### **Application summary**

### **Application title**

This is the title of your proposed project.

### **Proposed duration of funding (months)**

Doctoral studentships for full-time research can last up to three years (36 months). Where there is a good justification, they can be part-time for up to six years (72 months).

### Proposed start date

### Name of administering organisation

If your application is successful, this is the organisation that will be responsible for administering the award.

### Lead applicant's address at administering organisation

If your application is successful, we will use this address in your award letter.

Department/Division

Organisation

Street

City/Town

Postcode/Zipcode

Country

### Research area

Select the most relevant area, based on the key aims of the research. This allocates your application to the relevant Grants team. We may reallocate your application to another area if we consider it appropriate.

Select 'Medical Humanities' if your proposal uses a predominantly humanities approach.

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 app	lica	ant de	tails								
Full Name	е										
Departme	ent										
Division											
Organisa	tio	า									
Address	Lin	e 1									
City/Tow	n										
Postcode	•										
Country											
Telephon	e N	lo.									
Email Ad	dre	ss									
ORCID ID											
ORCID ID	)										
Career hi	sto	rv (cı	ırrent	/most rece	ent first)						
From		To	1110110	Position	, iii iii 3t,		0	Organisation			
110				1 controll			Ĭ	rgumoution			
Educatio	n/tr	ainin	g								
From	То		Quali	fication		Subject	t		Organis	sation	
Clinical s	tatı	us									
			re pro	fessional?							
Indicate		b a a liti	h a a r a	profession							
indicate y	our	neall	ncare	profession							
Are you c	linic	ally a	ctive?								
What is y					last 'Other'	and ana	oif.	.,			
ii your spe	Cla	iity is	HOL OI	i tile list, se	elect 'Other'	and spec	City	y.			
Specify											
Career br			orock	from ross=	rob or one	oriodo -	ıf ∽	art time want.	Thio		
⊤⊓ave vou	ιaκ	enal	neak	nom resea	ren or any p	Jenous o	ıρ	art-time work?	HIIS		

could include periods of parental or long-term sick leave, or if you had caring responsibilities. You can also include any periods where you were unable to work because of the COVID-19 pandemic.

We take breaks from research into account when we consider your track record. State when and for what period you took a break, or were working part-time. We are not asking for the reasons for this break so please do not provide these here, including sharing any sensitive personal health information.

Provide details

Do you wish to undertake this award part time?

We provide flexible research career opportunities. If you're applying for funding, you can request flexible and part-time working. This could be to help you manage family commitments or if you have individual needs which make undertaking an award full time challenging.

We always try to accommodate requests, as long as your employing organisation agrees to the working arrangement. Your Grants Adviser will contact you to acknowledge receipt of your application after the scheme application deadline; you should discuss any flexible working plans with them as early as possible. If you have any questions before you apply, please contact our Grants Information Desk.

### **Current education/training**

Provide the title of your present degree course and of any other degree(s) you hold, along with the degree(s) subject courses. List all modules you took for your Master's and the topic of your dissertation. Summarise any research projects you have undertaken as part of your degree during vacation scholarships.

(350 words max.)

Have you already graduated?

Indicate class of degree

### Reasons for applying

Why do you want to study for a PhD? What career do you want to pursue? We do not necessarily expect this to be an academic career path.

(350 words max.)

### Research outputs

List up to 20 of your most significant research outputs; at least five of these must be from the last five years. For 10 of these outputs, provide a statement describing their significance and your contribution (up to 50 words maximum 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. You can find more information on this in the guidance to this question.

Give the citation in full, including the title of paper and all authors (unless more than 10, in which case please use 'et al', ensuring that your position as author remains clear). Citations to preprints must state "Preprint", the repository name and the articles persistent identifier (e.g DOI).

Include here systematic reviews (e.g. Cochrane Reviews) and meta analyses, but exclude abstracts and literature reviews. We encourage you to include 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.

Only include preprints, complete manuscripts that have been submitted to a preprint repository or service (for example, bioRxiv, PeerJ Preprints, arXiv, SocArXiv or PsyArXiv), if they have a permanent identifier such as a DOI or arXiv identifier. Our open access policy requires all original peer-reviewed research papers, supported in whole or in part by our 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.

