

Application summary

Application title

This should be the title of your proposed project.

Proposed duration of funding (months)

*Climate Change and Health Awards will normally be made for **up to three years**.*

Proposed start date

Is your application being submitted through a university?

Name of administering organisation

Please enter the name of the organisation where you intend to hold the award. If your application is successful, this is the organisation that will be responsible for administering the award.

Lead applicant's address at administering organisation

Department/Division

Organisation

Street

City/Town

Postcode/Zipcode

Country

Please enter the address where you will be working at the administering organisation. If your application is successful, this is the address that will be used in the award letter.

Focus area(s)

Select the relevant focus area(s) for your application

Lead applicant

Lead applicant details

Full Name	
Department	
Division	
Organisation	
Address Line 1	
City/Town	
Postcode	
Country	
Telephone No.	
Email Address	

ORCID iD	
ORCID iD	

Lead applicants must add their ORCID iD. Find out more about ORCID on our website.

Career history (current/most recent first)				
From	To	Position	Organisation	

Please provide details of your current position (if applicable) and all previous posts held, listing most recent first.

Education/training				
From	To	Qualification	Subject	Organisation

Please provide details of relevant education/training, listing the most recent first.

Source(s) of personal salary support

Your source of salary may have an impact on your eligibility to apply for Wellcome Trust funding. Please, therefore, state the source of funding of the salary of your post (for example, if it is funded through your organisation's block grant from a higher education funding body). If your salary is being funded from more than one source, please provide details of all funding sources, including their relative contributions. If there are any ties on intellectual property rights or publications arising from the research you undertake, please contact the Wellcome Trust for advice. Restrictions on intellectual property may affect your ability to apply to the Wellcome Trust.

If you are not currently in employment, this question should be answered 'not applicable'.

Experience relevant to this proposal
Please summarise your key achievements and experience which are relevant to this proposal. (350 words max.)

Please summarise what you consider to be your key achievements and experience and their relevance to this proposal; state which period of your career they relate to. You do not need to list all of your positions.

Research outputs

List up to 10 of your most significant research outputs, ensuring that at least five of these are from the last five years. For up to five of these outputs, provide a statement describing their significance and your contribution (up to 50 words per output).

Research outputs may include (but are not limited to):

- Peer-reviewed publications and preprints
- Datasets, software and research materials
- Inventions, patents and commercial activity

For original research publications indicate those arising from Wellcome-funded grants in **bold**, and provide the PubMed Central (PMCID) reference for each of these. Please refer to guidance notes.

Please give citation in full, including title of paper and all authors Citations to preprints should state "Preprint", the repository name and the articles persistent identifier (e.g DOI).*

*(*All authors, unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear.)*

You should include here systematic reviews (e.g. Cochrane Reviews) and meta analyses, but exclude abstracts and literature reviews. We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

Preprints, i.e. complete manuscripts that have been submitted to a preprint repository or service (e.g. bioRxiv, PeerJ Preprints, arXiv, SocArXiv or PsyArXiv), can be included only if they have a permanent identifier such as a DOI or arXiv identifier.

The Wellcome Trust's open access policy requires all original peer-reviewed research papers, supported in whole or in part by Trust funding, to be made available through PubMed Central (PMC) and Europe PMC as soon as possible and in any event within six months of the journal publisher's official date of final publication.

The PubMed Central ID (PMCID) is the unique identifier assigned to every full text paper in PubMed Central (PMC) and Europe PMC.

Please note that:

We actively monitor compliance with our open access policy and successful applicants will be asked to provide a full list of all their Wellcome-funded research papers, and confirm compliance by providing the PMCID identifier for these, before the award letter can be issued.

For further guidance, please refer to the Trust's open access policy statement and authors' information.

Total number of peer-reviewed publications which you have authored/co-authored. Please exclude abstracts and literature reviews.

You should include here systematic reviews and meta analyses. We encourage the inclusion of articles published via open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

Current and recent research funding (including Wellcome Trust grants)

Please list all held in the last five years and any key prior grants (list the most recent first). State the name of the awarding body, name(s) of grantholder(s), title of project, amounts awarded, your role in the project, and start and end dates of support. For all active grants, indicate the number of hours per week that are spent on each project.

