



PCD Research

PCDresearch.org

PCD Research - Funding Policy

PCD Research is committed to improving outcomes for people with Primary Ciliary Dyskinesia (PCD) and believe the best way to do this is to fund high impact and collaborative research. We will consider supporting all stages of research from laboratory projects, translational research, pilot projects to clinical trials. We will grant funding for research that promotes understanding of the cause, cure and care of PCD.

We place importance on maximising the impact of research for the advancement of understanding and curing PCD by:

1. Nurturing the careers of early-stage research staff with an interest in PCD research
2. Working with research teams to develop their research ideas through a pilot grant scheme
3. Supporting proposals that are likely to win support from larger funding bodies
4. Encouraging collaboration between research groups
5. Encouraging interdisciplinary teamwork and partnership
6. Facilitating access to primary tissue and clinical data

Epidemiology and quality of life-based projects will not be considered.

1. Application Deadlines

Applications may be submitted at any point (unless specific information to the contrary), and will be considered at the next available meeting of PCD Research's Independent Scientific Advisory Panel (SAP).

2. Grant Application Process

Proposals should clearly describe background evidence to support the project, including figures, data and publications. Planned experiments should be described in clear work packages, detailing how these experiments will answer the hypotheses posed. It is important that proposals demonstrate how the research may lead to patient benefit according to the objectives of PCD Research. Grant application is by submission of the PCD Research Grant Application.

3. Eligibility Criteria

To be eligible to apply for PCD Research funding, the following criteria must be met:

a) Applicants and Grant Holders

Sole applicants or applicant supervisors must have:

- i. International standing as a research leader in the field
- ii. Experience of leading innovative and creative research
- iii. Track record of managing and training others

We will review sole applicant or lead applicant's:

- i. Research outputs and contributions to the research community
- ii. Previous contributions to, and plans for, developing team members and other researchers
- iii. Leadership and management skills, and how the applicant (s) plan to develop these during the award
- iv. Rationale for a team approach, team composition (including the applicant's approach to diversity, inclusion and career stage) and the contribution of each team member.
- v. Appropriate scientific or medical degree qualifications.

b) Research Proposal

To be competitive, the research proposal will be:

- i. High quality. It is well-designed, clear, supported by evidence and the proposed outcomes/outputs are feasible.
- ii. Bold. It aims to deliver a significant shift in understanding and/or it provides a significant advance over existing methodologies, conceptual frameworks, tools or techniques. It has the potential to stimulate new and innovative research.
- iii. Creative. The proposed approach is novel. It develops and tests new concepts, methods or technologies, or combines existing ideas and approaches in a new way.
- iv. Specific. Demonstrates the purpose is primarily for the benefit of understanding/advancing outcomes in PCD, rather than allied diseases.

c) Institution

All applicants must have sponsorship from one of the following types of institution:

- a. higher education institution
- b. research institute
- c. non-academic healthcare organisation
- d. not-for-profit organisation

PCD Research does not fund:

- Applicants that are applying for, hold, or employed on a research grant from the tobacco industry.

4. Peer Review of Funding Applications

PCD Research is committed to funding the highest quality research in a fair and transparent manner. To facilitate this, peer review is carried in line with the following principles:

- **Accountability:** Charities are open and transparent about their peer review procedures and publish details of the process, including the names of the members of scientific advisory panel or other decision making bodies.
- **Balance:** The scientific advisory panel reflects a fair balance of experience and scientific disciplines.
- **Independent decision making:** The scientific advisory panel is independent of the charity's administrative staff and trustees.
- **Impartiality:** The scientific advisory panel should include a significant number of non-beneficiaries of research grants from PCD Research. Each member of the Scientific Advisory panel will abide by the conflict of interest policy and potential beneficiaries to research funding will not present when decisions are made.