We actively monitor compliance with our open access policy and we ask successful applicants 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. You can find further guidance in our open access policy statement and authors' information

# How many peer-reviewed publications have you authored/co-authored? Include systematic reviews and meta analyses but exclude abstracts and literature reviews.

We encourage you to include articles published on open research publishing platforms, such as Wellcome Open Research, providing they have passed peer review.

#### **Current and recent research funding (including Wellcome Trust grants)**

List all research funding you have held in the last five years and any key funding before then.

List the most recent first. State the name of the funder, name(s) of grantholder(s), title of the project, total amount awarded (and how much of this you received), your role in the project, and the start and end dates. State the percentage of your time spent on the research; if the grant is active state the number of hours per week that you spend on the research.

Include details of any recurrent or core funding you have held. Explain your role in obtaining the funding. For example, whether you held them in your own right as lead applicant, coapplicant, or as part of a consortium.

We look at your success in getting research funding when we assess your track record. We also want to understand how this proposal is distinct from other funding you hold.

### Academic or professional recommendation

Upload a letter of support from an academic referee or from a professional/voluntary equivalent. They must be based at the organisation from which you have graduated/worked, or will graduate.

If your academic referee is also your prospective supervisor, you do not need to provide a separate letter of recommendation.

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?

Upload the letter of support from your professional/voluntary referee (500 words maximum)

Upload the letter of support from your academic referee (500 words maximum)

### Project supervisor(s) recommendation

You may upload a letter of support from any project supervisors, such as the supervisor of a Master's scholarship or final year undergraduate project. The letter should explain how you have demonstrated an aptitude 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 support, upload these as a single PDF.

### **Supervisors**

### **Prospective supervisors**

You can have more than one supervisor, if appropriate. For example, for research involving interdisciplinary approaches which needs dual supervision.

<u>·</u>	
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	То	Position	Organisation	

### Source(s) of personal salary support

State all your sources of salary funding (for example, through your organisation's block grant from a

higher education funding body), and the percentage of your salary they contribute.
Relationship of current application to other work in the supervisor's department  How will the applicant and the research project relate to other work in your department? Explain to what extent the project is either similar to ongoing work or is a new development.  (500 words max.)
Recent publications List up to five publications that you consider the most important and relevant to this application. List these in chronological order with the most recent first. Give the citation in full, including the title of paper and all authors (unless more than 10, in which case you may use 'et al', ensuring that your position as author remains clear).
Current and recent research funding (including Wellcome Trust grants) List all research funding you have held in the last five years and any key funding before then.
List the most recent first. State the name of the funder, name(s) of grantholder(s), title of the project, total amount awarded (and how much of this you received), your role in the project, and the start and end dates. State the percentage of your time spent on the research; if the grant is active state the number of hours per week that you spend on the research.
Include details of any recurrent or core funding you have held. Explain your role in obtaining the funding. For example, whether you held them in your own right as lead applicant, coapplicant, or as part of a consortium.
We look at your success in getting research funding when we assess your track record. We also want to understand how this proposal is distinct from other funding you hold.
Supervisor's research and training record Provide full details of your research and training record.
We ask this to understand you have the relevant research and training experience to supervise.
How many PhD students have you supervised to date?
How many PhD students submitted their theses within three years?
How many DhD students took longer than four years to submit their theses?
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? List these students alongside their PhD project start date.
Did any PhD students take longer than four years to submit their theses?
Why did these students take longer than four years to submit their theses? Please do not provide any sensitive personal information here.
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
What research training needs does the applicant have? How will you address these? Distinguish between induction, training in methods, techniques, historiography and the teaching of study skills. (200 words max.)
Lieu often will you most with the applicant, conscielly during the first and third years of the award?
How often will you meet with the applicant, 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
Provide a detailed timetable of the key stages which will ensure the student can complete their research and submit their PhD thesis within the period of the studentship. (250 words max.)
Recommendation
Upload your letter of support, stating why and how the applicant has been selected (500 words maximum).

### **Sponsors**

Sponsoi	S	p	o	n	s	o	ı
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If a supervisor leaves or is unable to carry out their role, the sponsor must be able to guarantee continued supervision and training of the student. This can be by taking over the supervision directly, or by finding another suitable supervisor.

The sponsor may also be the supervisor if they can fulfil the responsibilities of both roles.