In addition to research grants, please include details of any recurrent or core funding support that you have held in the last five years, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example,

whether you held them in your own right as lead applicant, co-applicant, or as part of a consortium. Please state the value of your own component of the award and the percentage of your time spent on the research.

Applicants

Applicants are expected to be actively involved in the project.

1

Applicant	
Full Name	
Department	
Division	
Organisation	
Address Line 1	
City/Town	
Postcode	
Country	
Telephone No.	
Email Address	

Career history (current/most recent first)				
From	To	Position	Organisation	
Education/training				
From	To	Qualification	Subject	Organisation

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Source(s) of personal salary support
<p>Your source of salary may have an impact on your eligibility to apply for Wellcome Trust funding. Please, therefore, state the source of funding of the salary of your post (for example, if it is funded through your organisation's block grant from a higher education funding body). If your salary is being funded from more than one source, please provide details of all funding sources, including their relative contributions. If there are any ties on intellectual property rights or publications arising from the research you undertake, please contact the Wellcome Trust for advice. Restrictions on intellectual property may affect your ability to apply to the Wellcome Trust.</p> <p>If you are not currently in employment, this question should be answered 'not applicable'.</p>

Experience relevant to this proposal
Please summarise your key achievements and experience which are relevant to this proposal. (350 words max.)
<p>Please summarise what you consider to be your key achievements and experience and their relevance to this proposal; state which period of your career they relate to. You do not need to list all of your positions.</p>

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List up to 10 of your most significant research outputs, ensuring that at least five of these are from the last five years. For up to five of these outputs, provide a statement describing their significance and your contribution (up to 50 words per output).

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Please give citation in full, including title of paper and all authors Citations to preprints should state "Preprint", the repository name and the articles persistent identifier (e.g DOI).*

*(*All authors, unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear.)*

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Success in obtaining funding for your research forms part of the assessment of your track record. In addition to research

grants, please include details of any recurrent or core funding support that you have held in the last five years, including any Wellcome Trust awards. Please state clearly your role in obtaining the awards, for example, whether you held them in your own right as lead applicant, co-applicant, or as part of a consortium. Please state the value of your own component of the award and the percentage of your time spent on the research.

Applicant details summary

Please also complete brief summary details for the lead applicant and each applicant listed above.

Name	Organisation	Role in project

This is to provide Wellcome with an overview of the applicants and their involvement in the programme.

Collaborators

Will you require any key collaborators for this proposal?

*These are collaborators who will be making a **significant** contribution towards the proposed research, for example, providing access to key resources, reagents or samples. Collaborators are not involved in the day-to-day execution of the project.*

If the answer is 'Yes', you will be asked to provide information of these collaborators and to confirm their willingness to participate in the proposed research.

Please list any key collaborators* (name and organisation) and provide a very brief outline of their role in the proposed research.

**The collaborators named may be replaced with suitable alternatives should it be necessary or appropriate to do so.*

I confirm that the collaborators named above have agreed to be involved, as described, in the proposed research and are willing for their details to be included as part of this application.

Related applications

Has this application, or part of this application, been submitted for consideration elsewhere, either previously or currently?

The Wellcome Trust will neither consider nor process an application for support where the same or a closely related application is under consideration by another organisation, unless agreed in advance with the Wellcome Trust. You are expected to inform us if you decide to submit this or a similar proposal to another funding body whilst the application to the Wellcome Trust is still under consideration.

Please provide name(s) of funding organisation(s) and decision date(s)

Is this a resubmission of an application submitted to the Trust within the last 24 months?

Applicants must contact the Wellcome Trust before resubmitting an application.

Please describe how this application differs from the original
(200 words max.)

Research summary

Research summary

Please provide a summary of your proposed research, including key goals, for an expert audience
(200 words max.)

Please provide a summary of your research proposal, aimed towards an expert audience. This will be used as a short form 'abstract' and is necessary to enable the Trust to classify your proposal by subject area. This synopsis may be disclosed on the Wellcome Trust website and may be used for other publishing purposes. For all our awards, we publish the synopsis as part of the grant details made available externally.

The summary should be as complete as possible within the word limit, and should include key words which best describe the proposal to enable text searching.

