandcolitis.org.uk/VR/Network_Volunteers/Creating_Communications/Branding/logo_only.png

Feedback to Crohn's & Colitis UK members and supporters

The Charity's members are very keen to learn of progress in research and it is important that

they receive regular feedback on what happens to the Charity's research funds. Our supporters have raised over £11 million for research. This is a tremendous achievement and you can help us to maintain their motivation by agreeing to give an occasional talk e.g. to a local Crohn's & Colitis UK network, and by providing the required project reports.

Our Communications Team is always pleased to receive contributions on research that will help members understand the overall context of the project, the work that is being undertaken and the hoped-for outcome(s). Pictures or illustrations are especially helpful if they are available, even general photographs of 'the researcher at work'.

The Charity hopes that any requests for a speaker will be viewed favourably provided they are not too frequent and do not involve extensive travelling. Any concerns may be directed to the Charity's Director of Services, Advocacy & Evidence, Ruth Wakeman ruth.wakeman@crohnsandcolitis.org.uk.

Press Statements about Crohn's & Colitis UK-funded Research

Please inform the Charity's press office (media@crohnsandcolitis.org.uk) in advance if you are issuing a press statement about research funded by us. This helps us to prepare a response for any journalist who may ask us to comment.

Obtaining publicity for Crohn's and Colitis is difficult and you can help the Charity greatly by giving us advance notice. Local or regional publicity is just as valuable as national coverage.