As the sponsor, you must have a contract of employment for at least the

<u>1</u>	
Sponsor	
Full Name	
Department	
Division	
Organisation	
Address Line 1	
City/Town	
Postcode	A 0.
Country	
Telephone No.	
Email Address	
Title of current post	
Recommendation You may upload a sponsor letter of support for the ap	plicant.

duration of the proposed studentship.

**Expected date of termination** 

**Source(s) of personal salary support**State all your sources of salary funding (for example, through your organisation's block grant from a higher education funding body), and the percentage of your salary they contribute.

Date of appointment	
---------------------	--

### **Collaborators**

Are any collaborations essential for this proposal? This could be through sharing facilities, providing access to resources (essential reagents, samples, data) or sharing subject-specific knowledge and guidance.

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

I confirm that the collaborators named below 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.

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

You can replace the collaborators named here with suitable alternatives if it is necessary or appropriate to do so.

### Related applications

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

We'll consider your application even if you have a similar application being considered by another funder. However, we will only consider one application from each applicant. If the other funder offers you funding, please tell us immediately. We will usually ask you to decide on that offer within one month. If you decide to apply to another funder with a similar application after you have applied to us, please also let us know.

Provide the name(s) of the funder(s) and the expected decision date(s).

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

Contact us before resubmitting an application.

How is this application different? (200 words max.)

### **Research summary**

### Research summary

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

The summary should be as complete as possible within the word limit. Include key words that best describe the proposito enable text searching.	sal
We will use this as a short abstract and to classify your proposal by subject. We may use it to describe your research our website and elsewhere (we publish summary details of all our awards).	on
Lay summary  Provide a summary of your proposed research for a non-specialist audience. You don't need to oversimplify your research, but try to explain it as clearly as possible. 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. If your application is successful, this summary will be automatically uploaded, without editing, to our website. Take care not to include anything confidential or commercially sensitive.	
We may use this to describe your research on our website and elsewhere (we publish summary details of all our awards).	
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 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 surroundit 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.	as o
Archival research	
Will you need access to archives for your research?	
Provide a list of the archives.	
Have these archives been catalogued?	
Have you been guaranteed access to these archives?	

### **Details of research project**

Below is an example structure for the description of your research project. This is intended as a guide, and is by no means prescriptive. If relevant you may include:

- (a) the research focus and/or question(s) you will address;
- (b) why the idea is important;
- (c) work which has led up to the project;
- (d) the methodology you will use;
- (e) your plan of research including brief timetable and milestones;
- (f) relevance of the project to scholarship, policy and/or practice.

Do not exceed 2,500 words, excluding graphs and figures.

If you do not understand any part of this guidance, contact us for advice.

The word count must not exceed 2,500 words in total, excluding graphs, figures. You may provide your answer to this question in text entry format or as a PDF attachment. If you are uploading your research vision, the uploaded document must be in 11 point Arial font and portrait format.

#### Research focus and/or questions

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

#### Additional information

Figures and additional information cannot exceed 2 A4 pages. Embed it in your upload for your research vision or upload it under 'Additional information'. If you choose to embed this information, any text present (such as legends, labels, or captions) can be excluded from the word count. If it exceeds two pages of A4 we will return your application to you to reduce the amount of information.

You must provide all information pertinent to your grant proposal within the application form. Do not refer to additional unpublished information on personal websites.

(2500 words max.)	

Does your proposal involve human participants?

#### Details of studies involving human participants

Describe the study design. This should include, as applicable:

- number of participants in each group;
- type, frequency and duration of interventions and/or health outcome measures;
- frequency and duration of planned follow up;
- any other activity with potential significant risks to participants;
- details of any investigational product, focusing on manufacture, quality and consistency.

(300 words max.)

Types of health outcomes or interventions can include but are not limited to:

- screening procedures
- collection of biological samples
- · biometric and clinical data
- experimental challenges
- · behavioural treatments
- process-of-care-changes

List the main research questions behind the involvement of human participants. (200 words max.)

Outline the strategy for recruitment and describe the inclusion/exclusion criteria for participants (if applicable). If any of the research will involve groups (e.g. focus groups, witness seminars), outline the rationale for allocating people to groups. (200 words max.)

Detail and justify the power calculation, sample size and proposed statistical analysis, including any interim analyses and/or subgroup analyses. What are the proposed methods for protecting against sources of bias?

