

Application summary

Application title

This is the title of your proposed project.

Proposed duration of funding (months)

Collaborative Awards can last up to five years (60 months).

Proposed start date

This date must be at least six months after the full application deadline.

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.

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	

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

Education/training				
From	To	Qualification	Subject	Organisation

<p>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. Answer 'not applicable' if you are not currently employed.</p>
<p><i>Your source of salary may affect your eligibility - please check the scheme webpage.</i></p> <p><i>If your source of salary places any restrictions on intellectual property rights or publications arising from your research, contact us as this may also affect your eligibility.</i></p>

<p>Clinical status Do you have a medical, veterinary, dental or clinical psychology degree?</p>	
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Specify

Are you clinically active?	
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<p>What is your specialty? If your specialty is not on the list, select 'Other' and specify.</p>

Specify

Career breaks

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

We encourage applications from researchers who have taken career breaks. We want to ensure that any such breaks are taken 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.

Career contributions

What are your most important research-related contributions? These may be from any stage of your research career. State what each contribution was, when it came about, why you think it is important and what impact it has had. Examples include publications, patents and impacts on policy. (350 words max.)

Experience relevant to this proposal

Summarise what you consider to be your key achievements and experience and their relevance to this proposal. State which period of your career they relate to. You do not need to list all of your positions. (350 words max.)

Research outputs

Use the link 'Add research output' below to add up to 20 of your most significant research outputs; at least five of these must be from the last five years, if applicable. For up to 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
- Datasets, software and research materials
- Inventions, patents and commercial activity

For original research publications, indicate those arising from Wellcome-funded grants in the statement field when you add your research output. You can find more information on this in the guidance to this question.

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.

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. **Ensure the PubMed Central ID (PMCID) reference is provided for each output.***

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 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 support 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.

Describe how the currently active grants listed above relate to this application. If you hold grants related to the topic of this application, explain how these differ and confirm there is no overlap in funding.

(200 words max.)

This helps us understand how your application is distinct and does not overlap with research activities already supported by other awards.

Time spent on research

How many hours per week do you spend on research?

How many hours per week will you spend on this project?

Applicants

Applicants must be actively involved in the project.

Applicant details

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

Career history (current/most recent first)

From	To	Position	Organisation	

Education/training

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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. Answer 'not applicable' if you are not currently employed.

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Provide details

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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.

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(200 words max.)

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Time spent on research

How many hours per week do you spend on research?

How many hours per week will you spend on this project?

Applicant details summary

Add brief summary details for the lead applicant and each applicant listed above.

Name	Organisation	Role in project
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Name	Organisation	Role in project

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 participate in the proposed research.

What is the difference between a co-applicant and a collaborator?

Co-applicants will have intellectual input into, and part ownership of, the research. Collaborators are individuals named in the body of the application who may, for example, assist with specific elements of the research or provide access to resources, reagents or samples, but who would not normally be involved in the day-to-day running of the work.

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.

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?

We'll consider your application even if you have a similar application being considered by another funder. 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 proposal to enable text searching.

We will use this as a short abstract and to classify your proposal by subject. We may edit your summary and then use it to describe your research on our website and elsewhere (we publish summary details of all our awards).

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.

We may edit your summary and then use it to describe your research on our website and elsewhere (we publish summary details of all our awards).

Example of a lay summary

In response to stress and environmental changes, bacteria generate hundreds of small RNA molecules that have key roles in regulating gene expression. This process of riboregulation involves chaperone proteins that facilitate the actions of regulatory RNAs, and enzymes that affect RNA transcript lifetimes. I aim to understand the molecular basis of riboregulation by taking a multidisciplinary approach. I will use biochemical and structural analyses, including cryoEM and cryoET, to visualise how RNA transcripts are captured and channelled to active sites, either for degradation or processing. I will also identify the RNA targets of chaperone proteins and the degradative machinery, and explore whether the patterns change with physiological state or during the cell cycle, and why. These studies will help to explain how small RNAs enhance the speed and accuracy of bacterial genetic regulation, enriching the capacity of the simplest organisms to exhibit complex behaviour.

Details of research project

Provide full details of your proposal. These should include:

- (a) Aims and research questions;
- (b) Essential background;
- (c) Approach;
- (d) Expected outcomes;
- (e) Timetable and milestones, where appropriate.

Do not use more than **5,000** words to describe your proposal (excluding graphs, figures, references).

Provide all relevant information within the application form; do not refer to additional unpublished information on personal websites. If you do not understand any part of this guidance, contact us for advice.

*The word count must not exceed **5,000 words** in total, excluding graphs, figures, references. You may provide your answer*

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. If you are including figures refer to the guidance notes to this question, 'Additional Information', and do not exceed the equivalent of two A4 pages of these.

If more than one organisation will be involved in the project, indicate what work will be undertaken at each organisation.

Approach and methods to be used in investigating this problem

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

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

Details of experimental design for animal studies should be provided as part of the justification for animals in the 'Proposals involving animals' section of the form.

Additional information

You may provide up to two A4 pages of additional information, such as figures, graphs or additional unpublished data. Embed it within the text of your upload for your research proposal or upload it separately 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 the embedded information exceeds the equivalent of two pages of A4 we will return your application to you to reduce the amount of information.

(5000 words max.)

Does your proposal involve human participants?

Does your proposal involve a clinical trial?

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

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

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

Details of studies involving human participants including clinical trials

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 restricted to:

- screening procedures
- collection of biological samples
- biometric and clinical data
- experimental challenges
- behavioural treatments

- *process-of-care-changes*

What are the primary and secondary outcome measures, and how will you assess these?
(200 words max.)