Lay summary

Please provide a summary of your proposed research that people who may not be familiar with the subject can understand. We may edit your summary and then use it to describe your research on our website and elsewhere.

You don't need to oversimplify your research, but try to explain it as clearly as possible. You should write in the first person ("I" and "we") and structure your summary in this order:

- *background to the research problem*
- *your approach*
- *expected impact of your work.*

Example of a lay summary

Complete diagnostic autopsies (CDA) remain the gold standard for determining cause of death, but performing them in low- and middle-income countries (LMICs) is challenging. Facilities are inadequate, skilled staff scarce and public acceptance low. A minimally invasive autopsy (MIA) procedure involving organ-directed sampling has been proposed as an alternative. Oxford University Clinical Research Unit (OUCRU) is evaluating the use of MIA in Vietnam, but the method's ultimate effectiveness will depend on its public reception. The public view on post mortem examinations and consent for them are complex and under-researched. I will use interviews, focus groups and participant observations to assess the practice and perceptions of autopsy in Vietnam and Nepal. I will investigate socio-cultural factors surrounding these perceptions and explore ethical barriers preventing autopsy uptake. I will try to determine whether MIA may be more acceptable than traditional forms of post mortem. I will then work alongside clinicians to develop more culturally sensitive and appropriate methods of obtaining consent to autopsy.

Details of research project

Detail (a) Aims and research questions; (b) Expected deliverables; (c) Work that has led up to the project; (d) Approach and methods to be used; (e) Timetable and milestones; (f) Contributions of team members.

No more than **2,500** words should be used to describe the proposal.

No more than 2,500 words should be used to describe the research proposal in total, excluding graphs, figures, etc. You may provide your answer to this question in text entry format or as a PDF attachment. If you are uploading your research proposal, the uploaded document must be in 11 point Arial font and portrait format.

Graphs, figures and essential quoted but unpublished information, including data, provided in support of the research proposal, may be embedded in the text or attached as supporting material – this must not exceed the equivalent of two A4 pages in length.

You must provide all information pertinent to your grant proposal within the application form (it is not acceptable to refer to additional unpublished information on personal websites).

Research questions

Please state what you consider to be the key question(s) that is/are being addressed by your proposal. For research that is not driven by an underlying hypothesis, please state the impact of the proposed studies.

Approach and methods to be used

For epidemiological, demographic, case control, cohort and related studies, give a full and detailed analysis of the study design, including details of any validation already undertaken or rationale for using standard protocols. Particular attention should be given to power calculations, sample size justification and, where appropriate, case definition and inclusion/exclusion criteria.

Clinical trials applications

If you are requesting support for a clinical trial, you must provide full details, including study design, in the 'clinical trial' section of the form.

(2500 words max.)

Does your proposal involve a clinical trial?

The World Health Organization defines a clinical trial as: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

For further information, refer to the Wellcome Trust's clinical trials policy statement.

If your proposal involves a clinical trial, you should provide details of it within this application form. If your proposal involves more than one clinical trial, please contact the Wellcome Trust for guidance.

Clinical trial details

What are the proposed participating centres, and the roles of the clinical trial team members? Provide details of any activity to be undertaken by a third party, and comment on the plans to ensure the presence of a formal contract.

(200 words max.)

Please describe the study design, including planned interventions (experimental and control), duration of treatment, and any potential significant risks to participants. Details of any investigational product should be provided with particular regard to manufacture, quality and consistency.

(300 words max.)

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Describe the inclusion/exclusion criteria. What are the proposed methods for protecting against sources of bias? What are the proposed arrangements for allocating participants to trial groups? (200 words max.)

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What are the envisaged primary and secondary outcome measures, and how will these be assessed at follow up? Describe the proposed frequency and duration of follow up and any anticipated problems with non-compliance and/or loss to follow up. (200 words max.)

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Detail and justify the sample size and proposed statistical analysis, including any interim analyses and/or subgroup analyses. Outline and justify the strategy for recruitment. (200 words max.)

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How have patients, patient advocacy groups or communities been involved in developing the clinical aspects of this proposal? (300 words max.)

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Describe anticipated regulatory and governance approvals, and the proposed arrangements for trial management. What is the proposed membership of the Trial Steering Committee and the Data Monitoring and Ethics Committees? (200 words max.)