The following sections set out how PCD Research's procedures will ensure compliance with these principles.

a) Independent decision making and Independent Scientific Advisory Panel (SAP)

- PCD Research's SAP is a committee independent from the Board of Trustees and is composed of independent scientific and medical experts who have agreed to meet, in a voluntary capacity, to give advice on research funding on behalf of PCD Research. Additionally, a lay member will be invited to join the SAP to provide patient representation.
- The role of the SAP will be to robustly select only the most scientifically and medically promising research.
- All research funding decisions and recommendations are made by PCD Research's SAP.
- PCD Research staff are involved in:
 - the administration research grant round process
 - providing secretariat for the grant review meetings
 - ensuring compliance with PCD Research's research management procedures
- Any individual who is a trustee, may chair meetings of PCD Research's SAP but does not have voting powers over any grant proposals.
- Members of the Board of Trustees may be present at meetings of the SAP as an observer to the decision making meeting where research applications are reviewed and discussed.
- Should a member of SAP decide to join the Board of Trustees, they must step down from PCD Research's SAP (or vice versa if a Trustee decides to join SAP).
- The grant review and decision making meeting of PCD Research's SAP must have at least three members of SAP to be quorate. When arranging PCD

Research's SAP meeting, as much notice as possible must be given as members may have clinical, teaching or academic commitments. The meeting may need to be delayed if no suitable date can be found. PCD Research's SAP grant review meetings will take place in line with the research grant cycle to assess applications and make recommendations to the Board of Trustees.

b) Impartiality

- i. No more than 80% of PCD Research's SAP can hold current PCD Research grants during their tenure on PCD Research's SAP.
- ii. Each member of SAP is required to sign the Conflict of Interest Policy and update this annually.
- iii. Members of PCD Research's SAP who are connected to a grant proposal, must declare a Conflict of Interest.
- iv. If a conflict of Interest is declared, the conflict of interest policy must be adhered to in terms of the SAP member's involvement in the grant review meeting.

c) Balance

PCD Research is committed to ensuring a fair balance of experience and scientific disciplines within our SAP. We aim to ensure PCD Research's SAP is comprised of a range of experts across all disciplines of ciliary research, including basic laboratory and clinical research. We seek to avoid discrimination to PCD Research's SAP on the basis of age, gender, ethnicity or geographical spread as per the protected Characteristics covered by the Equality At 2010:

- Age
- Disability
- Gender reassignment
- Marriage or civil partnership (in employment only)
- Pregnancy and maternity
- Race
- Religion or belief
- Sex

PCD Research's SAP must comprise at least five members, and we aim to ensure there is cover across scientific disciplines. All appointments made to the SAP must be approved by the Board of Trustees.

5. Application and Review Overview

- i. Research applications are submitted by Principal Investigators (PI's) to a deadline date.
- ii. All applications received are acknowledged and assigned an internal research reference number.

- iii. They are initially triaged by PCD Research's Head of Research and Information (or other suitably qualified staff member) against the eligibility criteria. Any applications which do not meet the eligibility criteria will be returned to the PI and host institution with an explanation of where the application was ineligible.
- iv. Eligible applications may then be assigned to peer reviewers, either internal or external. The Head of Research and Information (or other suitably qualified staff member) will liaise with the Chair of PCD Research's SAP over appropriate reviewers.
- v. Grant applicants will be called to interview by the SAP, with a minimum of three members of the SAP to be quorate.
- vi. Following the decision making meeting of PCD Research's SAP, the Chair of PCD Research's SAP or the Head of Research and Information (or other suitably qualified staff member) will present the recommendations of the meeting to the Board of Trustees for approval.

6. External and Internal Reviewers

All competitive research applications will be peer reviewed by either an internal or external reviewer. For these purposes, members of PCD Research's independent Scientific Advisory Panel (SAP) are classified as internal reviewers and external are the wider research and clinical community.

- i. If the SAP deems they are unable to suitably provide peer-review for the grant application either through lack of expertise, or conflict of interest, then external review will be sought.
- ii. External peer reviewers will be sent the Conflict of Interest Policy and asked to declare any interest before committing to review a project.

Internal review only:

- i. all applications for funding will require internal review.