(200 words max.)

Describe the supporting personnel and infrastructure that you'll use to deliver the proposed research (for example key support staff, roles of team members, participating centre(s) or facilities). Detail any activities a third party will undertake, and explain what agreements or formal contracts will be in place.

(200 words max.)

Have you involved any related non-academic groups (for example, patients, patient advocacy groups, healthcare professionals, or community groups) in developing this proposal? This is not a requirement but we consider this to be good practice in many contexts. (200 words max.)

#### Additional information

Figures and additional information cannot exceed 2 A4 pages.

You can upload additional information here or embed it in your upload for your proposal. If you choose to embed this information, any text present (such as legends, labels, or captions) can be excluded from the word count. If it exceeds two pages of A4 we will return your application to you to reduce the amount of information.

### Bibliographical references

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. Ensure that all references you include 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. For citations to preprints you 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.

Have you listed any "in press" papers in your References section that you want to submit to us?

Upload 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? Give details of those audiences. (250 words max.)

Through our work in Humanities and Social Science we want to encourage the application of research by developing strategies and mechanisms for making research useful to practitioners, policy makers and others. You should therefore carefully consider how you will disseminate your research findings to the relevant audiences. Rather than a list of outputs, explain what sorts of audiences you aim to engage, and describe how you will do so.

### **Outputs management and sharing**

#### Provide an outputs management plan

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. Our guidance on developing an outputs management plan, which includes a link to some good examples, is available here.

If an outputs management plan is not required, please briefly explain why below. (700 words max.)

Your plan should be clear, concise, proportionate and focus specifically on how outputs will be identified, managed and used to advance potential health benefits.

You should use the following questions as a template for your answer.

- 1. For data, software and materials outputs
- (i) What outputs will your research generate?
- (ii) What metadata and documentation (e.g. the methodology of data collection and way of organising data) will accompany the outputs?
- (iii) When will these outputs be made available?
- (iv) Where will you make these outputs available?
- (v) How will they be discovered and accessed by the research community? (e.g. via presentations/press releases)
- (vi) Are there possible restrictions to data sharing or embargo reasons?
- (vii) How will data and metadata be stored, backed up and preserved?
- (viii) What resources (e.g. financial and time) will be dedicated to outputs management and ensuring all data is findable, accessible, interoperable and reproducible?

If your study involves a clinical trial, please see the clinical trial specific guidance on the webpage. This includes additional points you must specify when your outputs include participant data.

- 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.

Select the approach you will use to maximise the impact of your significant research outputs to improve health and benefit the wider research community. If an outputs management plan is not required, select 'Not applicable'.

### **Public engagement**

How could members of the public and non-academic communities, inform, use, or find value in your

research? (250 words max.)	
We want to foster a culture that values, recognises and better supports public engagement with re applicants are encouraged to apply for additional funds to support their engagement plans through Enrichment scheme. Further information on the scheme and on Wellcome's approach to public en on our website.	n our Research
Engagement that is essential for the ethical conduct of your research, such as patient information advisory boards, should be part of your research methodology. You should include costs for this was research costs.	
Have you discussed your ideas and plan with your institutional Public Engagement Officer (if you have one?)	
Answers to this question are for monitoring purposes only. You will not be penalised for answering strongly recommend you utilise any Institutional public engagement support available in planning y	
Location of activity	
Will the funded activity take place at more than one location? List any locations outside of your administering organisation where you will be conducting research or redirecting funds. This includes, but is not limited to, anywhere in receipt of indirect funding, fieldwork sites, and time spent working in another organisation/laboratory. This does not include conference attendance.	
For each location, select the organisation and then select 'Edit' to add the opercentage of funds. You must include the administering organisation. Enter the approximate percentage of the total funds that will be spent in each locations where activity will take place but no significant funds will be spent. If you salary costs, attribute them to the employing organisation.	ation. Enter zero for
Costs requested and justification	
Costs requested and justification	
Select the currency in which you want to apply. Submit costs in the currency you think will best enable you to undertake the active probably be your local currency; if not, explain why not.	vity. This will
If you think that the currency may not be readily available, email grantpayments@wellcome.org. For see our website.	or more information
If we cannot award in the currency requested, we will talk to your administering organisation about	t using another.
Is this your local currency?	
What is your local currency?	

