

Application summary

Application title

This should be the title of your proposed project.

Proposed duration of funding (months)

This scheme enables scholars to undertake three years (36 months) of full-time research. In exceptional circumstances applicants may apply for a maximum of 72 months of part-time research.

Proposed start date

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 based at the administering organisation. If your application is successful, this is the address that will be used in the award letter.

Research funding area

Please select the research funding area for your application

This will help us to route your application to the appropriate grants team when it arrives at the Trust. Please select 'Medical Humanities' if your proposal uses a predominantly humanities approach. Please select 'Social Science and Bioethics' if your proposal uses a predominantly social science approach, or involves a normative, empirical or conceptual ethical enquiry.

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.

Clinical status	
Do you have a medical/veterinary degree?	

Please note that this includes dental and clinical psychology degrees.

Please specify

Are you clinically active?	
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What is your specialty?

Please choose your specialty from the dropdown list – if it is not on the list, select 'Other' and specify.

Please specify

Career breaks

Have you had any career breaks or periods of part-time work, for example parental or long-term sick leave?

We encourage applications from researchers who have taken career breaks, and wish to ensure that any such breaks are duly taken into account when considering your track record. Please state when and for what period of time you took a break, or were working on a part-time basis. We are not seeking any information on the reasons for this break so please do not provide this here, including sharing any sensitive personal health information.

Please provide details

Do you wish to undertake this award part time?

If you wish to undertake this award part time, please contact the Trust to discuss your requirements.

Current education/training

Provide the title of your present degree course and of any other degree(s) held, along with the degree(s) subject courses. Give a detailed specification of modules taken for Master's and of your dissertation topic. Briefly summarise any research projects undertaken as part of the degree during vacation scholarships.
(350 words max.)

Please state the organisation at which you are a final year student, or from which you have graduated. State the dates of attendance and also indicate class of degree if you have already graduated.
(200 words max.)

Reasons for applying

Outline the reasons why you wish to study for a PhD and the career you intend to pursue
(350 words max.)

The Trust does not necessarily expect this to be an academic career path.

Research outputs

List up to 20 of your most significant research outputs, ensuring that at least five of these are from the last five years. For 10 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
- Policy guidelines or briefings

- 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 ID (PMCID) reference for each of these. Please refer to guidance notes.

Publications should be in chronological order with the most recent first. 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.

Please tell us if any publications are:

- in press
- accepted subject to revisions
- submitted or under review

If you have any updates during the application process, please let us know.

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.

Academic or professional recommendation

Please provide a recommendation from an academic referee, or a professional/voluntary equivalent, who is a member of the organisation from which the applicant has graduated/worked, or will graduate. In some cases the academic referee may also be the prospective supervisor, in which case a separate letter of recommendation is not required here.

Is the recommendation from an academic referee?

The uploaded letter should show clearly the referee's name, position and address.

Is the academic referee also your prospective supervisor?

Please upload the letter of recommendation from your professional/voluntary referee (500 words maximum)

Please upload the letter of recommendation from your academic referee (500 words maximum)

Project supervisor(s) recommendation

You may upload a letter of recommendation from any project supervisors, e.g. the supervisor of a Master's scholarship or final year undergraduate project. What aptitude has the applicant already demonstrated for research? (500 words maximum)

The uploaded letter should show clearly the project supervisor's name, position and address.

If there is more than one letter of recommendation, please upload as a single PDF.

Supervisors

Prospective supervisors

You can have more than one supervisor, if appropriate, e.g. for research involving interdisciplinary approaches requiring dual supervision.

1

Prospective supervisor	
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
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Source(s) of personal salary support

Please 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 Council). 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.

Relationship of current application to other work in the supervisor's department (500 words max.)

The supervisor should set out the way in which the applicant and the research project would relate to other work going on in the supervisor's department. The supervisor should describe how the project is similar to other ongoing work and the extent to which it is a new development.

Recent publications

List no more than ten publications that you consider the most important and relevant to this application.

Publications should be in chronological order with the most recent first. Please give citation in full, including title of paper and all authors*.

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

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 grant holder(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.

Supervisor's research and training record

Please note that this information is extremely valuable to the Wellcome Trust and full details should be provided if available.