External and Internal review: applications for funding will require both external and internal review if:

- i. If an application is received and there is no appropriate member of SAP with the relevant expertise in that field to peer review, the Chair of PCD Research's SAP or the Head of Research and Information (or other suitably qualified staff member) will agree to a list of potential external peer reviewers to contact.
- ii. External peer reviewers will be sent the Conflict of Interest Policy and asked to declare any interest before committing to review a project.

In these instances, external review will be sought before being reviewed by PCD Research's SAP. The external peer reviewer's comments will be used by PCD Research's SAP in any decision making process. A minimum of two external reviews will be sought, although this may be more for higher levels of funding. External reviewers may be sourced from the field of ciliary research and overlapping disciplines.

7. Accountability

PCD Research is committed to awarding research funding in an open and transparent manner with clear accountability.

- i. The PCD Research website is a resource for all types of research information, including policies and procedures relating to research. It also includes details on:
 - a. the members of the SAP
 - b. the Conflict of Interest policy
 - c. research projects funded by PCD Research
 - d. details on current funding opportunities
- ii. Feedback on applications is provided to all applicants at the end of the review process, with details of the peer reviewers' anonymised.
- iii. We support the position of the AMRC statement on the use of animals in research and include this on our website

www.amrc.org.uk/sites/default/files/doc_lib/AMRC_Statement_on_the_use_of_animals_in_research_Updated_Oct_2014.pdf

We ask all peer reviewers, internal and external, to assess and comment on the replacement, refinement and reduction (3Rs) of animals in research applications. Where possible, an additional expert external reviewer in this field is sought for all proposals including the use of animals. Reviewers are provided with guidance to support this. All research applications which involve non-human primates, cats, dogs and equine species are referred to the National Centres for 3R's for special review. For further guidance please see PCD Research Animal Research Policy.

8. Long Term Funding and Block Grants

PCD Research will commit to funding long-term grants to support clinical centres with sample collection for use in active research projects. Grant applications will be reviewed as per normal practice, however, in order to manage the continuous review and recommendations for the continuation of funding, PCD Research have implemented the following:

- i. Progress and impact of these grants will be measured yearly
- ii. The progress report is available on the PCD Research website and will be used as part of the review process
- iii. PCD Research may conduct audits of the centres to measure progress
- iv. Review of the centres and recommendations for the continuation or discontinuation of funding will be made by the SAP to the Board of Trustees
- v. The Board of Trustees will give final approval for the continuation of funding
- vi. Centres will be informed of the decision and feedback given on the review in a timely manner

9. Additional Funding Support For Ongoing Clinical Trials

Proposals for funding for clinical trials should clearly describe the funded trial, including the value of funding already secured, start date and duration of the funding award and details on data sharing, intellectual property and terms and conditions. The proposal should describe the background evidence, including figures and previous publications, that have been used to support the submitted project, how the described design will answer the questions posed in the proposal and how the additional support will give added value to the current trial.

The input from patients on the design and development of the proposal should also be described. Costings submitted will be fully scrutinised and so applicants should fully justify all costs included.

10. Resubmission Policy

At PCD Research, we do not allow the resubmission of any previously unsuccessful proposals, unless explicitly invited to resubmit.

Details of any requirements for resubmission, as requested by our Independent Scientific Advisory Panel, will be described in detail in the application and review feedback.

Where a resubmission is invited, a covering letter summarising the major revisions must accompany the application. If a previously unsuccessful application is resubmitted without invitation, this will be rejected during the internal sifting process before applications are sent for review.

11. Successful Grant Applications

Applicants who successfully pass the review and interview process will receive an Award Letter. This will include the details of the award and the terms and conditions on which the grant is made.

12. Research Practice, Legal Compliance and Governance

1. Grant Activities must be carried out in accordance with all relevant:
 - a. legislation and codes of practice, including but not limited to those relating to health and safety, data protection, modern slavery, safeguarding, bribery, tax evasion and relevant financial sanctions laws;
 - b. regulatory requirements
 - c. ethical guidelines and principles.
2. All necessary licences and approvals have been obtained and are in place at all times during the Grant Period.