Explain why you are requesting costs in the selected currency and what exchange rate you have used.

(100 words max.)		
·		
Studentship stipends and Tuition fees Enter the total studentship stipend here; £64,759 if your host institution based outside of London, £72,428 if your host institution is based		
Include any studentship fees requested on a separate line.		
State the annual amount of approved university and college tuition fees (if appround the local provided include estimates of fees for the second and third years of study.	opriate) at the UK/EC student	rate.
International fees can only be requested by applicants from low- and middle-inc	ome countries.	
We will add inflation to your fees – you do not need to add it to your application.		
Studentship fees Description		Total
Justification for studentship fees. (300 words max.)		
	<u> </u>	
Materials and consumables Are you requesting materials and consumables?		
Materials and consumables	·	
Description		Total
Justification for materials and consumables.		

### Travel and subsistence

Are you requesting travel and subsistence?

Include here conference attendance, collaborative visits and other travel related to this grant separately. Where necessary, state the host organisation. Enter the total carbon offset costs requested as a single line under travel and subsistence. Find out more about our carbon offset for travel policy here.

#### Conference attendance

The lead applicant can request costs to attend academic/scientific conferences, including conference registration fees and carbon offsetting the travel, up to a maximum of £5,000. Specify the amount being requested and tell us how you calculated any carbon offset costs.

#### Collaborative visits

If you are requesting costs for collaborative visits, state the host organisation and provide a detailed breakdown of the travel and subsistence costs. You can include the cost of carbon offsetting the travel involved. Justify the need for each visit, its duration and your mode of transport separately, and tell us how you calculated any carbon offset costs.

#### Other travel related to this grant

You can request costs for other essential visits, for example for sample collection and trips to facilities. You can include the cost of carbon offsetting the travel involved. Justify the need for the visit, its duration and your mode of transport separately, and tell us how you calculated any carbon offset costs.

-			
Iravei	and	SIINS	istence
	ana	Jubo	

Description	Total

Justification for travel and subsistence costs. (300 words max.)

Provide a clear breakdown of how costs have been calculated, and quotes where applicable. For example: Hotel London - £100 per night x 5 = £500

### Miscellaneous costs

Are you requesting miscellaneous costs?

Provide a detailed breakdown of the miscellaneous costs requested. Enter costs that do not fall under any other category in this section. These may fall under specific subheadings (such as Overseas allowances); where they do not, select Other and type a description of the item.

#### 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, 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.

### Miscellaneous - other

Туре	Description	Total

Justification for miscellaneous costs. (300 words max.)

Are you requesting overheads under the miscellaneous costs heading?

Upload a letter from the Finance Director of each organisation. If there is more than one letter, upload these as a single PDF.

Each letter must include:

- a full breakdown of costs requested (you can't ask for a percentage of the project costs)
- an explanation of why these costs are necessary for the project
- confirmation that the breakdown is a true representation of the costs incurred.

Are you based at a UK university and requesting overheads on subcontracted costs?

Confirm that the university will not include these subcontracted costs in its annual return for the Charity Research Support Fund.	

Summary of costs requested	
	Total
Total	

### Full economic costing

Is your organisation based in the UK?	
Is your organisation calculating the full economic cost of this proposal?	
What is the total full economic cost of your research proposal (£)? Include inflation in your costs at the percentage rate currently used by your administering 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?

This information is intended to provide advice on how to complete these questions. It is not a comprehensive review of the legal and regulatory environment in which your application is made.

We use the World Health Organization definition of research with human beings: "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:

- are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment
- become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records."

Read our Research involving human participants policy for information on what we expect from the researchers and organisations we fund.

You must have ethical approval for any research Wellcome funds that involves:

- human participants
- human biological samples
- personal data.

The Data Protection Act 2018 defines personal data as any information relating to an identified or identifiable living person. For example, 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, must comply with all relevant legislation where you are working.

You must get approval from other regulatory bodies such as the Human Fertilisation and Embryology Authority (HFEA) or the Gene Therapy Advisory Committee in the UK where necessary. Foe example, research involving human embryos may require a licence from the HFEA (see the HFEA website for more information).

If your proposal involves research on gene therapy which requires regulatory approval, you should apply for this from:

- your Local Research Ethics Committee
- your University's Genetic Manipulation Committee
- the Gene Therapy Advisory Committee
- the Medicines and Healthcare products Regulatory Agency (MHRA).