How many PhD students have you supervised to date?

How many PhD students submitted their theses within three years?

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How many PhD students took longer than four years to submit their theses?

How many students were awarded a PhD?

How many PhD students do you currently supervise? Please list, providing their PhD project start date.

Did any PhD students take longer than four years to submit their theses?	
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State the reasons why PhD students you have supervised took longer than four years to submit their theses, e.g. the award was for longer than three years, the studentship was held overseas or the student was unwell.

State the name, subsequent career and last known position of all the PhD students you have supervised in the last ten years.

Supervisory environment and academic timetable and support

Please identify the particular research training needs of the applicant and indicate how these will be met. Please distinguish between induction, training in methods, techniques, historiography and the teaching of study skills. (200 words max.)

State the regularity of supervision and supervisory procedures you intend to provide, especially during the first and third years of the award. (200 words max.)

Give brief details of other staff with relevant experience to whom the applicant will have access (200 words max.)

State your department's last two RAE/REF ratings

Give brief details of your organisation's facilities, library holdings and support of particular value to

the applicant's proposed topic.
(200 words max.)

Please give details of other grants held by you that relate to the applicant's proposed topic, including their relevance.
(300 words max.)

Provide a timetable of the predicted key stages in the research and academic progression of the student during the period of the Wellcome Trust award.
(250 words max.)

The supervisor should set out a detailed timetable indicating the key stages necessary to ensure the completion of the research and submission of the PhD thesis within the period of the studentship.

Please detail the code of practice for academic support of PhD students currently operating in your organisation. Upload a copy of any published details below.
(500 words max.)

Please provide a summary of any code of practice for the academic and pastoral support of PhD students that is currently operating in your organisation. If there is a published local code of practice a copy of this should be uploaded below.

Upload code of practice here

Recommendation

Please upload your letter of recommendation, stating why and how the applicant has been selected
(500 words maximum).

Sponsors

Sponsor

The sponsor must have a contract of employment (or an honorary academic appointment, where appropriate) at the administering organisation for at least the duration of the studentship.

Should a supervisor leave or be unable to carry out their role, the sponsor must be able to guarantee continued supervision of the student, either by taking over the supervision directly, or undertaking to find another supervisor suitable and willing to take over the training of the student.

In some cases, the sponsor may also be the supervisor.

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Sponsor

Full Name

Department

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

The sponsor must be based at the administering organisation.

Title of current post

Recommendation You may upload a letter of recommendation from the sponsor

Expected date of termination	
<i>The sponsor must have a contract of employment for at least the duration of the proposed studentship.</i>	

Source(s) of personal salary support
<i>Please 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 Council). 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.</i>

Date of appointment	
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Collaborators

Will you require any key collaborators for this proposal?	
<i>These are collaborators who will be making a significant contribution towards the project, for example, assisting with specific elements of the proposed research or providing access to resources. Collaborators are not involved in the day-to-day execution of the project.</i>	
<i>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.</i>	

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

Is this or a similar application for funding currently under consideration elsewhere?

The Wellcome Trust will consider a studentship application which is currently under consideration elsewhere. The Trust will not, however, consider more than one nomination for each applicant. You are required to inform the Wellcome Trust of the result of any other application immediately it is known.

You are also 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 Wellcome Trust within the last 24 months?

Resubmissions are only allowed in exceptional circumstances. 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 (200 words max.)

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.

Archival research

Will the research project require access to archives?	
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Please provide a list of archives	
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Have the intended archives been catalogued?	
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Is access guaranteed?	
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Details of research project

Detail (a) research focus and/or question(s) to be addressed, (b) why the idea is important, (c) work which has led up to the project, (d) methodology to be used, (e) plan of research including brief timetable and milestones, and (f) relevance of the project to scholarship, policy and/or practice.

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

Please note, this is an example structure. It is intended as a guide and is by no means prescriptive.

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 focus and/or questions

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

(2500 words max.)

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.

Bibliographical references

You should give the citation in full, including title of paper and all authors, in alphabetical order, and include any primary sources to be consulted.