3. Any element of the Grant Activities that involves the use of animals and that is conducted outside the United Kingdom is, as a minimum standard, carried out in accordance with the principles of UK legislation (for further information, consult the UK Government Home Office website, in particular the Animals (Scientific Procedures) Act 1986).

13. Employment

We do not employ the Grantholder or any of the Participants. It is the Grantholder's responsibility to issue any necessary contracts of employment in relation to the Grant, and to comply with any relevant employment law and regulation, including the duty of care as an employer.

14. Management of the Grant and Reporting

1. The Grant Activities must be started as soon as possible and in any event within 12 months of the proposed start date given in the Award Letter.
2. The grant must only be used for the Grant Activities as approved by the review process
3. PCD research must be informed immediately of any significant change to the scope or management of the Grant Activities, or if there are any factors that may adversely affect the Grant Activities or compliance with the Terms and Conditions. This includes but is not limited to:
 - a. suspicion of or actual fraud, corruption, breach of relevant financial sanctions laws or financial impropriety;
 - b. any change to the Grantholder's status, or the status of any other Participant, including suspension from duty or dismissal due to research misconduct, bullying or harassment;
 - c. if the Grantholder moves organisation during the Grant Period;
 - d. any significant increase in the number of animals used, where relevant.
4. The Grantholder is responsible for ensuring that PCD Research is sent progress reports as set out in the award letter and an end of grant report as we require.
5. Financial reports as set out in the Award Letter or as we request, and the Final Expenditure Report must be sent to PCD Research within three months of the Grant end date.
6. If the Grant Activities include research, a Consolidated IP and Commercialisation Report must be sent to PCD Research during the Grant Period and until the PCD Research IP has expired. If there are commercialisation activities to report, we also require that this is confirmed.

15. Audit and Financial Administration

1. It is required that appropriate policies and procedures are in place to ensure audit and control arrangements, including those for monitoring and preventing fraud, tax evasion, bribery, breach of relevant financial sanctions laws, or any other

improper practices, and that the Grant expenditure is controlled in accordance with these arrangements.

2. The Grantholder must have a bank account in the currency specified in the Award Letter with a bank that is acceptable to PCD Research, and tell us of any changes to these details during the Grant Period.
3. All income and expenditure related to the Grant must be accounted for by the Grantholder.
4. PCD Research requires at our expense and on reasonable notice, to audit the Grantholder's accounts, records, systems and facilities in relation to the Grant.
5. The Grantholder must give reasonable assistance to PCD Research in complying with our legal requirements relating to accounts, audit or examination of accounts, annual reports and annual returns.
6. The Grantholder must keep all invoices, receipts, accounts and other relevant documents relating to the Grant in accordance with your data retention policy, and at a minimum for three years after the Grant end date, and provide these to PCD Research if we ask for them.
7. PCD Research will hold back 10% of the Grant until we have received:
 - a. the Final Expenditure Report; and
 - b. the completed end of grant report form (if required).
8. The grant must be repaid to PCD Research according to the following criteria:
 - a. any part of the Grant that has not been spent when the Grant Activities have been completed
 - b. any part of the Grant used in breach of the Terms and Conditions.
9. The Grantholder is responsible for:
 - a. any expenditure on the Grant Activities which exceeds the amount of the Grant
 - b. any costs arising from any organisational restructuring carried out by the Grantholder which affects the Grant Activities.

16. Equipment

1. Any equipment funded by the Grant is purchased in accordance with the Grantholder's procurement procedures in a manner that delivers value for money, is used for the Grant Activities, and is adequately maintained and insured for all appropriate risks.
2. Use of the equipment for any other purpose requires written permission from PCD Research.
3. Additionally, if the Grantholder wishes to charge for, hire out, lend, sell or gift equipment purchased in part or fully from PCD Research funds, the Grantholder must ask for written permission from PCD Research.