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You may submit up to two A4 pages of additional information (such as graphs, figures, tables and essential unpublished data).

The additional information (such as graphs, figures, tables and essential unpublished data) provided in support of the research proposal may be embedded in the text of your file upload or attached here as a separate file. If you choose to embed this information, any text present (such as legends, labels, or captions) can be excluded from the word count.

Please note that this form asks for all the information we require to consider your application. You should not provide additional information (e.g. letters of support) unless specifically requested in the form.

Strategic goals

Which of our strategic goals will your proposal advance?

Select all that apply

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You are not required or expected to advance each goal, though we're interested to know if your proposed work would do so.

Capacity building

Explain how your work would build the number and capacity of planetary health researchers. (100 words max.)

This could be through training of early-career researchers, expanding the focus of established researchers, or in other ways.

Shifting the centre of gravity to the global South

Explain how your work would engage researchers and/or practitioners from low- and middle-income countries or otherwise benefit the populations in such countries. (100 words max.)

Interdisciplinarity

Explain how your work would embody interdisciplinarity. (100 words max.)

OPOH aims to support and advance research that combines biomedical and epidemiologic approaches with those of earth, atmospheric, and ecological sciences, and with those of social sciences and economics.

Making a difference

Explain how your work would be relevant to policy or practice and how, if translated, it would help promote health, well-being, and/or environmental sustainability. (100 words max.)

OPOH favours policy-relevant research that is likely to contribute to making a difference in practice.

Outputs management and sharing

Will the proposed research generate outputs of data, software, materials or intellectual property that hold significant value as a resource for the wider research community?

As set out in our Data, Software and Materials Management and Sharing Policy, all Wellcome-funded researchers are expected to manage their research outputs in a way that will achieve the greatest health benefit, maximising the availability of research data, software and materials with as few restrictions as possible. If your proposed research is likely to generate significant outputs - data, software, materials and/or intellectual property - that will hold clear value as a resource for others in academia or industry, you are required to provide an outputs management plan.

Our guidance on developing an outputs management plan sets out the circumstances under which such a plan is required and gives an overview of what you should consider.

Your plan should be clear, concise, proportionate and focus specifically on how outputs will be identified, managed and then used to advance potential health benefits. You should set out and address clearly the following:

- 1) For significant data, software and materials outputs
 - (i) What significant outputs will your research generate?
 - (ii) When do you intend to share these outputs?
 - (iii) Where will you make these outputs available?
 - (iv) How will they be discovered and accessed by others?
 - (v) Are limits on sharing required?
 - (vi) How will these outputs be preserved?

2) For intellectual property outputs
 (i) What IP will your research generate?
 (ii) How will you protect this IP?
 (iii) How will the IP be used to achieve health benefits?
 (iv) Provide the name and contact details for the person in your organisation (e.g. Technology Transfer Officer or Business Development executive) who can act as a point of contact for Wellcome in connection with the protection and commercialisation of this IP.

3) Describe any resources that you will need to deliver your outputs management plan.

Please note that regardless of whether or not a plan is required, you must ensure that data and original software underlying published research findings are accessible at the point of publication.

Which approach do you intend to use to maximise the impact of your significant research outputs to improve health and benefit the wider research community?

Please provide an outputs management plan. Ensure this describes any significant data, software, materials or intellectual property outputs, their management, and resources required (refer to guidance).
 (700 words max.)

Please refer to guidance for the above question: 'Will the proposed research generate outputs of data, software, materials or intellectual property that hold significant value as a resource for the wider research community?'

Location of activity

Will the funded activity take place at more than one location?

It is important that we are able to track the countries and organisations where research activity is taking place and the approximate proportion of funds that will be spent at each location.

You should list any locations where you will be conducting research or redirecting funds outside of the administering organisation. This includes, but is not limited to, anywhere in receipt of indirect funding, fieldwork sites, and time spent working in another institution/laboratory. This does not include conference attendance.

Salary costs, if requested, should be attributed to the employing organisation.

For each location, select the country and, where applicable, state the organisation (please include the administering organisation). Indicate the approximate percentage of the total funds that will be spent in each location, entering zero for locations where activity will take place but no significant funds will be spent. Salary costs, if requested, should be attributed to the employing organisation.