You may provide up to the equivalent of two A4 pages of primary and/or secondary literature relevant to the research project. Please ensure that all references included are pertinent to your research proposal and are cited in full, including all authors, the full title of each publication, journal title, year, volume and pages. Citations to preprints should state "Preprint", the repository name and the article persistent identifier (e.g DOI).

References with more than 10 authors may be shortened to et al, but please ensure that your position as author (if applicable) remains clear.

Are there any papers listed in your 'References' section as being "in press" that you wish to submit to us?

Upload papers "in press"

Please submit papers "in press" as a single PDF.

Dissemination of research findings

How do you intend to disseminate the findings and/or outputs of your research to the audience(s) you have identified? Please give details of those audiences.
(250 words max.)

One of the aims of the Humanities and Social Science programme is to encourage the application of research by developing strategies and mechanisms for making research useful to practitioners, policy makers and others. Applicants should therefore give careful consideration to how they will disseminate the research findings to the relevant audiences. Rather than a list of outputs, please detail what sorts of audiences you aim to engage, and describe how you will do so.

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?	
<p><i>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.</i></p> <p><i>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.</i></p> <p><i>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:</i></p> <p><i>1) For significant data, software and materials outputs</i></p> <ul style="list-style-type: none"><i>(i) What significant outputs will your research generate?</i><i>(ii) When do you intend to share these outputs?</i><i>(iii) Where will you make these outputs available?</i><i>(iv) How will they be discovered and accessed by others?</i><i>(v) Are limits on sharing required?</i><i>(vi) How will these outputs be preserved?</i> <p><i>2) For intellectual property outputs</i></p> <ul style="list-style-type: none"><i>(i) What IP will your research generate?</i><i>(ii) How will you protect this IP?</i><i>(iii) How will the IP be used to achieve health benefits?</i><i>(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.</i> <p><i>3) Describe any resources that you will need to deliver your outputs management plan.</i></p> <p><i>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.</i></p>	

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.)
<i>Please refer to guidance next to 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?'</i>

Public engagement

Do you have plans for engaging with the non-academic public about your work?	
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The Wellcome Trust is committed to engaging with society about the research it supports. We aim to foster mutual trust and understanding and place science within a societal, historical and cultural context. Further information is available on the Wellcome Trust's website.

We expect those researchers who receive funding from the Wellcome Trust to help support an environment within which science can flourish by informing, consulting and collaborating with the non-academic public.

Please provide a brief outline of your public engagement plans.
(250 words max.)

Describe your plans to engage the non-academic public about your work beyond press and media activity. Engagement that is essential for the ethical conduct of the research, such as patient information leaflets or community advisory boards, should be part of your research methodology and included within your main research costs.

Please note that we provide support for Wellcome Trust funded researchers to engage with the non-academic public. Do you wish to receive information about training, funding and other public engagement opportunities?

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

Studentship fees Are you requesting studentship fees?	
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State the annual amount of approved university and college fees (if appropriate) at the UK/EC student rate. Include estimates of fees for the second and third years of study.

International fees can only be requested by applicants from low- and middle-income countries.

Studentship fees

Description	Total

Materials and consumables Are you requesting materials and consumables?	
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Materials and consumables

Description	Total

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

Conference attendance

You may request costs to attend academic/scientific conferences, including conference registration fees, up to the maximum total amount of £5,000.

Collaborative and other visits

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?	
<i>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'); where they do not, please select 'Other' and type a description of the item.</i>	
<i>Working abroad</i> <i>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.</i>	

Miscellaneous other

Type	Description	Total

Justification for resources requested Please provide a complete justification for all the resources requested, ensuring that you present this information according to the cost headings requested above. (300 words max.)

Full economic costing

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, in the context of the 1998 Data Protection Act (Section 3.2, and Annex 3), comprise information about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: <http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/> and <http://www.insight.mrc.ac.uk/2015/02/12/getting-the-best-out-of-biological-samples/>.

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."

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, in the context of the 1998 Data Protection Act (Section 3.2, and Annex 3), comprise information about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: <http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/> and <http://www.insight.mrc.ac.uk/2015/02/12/getting-the-best-out-of-biological-samples/>.

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/).

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.

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/managing-grant/policy-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