17. Publication and Publicity

1. The outcomes of the Grant must be published or otherwise disseminated in an appropriate form; although publication or release of findings funded by the Grant may be delayed for a reasonable period to allow for protection and

commercialisation of intellectual property in accordance with our Intellectual Property Policy.

2. All publications relating to the Grant must acknowledge the contribution by PCD Research.
3. All original research supported in whole or in part by the Grant must be made available from Europe PubMed Central as follows:
 - a. peer-reviewed journal articles - immediately upon final publication
4. Scholarly monographs and book chapters must be published as soon as possible and no later than six months from the date of final publication.
5. The Grantholder must grant a Creative Commons Attribution licence (CC-BY 4.0) Public Copyright Licence to all future Author Accepted Manuscripts (AAMs). This is to ensure that the manuscript may be freely copied and reused, providing that the original authors are properly cited. If the Grantholder allows others to own copyright in AAMs, then the Grantholder must ensure that such a licence is granted.
6. All submissions of original research to peer-reviewed journals must contain the following statement:

“This research was funded in whole or in part by PCD Research [Grant number].”
7. PCD Research must be consulted before release of any press statement about the Grant.
8. PCD Research must be immediately informed of anything related to the Grant that may have an adverse reputational impact on PCD Research, the Grantholder, a Participant, or an Organisation.
9. A lay summary must be produced as part of the application process, during the terms of the grant (depending on the length of funding), and end grant report. This is for the benefit of the public and patient representatives and to raise greater awareness. Details of publication of this lay summary by the Grant Holder will be set out in the Award Letter.

18. Intellectual Property (IP) and It's Commercialisation

1. Reasonable procedures for the identification, protection, management and commercialisation of PCD Research funded IP must be followed in line with our Intellectual Property policy, particularly where the Grant Activities involve collaboration with, or the contribution(s) of, third parties.
2. When commercialising PCD Research funded IP the delivery of public benefit, with no excessive private or personal benefit(s) must be prioritised. The Grantholder must also:
 - a. obtain the written consent from PCD Research before the start of commercialisation
 - b. report fully on the commercialisation activities via the Grantholder's Consolidated IP and Commercialisation Report; and
 - c. enter into our revenue and equity sharing agreement in place at that time as consideration for our consenting to commercialisation. See the Consent and Revenue and Equity Sharing policy for further details.

3. If the Grantholder does not protect, manage or commercialise any PCD Research-funded IP to our reasonable satisfaction, then we will have the right by giving six months' written notice to protect, manage and commercialise the PCD Research-funded IP on the Grantholder's behalf. We may exercise this right sooner where we reasonably consider that the opportunity to protect, manage or commercialise the PCD Research-funded IP for the public benefit could be lost if more immediate action is not taken. The Grantholder must ensure that any Participants and Organisations comply with all acts required to assist us in such protection, management and commercialisation.

19. Liability

PCD Research does not accept any responsibility for financial or other liability incurred by the Grantholder, any Organisation, or any Participant that may arise out of the Grant Activities.

20. Variation and Termination

1. PCD Research reserves the right to amend these Grant Conditions, our Grant funding policies, and the terms of the Award Letter at any time. We will publish on our website any changes to these Grant Conditions or our Grant funding policies. Once published, any changes will apply to the Grant.
2. Where there is any conflict between these Grant Conditions and the Award Letter, the provisions of the Award Letter will take precedence.
3. PCD Research reserves the right to terminate the Grant at any time. If we do this, we will set out our reasons to the Grantholder in writing in a reasonable timeframe.

21. Governing Law and Jurisdiction

The Grant Conditions shall be governed by and interpreted in accordance with the law of England and Wales and any disputes in connection with these Grant Conditions shall be governed exclusively by the courts of England and Wales.

22. Position Statement on Research in Universities in the UK

PCD Research endorses the AMRC statement on supporting research in universities.
<https://www.amrc.org.uk/position-statement-on-supporting-research-in-universities>