Country	Organisation	Percentage of funds

Costs requested and justification

Please select the currency in which you wish to apply.

It is expected that costs within the application will be submitted in the currency which, in the view of the applicant(s), best

enables the activity to be undertaken. In the majority of cases, the currency specified is likely to be the local currency. Where this is not the case, please explain the reasons for selecting the chosen currency.

Please refer to the Wellcome Trust's website for further information regarding selecting a currency.

If at any point, the Wellcome Trust is unable to award in the currency requested, discussions will be held with the administering organisation to decide whether an alternative currency should be used. If you have any concerns that the currency you would like to request may not be readily available, please contact the Wellcome Trust by e-mailing: grantpayments@wellcome.ac.uk.

Is the selected currency your local currency?

What is your local currency?

Please state clearly the reasons for requesting costs in the selected currency and the exchange rate used (100 words max.)

Salaries

Are you requesting salaries?

Please refer to guidance notes and definition of terms for further details

Please include the full employment costs for all staff requested.

Definition of terms

Staff category: For example: "Postgraduate research assistant", "Postdoctoral research assistant", "Technician", "Fieldworker". Please specify level of seniority of the post where relevant, e.g. "Junior postdoctoral research assistant", "Senior postdoctoral research assistant".

Salary grade/scale: The national or local salary grade/scale on which the individual will be employed.

Basic starting salary: Annual salary to be paid to the individual upon their appointment to the post, exclusive of any allowances for which the individual is eligible. If the post is part time, the annual salary should be quoted on a pro rata basis.

Total cost on grant: Total cost of the post, inclusive of any locally-recognised allowances (e.g. London allowance), employer's contributions and increments, over the period of the grant. Employer's contributions should include any statutory obligations (e.g. for the UK, National Insurance contributions) and contributions towards an organisational pension scheme.

Salaries / Stipends

Staff category	Name (if known)	Basic starting salary (p.a.)	Salary grade / scale	Period on project (months)	% time	Total

Are you requesting salary recovery?

Please upload a letter from a senior member of each organisation requesting research salary recovery costs. The letter should confirm that your salary must come from external grant funding, and that the amount of salary you are asking for is proportionate to the amount of time you will spend on the grant.

If there is more than one letter, please submit these as a single PDF.

Materials and consumables

Are you requesting materials and consumables?

Materials and consumables

Description	Total

Equipment

Are you requesting equipment or equipment maintenance?

The organisation's Director of Procurement/Head of Purchasing (or equivalent) should be aware of all potential capital purchases and the organisation is required to use best procurement practice when purchasing equipment funded with Wellcome Trust funds.

Equipment to be purchased

The Trust expects applicants to consider the cost-effectiveness of the proposed purchase of equipment. The estimated price of the equipment should cover all aspects including delivery, installation, maintenance and training, where appropriate. Discounted prices should be quoted wherever possible. A copy of at least one formal quote is required for each piece of equipment with a list price of £100,000 or more. The level of discount that has been negotiated should be clearly stated in the quote.

A contribution from the host organisation, or other source, will normally be expected where the application includes a substantial equipment request. Please refer to the scheme webpage for further details.

If there is a preferred manufacturer for certain items of equipment, you may enter this detail in the 'Type of equipment' field.

It is expected that the equipment requested will be covered by the manufacturer's warranty for the first year after it is purchased. The Wellcome Trust will fund reasonable maintenance costs for four years after the initial period of warranty on all equipment (irrespective of the length of award made), where this is negotiated as part of the capital purchase cost. In cases where support is being requested for a period greater than 60 months, consideration will be given to providing maintenance funds for equipment more than five years old only if the applicant can demonstrate that it is cost-effective to do so.

Value Added Tax (VAT)

For grants to be held in the UK, the costs of all equipment to be used for medical and veterinary research should be quoted exclusive of VAT. For equipment that does not fall within this definition, VAT costs should be shown.