You must get ethical review in all countries where any part of the research is to take place. Read our guidance for research involving people living in low- and middle-income countries.

You must have all the necessary relevant regulatory and ethical approval in place at all relevant times during the project. These must be in place for every site where research will be carried out.

Confirm that you have read our guidance on the feedback of health-related findings in research and that you are in the process of considering your approach to this.

Who has, or will, review the ethics of the project and when? Detail any other regulatory approvals you have obtained, or will seek.

We reserve the right to see relevant approval documents at any point during the grant and after it has ended. This is in accordance with our research involving human participants policy.

Do you propose to use facilities, staff or patients within the National Health Service (NHS) in the UK?

By agreeing to fund work which requires NHS support, Wellcome agrees 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). You 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. Wellcome cannot act as sponsor.

Have you completed a Schedule of Events Cost Attribution Tool? This must be signed off by an AcoRD specialist. Download a template SoECAT from the NIHR website. Read our guidance on why you need to complete a SoECAT.

Explain why you have been unable to complete a Schedule of Cost Attribution Tool. You can submit your SoECAT whilst we are reviewing your application but Wellcome cannot make a funding decision without it. If you do not have a signed off SoECAT form your research will not receive HRA approval (or equivalent). (100 words max.)

Do you need a formal sponsor 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.

Which organisation(s) has/have agreed to fulfil this role? Wellcome cannot act as sponsor.

### Risks of research misuse

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

Wellcome encourages 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. These 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

Have you identified any tangible risks of this type?

Briefly describe these risks and explain how you and your organisation will manage them. (250 words max.)

Where you judge there are **tangible** (real and non-hypothetical) risks that the proposed research **will itself** generate outcomes that could be misused to cause harm, you (and your fellow researchers and host organisations) must 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. You must also ensure that all members of your 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.

Refer to the joint BBSRC, MRC and Wellcome policy and position statement on managing risks of research misuse, and our guidelines on good research practice.

### Freedom to operate/conflicts of interest

Describe any freedom to operate or other intellectual property related issues that might affect your ability to carry out the proposed research and/or to use, share or commercialise the research outputs. Explain how you will address these.

In particular, consider the following:

Will your research use technology, software, databases, materials or patented inventions

- that are owned or controlled by others and which you do **not** already have written permission to use?
- Will the ownership, use, commercialisation and/or sharing of research outputs with the wider research community, be subject to agreements with commercial, academic or other organisations? This includes arrangements with collaborators named in this application.
   (250 words max.)

Refer to Clause 8 of our Grant Conditions at www.wellcome.org/funding/managing-grant/grant-conditions.

Disclose all relevant information pertinent to your grant proposal, including proprietary information where appropriate, to provide the most comprehensive picture of how any commercial/IP matters may affect the delivery of your proposed research and the subsequent use, commercialisation and/or sharing of your research outputs.

If you are satisfied that there are no issues, enter N/A. If you have fully addressed such issues in your outputs management plan under the question on "Outputs management and sharing", then you may refer to that answer.

Describe any conflicts of interest which might affect your ability to carry out the proposed research and/or to share or commercialise the research outputs. Explain how you and your organisation will manage these and how you will comply with your organisation's requirements in relation to conflicts of interest.

In particular, consider the following: Does anyone involved in your project hold any consultancies, advisory roles, or equities in, or directorships of, companies or other organisations that might have an interest in the results of your proposed research?

Confirm in each case whether the conflict has been disclosed to your organisation. (250 words max.)

Refer to our policy on conflicts of interest related to Wellcome-funded researchers and commercial organisations: www.wellcome.org/funding/managing-grant/policy-relationships-between-trust-funded-researchers-and-commercial-organisations.

If you are satisfied that there are no issues, enter N/A.

### Carbon offset for travel

Are you requesting costs to offset the carbon emissions involved in your travel?	
How much are you requesting for carbon offset costs ()? You must also enter this amount under travel and subsistence in the 'Costs requested' section.	
How much carbon will this offset (in tonnes)?	
Are you requesting costs for alternatives to travel, so you can travel less?	
How much are you requesting for these alternatives ()?	
How much carbon will you save by using alternatives to travel (in tonnes)?	

### **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?

Specify		