Equipment

Type of equipment	No. of items	Cost per item	Cost of maintenance contract	Contribution from other sources	Total

Maintenance for existing equipment

Details of equipment/ facility	Wellcome Trust grant number	Date of purchase	End date of current contract	Total cost of contract	% time on project	Total

Requests for maintenance of existing equipment may be considered if the original grant period has ended. For equipment more than five years old, maintenance costs will be provided only if it is cost-effective to keep maintaining it.

Are you requesting a piece of equipment with a list price of £100,000 or more?	
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Please upload a copy of at least one formal quote

If there is more than one quote, please submit these as a single PDF.

Synchrotron radiation sources Will the proposed research require access to a synchrotron source?	
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We wish to collect data on access to synchrotron sources for information purposes.

Applicants should apply directly to the synchrotron facility they wish to use. These facilities are normally free at the point of access for researchers who are prepared to publish their results in the public domain. If this is not the case for the facility that you have selected, access costs may be requested from the Wellcome Trust.

Which source(s) will you be applying to? (Please select all that apply)

Please specify:

Are you requesting costs from the Trust?	
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These facilities are normally free at the point of access for researchers who are prepared to publish their results in the public domain.

In instances where the costs of travel and subsistence will not be met by the facility, they may be requested from us. Please provide details of these costs in the 'Travel and subsistence' costs section.

Access charges Are you requesting access charges?	
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Please refer to the scheme webpage for information on allowable access charges.

Access charges

Details of equipment/facility	Original source of funding	Wellcome Trust grant number, if applicable	Standard access charge per unit	Specify unit	No. of units to be used for this project	Total

Travel and subsistence Are you requesting travel and subsistence?	
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Items that should be detailed here can include conference attendance and collaborative visits. Where necessary, please state the host organisation.

Conference attendance
Costs to attend academic/scientific conferences, including conference registration fees, may be requested for the Lead

Applicant and any research staff to be employed on the grant, up to the maximum annual amount specified on the scheme webpage. Please specify the amount being requested per person.

Collaborative visits

Where any costs for collaborative visits are requested, please state the host organisation and provide a detailed breakdown of the travel and subsistence costs. The need for the visit, and its duration, must be justified in the application.

Travel and subsistence

Description	Total

Miscellaneous costs	
Are you requesting miscellaneous costs?	
<p>We require a detailed breakdown of the miscellaneous costs requested. Costs that do not fall under any other category should be entered in this section. These may fall under specific subheadings (such as 'Overseas allowances' and 'Research Management costs'); where they do not, please select 'Other' and type a description of the item.</p> <p>Research management and support costs Where research management and support costs are allowed and are being requested, you will need to provide a letter from the Finance Director of each organisation requesting these costs. The letter should provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred.</p> <p>Working abroad If costs are requested for the applicant(s) and/or research staff to be employed on the grant to carry out any of the proposed research abroad, please state the overseas host organisation, and detail the travel costs and other overseas allowances. Allowances should be itemised (e.g. "baggage/freight", "medical insurance"). Further guidance can be found on the scheme webpage.</p>	

Miscellaneous other

Type	Description	Total

Are you requesting research management costs under the miscellaneous costs heading? (for low- and middle-income country organisations only)	
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Please upload a letter from the Finance Director of each organisation requesting research management and support costs. The letter should provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred. These should be uploaded as a single PDF document.

<p>Justification for resources requested</p> <p>Please provide a complete justification for all the resources requested, ensuring that you present this information according to the cost headings requested above. (1000 words max.)</p>
<p>You should present the justification according to the high-level cost headings in this form, e.g. "Salaries"; "Equipment"; "Miscellaneous".</p> <p>Where staff requested will be working in different locations, please indicate where they will be working.</p>

Please include justification of the need for any collaborative/overseas visits and their duration.

Where a piece of equipment exceeds £100,000, please provide details of:

- similar equipment in the applicant's department and adjacent departments, and the reasons why it cannot be used for this particular project;
- any other individuals likely to benefit from use of the equipment.

Summary of financial support requested

	Total
Total	

Full economic costing

Full economic costing (UK organisations only) We do not fund the full economic cost of research proposals, but wish to collect this data for information purposes.

Is your organisation based in the UK?	
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Is your organisation calculating the full economic cost of this proposal?	
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What is the total full economic cost (£)?	
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Please provide the **total** full economic cost of your research proposal. Costs should be inflated at the recognised percentage rate currently used by the organisation.

Research involving human participants, human biological material and identifiable data

Does your project involve human participants, human biological material, or identifiable/potentially identifiable data?	
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The following notes relating to 'Research involving human participants, human biological material and identifiable data' are intended to provide guidance and advice in completing the form, rather than a comprehensive review of the legal and regulatory environment in which the application is made.

The World Health Organization defines research with human subjects as "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or ii) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."

The Wellcome Trust policy position on research involving human participants can be found on the Wellcome Trust website (www.wellcome.ac.uk/wellcome-trust-policy-position-research-involving-human-participants)

Ethical approval (usually from the appropriate National Health Service (NHS) research ethics committees) is required for all Wellcome Trust funded research involving human participants, biological samples or personal data. Personal data (as defined in the Data Protection Act 2018) is any information relating to an identified or identifiable living person i.e. a person who can be identified either directly from that information or indirectly by combining it with other available information. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available

at: http://www.highlights.rsc.mrc.ac.uk/PIHR/index.html#/?_k=opxohv and <https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research>.

Approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK should also be sought where necessary, e.g. research involving human embryos

may require a licence from the HFEA (please refer to www.hfea.gov.uk for more information). If your proposal involves research on gene therapy which requires regulatory approval, approval should be sought from your Local Research Ethics Committee, the University's Genetic Manipulation Committee, the Gene Therapy Advisory Committee and the Medicines and Healthcare products Regulatory Agency (MHRA).

The organisation must ensure that ethical approval is in place at all relevant times during the project. For research carried out at multiple sites, ethics committee approval must cover each site.

Where the research, or part of the research, is to be performed outside the UK, independent ethics review must be obtained. For research involving people living in low and middle income countries, see the Wellcome Trust's website (www.wellcome.ac.uk/funding/managing-grant/guidance-notes-research-involving-people-low-and-middle-income-countries).

Please confirm that you have read the Trust's guidance on the feedback of health-related findings in research and that you are in the process of considering your approach to this.

The Wellcome Trust's guidelines on the feedback of health-related findings in research can be found on the Trust's website.

Please state by whom and when the ethics of the project has been, or will be, reviewed and specify any other regulatory approvals that have been obtained, or will be sought.

We reserve the right to see relevant approval documents at any point during the lifetime of the grant, in accordance with our policy position on research involving human participants.

The following notes relating to 'Research involving human participants, human biological material and identifiable data' are intended to provide guidance and advice in completing the form, rather than a comprehensive review of the legal and regulatory environment in which the application is made.

The World Health Organization defines research with human subjects as "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or ii) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."

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countries).

Is the proposed clinical trial covered by The Medicines for Human Use (Clinical Trials) Regulations in the UK?

Under the Medicines for Human Use (Clinical Trials) Regulations 2004, applicants must identify a sponsor (which will normally be either a university or NHS Trust) who fully understands the responsibilities and costs associated with assuming this role. Please note that the Wellcome Trust cannot act as sponsor.

Please confirm that the trial will be registered on the International Standard Randomised Controlled Trial Number Register (ISRCTN), ClinicalTrials.gov, or on another register listed on the WHO International Clinical Trials Registry Platform (ICTRP).

In the course of your project, do you propose to use facilities within the National Health Service (NHS) or to involve patients being cared for by the NHS?

By agreeing to fund work which requires NHS support, the Wellcome Trust is agreeing to abide by the Statement of Partnership on Non-commercial R&D in the NHS in England (and the corresponding statements in Northern Ireland, Scotland, and Wales). Researchers must therefore meet the obligations of the Partnership and may not carry out any research until the NHS has given its consent.

The Research Governance Framework for Health & Social Care, published by the Department of Health in England can be downloaded from the Department of Health website <http://www.dh.gov.uk/health/category/research>. Please note that the Wellcome Trust cannot act as sponsor.

Is a formal sponsor required for the project, for example under the Medicines for Human Use (Clinical Trials) Regulations or the Research Governance Framework for Health and Social Care and equivalent guidance?

Please indicate which organisation(s) has/have agreed to fulfil this role. Please note that the Wellcome Trust cannot act as sponsor.

If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.

Please answer 'not applicable' if no potentially commercially exploitable results (based on human tissues or samples) will be produced during the course of the proposed research.

Risks of research misuse

Please confirm that you have considered whether your proposed research could generate outcomes that could be misused for harmful purposes.

In preparing research proposals, Wellcome wishes to encourage applicants and their host organisations to consider carefully any risks that the potential outcomes (information, products or technologies) of the research could be misused for harmful purposes. Such purposes would include actions that pose a significant threat to humans, animals, plants or the environment - including terrorist misuse.

Examples of possible research areas that are associated with dual-use risks of this type, include (but are not restricted to) research that aims to:

- demonstrate how to render a vaccine ineffective
- confer resistance to a therapeutically useful antibiotic or antiviral agent
- enhance the virulence of a pathogen or renders a non-pathogen virulent
- increase the transmissibility or alter the host range of a pathogen
- enable the evasion of diagnostic and detection methods
- enable the weaponisation of a biological agent or toxin
- generate or reconstitute an eradicated or extinct agent or toxin

Where there are judged to be **tangible** (i.e. real and non-hypothetical) risks that the proposed research **will itself** generate outcomes that could be misused to cause harm, researchers and organisations should take appropriate steps to monitor the research as it proceeds and minimise these risks. Risk mitigation could include establishing a process to review dual use risks on an on-going basis through the project and to gain independent expert advice as appropriate. Researchers should also ensure that all members of their team are aware of these risks in progressing their research, and receive appropriate education and training on these issues.

The identification of tangible risks in a research project should be clearly balanced against the benefits and value that is to be gained for health, science and society. We recognise that most research could conceivably generate results that might hypothetically be misused at some point in the future, and we are not asking applicants to appraise these kinds of remote and hypothetical risks.

Applicants should refer to the joint BBSRC, MRC and Wellcome policy and position statement on managing risks of research misuse (<https://wellcome.ac.uk/funding/managing-grant/managing-risks-research-misuse>), and our guidelines on good research practice (<https://wellcome.ac.uk/funding/guidance/guidelines-good-research-practice>).

Have you identified any tangible risks of this type?

Please briefly describe these risks and the steps that you and your organisation will take to manage them
(250 words max.)

Freedom to operate/conflicts of interest

Describe any freedom to operate issues or potential conflicts of interest that have been identified or that might arise and how these will be or have been addressed.

In particular, please consider the following:

- Do any of the individuals involved in the project hold any consultancies or equities in, or directorships of, companies or other organisations that might have an interest in the results of the proposed research?
- Will the proposed research use technology, materials or other inventions that are subject to any patents or other form of intellectual property protection?
- Will any element of the research be subject to agreements with commercial, academic or other organisations, including arrangements with collaborators named in the grant application, that might lead to intellectual property issues or restrictions?

(350 words max.)

Please describe any freedom to operate issues or potential conflicts of interest that may affect your ability to carry out the proposed research and/or to comply with the Trust's grant conditions.

Where the proposed research, in whole or in part, is subject to agreements with commercial, academic or other organisations, e.g. Materials Transfer Agreements, the Wellcome Trust will expect a written assurance from the administering organisation that the terms of any such agreement do not conflict with the Trust's grant conditions, particularly in relation to the publication of research and the granting of research rights.

Please refer to the Wellcome Trust's website for our policy on the relationship between Trust-funded researchers and commercial entities: www.wellcome.ac.uk/funding/managing-grant/policy-relationships-between-trust-funded-researchers-and-commercial-organisations.

Details of our policy on intellectual property can be found in our Grant Conditions www.wellcome.ac.uk/funding/managing-grant/grant-conditions.

Applicants should disclose all relevant information pertinent to their grant proposal, including proprietary information where appropriate, in order to provide the most comprehensive picture of their proposed research.

If no issues have been identified, please enter N/A.

Wellcome Trust supported facilities

Will the project be based in one of the following Wellcome Trust supported facilities:

- the Wellcome Trust Sanger Institute
- a Wellcome Trust Centre
- an Africa and Asia Programme
- the Francis Crick Institute?

We are interested to find out about Trust-funded projects based in these facilities and wish to collect this data for information purposes.

Please specify