Outline the strategy for recruitment and describe the inclusion/exclusion criteria for study participants (if applicable). What are the proposed arrangements for allocating participants to study 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 will be used to deliver the proposed research (for example key support staff, roles of team members, participating centre(s) or facilities). Detail any activity a third party is undertaking, and explain what agreements or formal contracts will be in place.
(200 words max.)

How have you involved patients, participants, patient advocacy groups or communities in developing this proposal?
(200 words max.)

Additional information

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

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

This form asks for all the information we need to consider your application. Do not provide extra information (such as letters of support) unless we ask for them.

Key references

Give the citation in full, including title of paper and all authors.

You may provide up to the equivalent of two A4 pages of references. Ensure that your references are pertinent to your research proposal and are cited in full. Include all authors, the full title of each publication, journal title, year, volume and pages. For citations to preprints, state Preprint, the repository name and the article persistent identifier (for example DOI).

You can shorten references with more than 10 authors to et al, but you must 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.

Team composition and management

Describe why a collaborative approach is necessary for this project, the roles of all applicants and how the project will be managed and led.

(500 words max.)

Host organisation(s)

Describe the commitment/contribution, if any, that the host organisation(s) will make to this project.

(500 words max.)

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?

Our Data, Software and Materials Management and Sharing Policy states that all Wellcome-funded researchers must 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.

Select the approach you will use to maximise the impact of your significant research outputs to improve health and benefit the wider research community.

Provide an outputs management plan

Our guidance on developing an outputs management plan sets out where such a plan is required and gives an overview of what you must consider.

(700 words max.)

Your plan must be clear, concise, proportionate and focus specifically on how you will identify outputs, manage these and then use them to advance potential health benefits. Set out and address clearly the following:

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

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

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

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.

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 research. Successful applicants are encouraged to apply for additional funds to support their engagement plans through our Research Enrichment scheme. Further information on the scheme and on Wellcome's approach to public engagement is available on our website.

Engagement that is essential for the ethical conduct of your research, such as patient information leaflets or community advisory boards, should be part of your research methodology. You should include costs for this within your main research costs.

Have you discussed your ideas and plan with your institutional Public Engagement Officer (if you have one?)	
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Answers to this question are for monitoring purposes only. You will not be penalised for answering 'no'. However, we strongly recommend you utilise any institutional public engagement support available in planning your approach.

Location of activity

<p>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.</p>	
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For each location, select the country and, where applicable, state the organisation. You must include the administering organisation.
 Enter the approximate percentage of the total funds that will be spent in each location. Enter zero for locations where activity will take place but no significant funds will be spent. If you are requesting salary costs, attribute them to the employing organisation.

Country	Organisation	Percentage of funds

<p>Will you require funds to be awarded directly to more than one location? If necessary, we can award a grant to more than one location. If you are requesting funds to be awarded directly to more than one location, state the</p>	
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location when providing detailed costs in the 'Costs requested' section.	
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For each location, select the country, state the organisation and enter the value and currency of funds. You must include the administering organisation.

Country	Organisation	Value of funds	Currency
			-

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 activity. This will probably be your local currency; if not, explain why not.

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If you think that the currency may not be readily available, email grantpayments@wellcome.ac.uk. For more information see our website.

If we cannot award in the currency requested, we will talk to your administering organisation about using another.

Is this your local currency?	
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What is your local currency?	
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Explain why you are requesting costs in the selected currency and what exchange rate you have used.
 (100 words max.)

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<p>Salaries Are you requesting salaries? For details of what staff costs you can request, refer to the relevant scheme page and check the guidance notes for this question.</p>	
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Include the full employment costs for all staff requested.

Provide the names of individuals for posts involving the handling of, and research on, non-human primates. Whilst your application is being considered, you must notify us of any change to the individual(s) named in the application.

Definition of terms

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

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

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

Total cost on grant: Total cost of the post, inclusive of any locally-recognised allowances (for example, London allowance), employer's contributions and increments, over the period of the grant. Employer's contributions should include any statutory

obligations (e.g. for the UK, National Insurance contributions) and contributions towards an organisational pension scheme.

Salaries / Stipends

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

Justification for personnel

Specify the role and responsibilities for the staff requested. Justify the type and seniority, including the level of salary requested, of each post.

You must also provide this information for any requests for replacement lecturers' and applicants' salaries.

(500 words max.)

If any staff requested will be working in different locations, indicate where they will be working. If you are requesting funds to be awarded directly to more than one location, you must indicate in the cost breakdown where the funds are to be allocated.

Materials and consumables

Are you requesting materials and consumables?

Materials and consumables

Description	Total

Justification for materials and consumables.

(500 words max.)

Animals

Are you requesting animals?

In order to ensure animal experimentation costs are accurate, you must complete this section after consultation with your animal house or biological services manager. Your organisation must apply a consistent costing methodology when presenting cost details.

We may ask for more detailed costing information where a large number of animals and/or substantial costs are involved.

Animals

Animal species	Total no. to be purchased	Total purchase cost	Total maintenance and procedures cost	Total

Animal associated costs

These costs cover specific and relevant training and environmental enrichment, including training for animal husbandry, welfare and associated training for animal technicians, and the cost of animal licences.

Associated animals costs

Description	Total

Justification for animal costs. (500 words max.)

Do not include a justification of the animal numbers you require; you can explain this in the 'Proposals involving animals' section.

Equipment	
Are you requesting equipment or equipment maintenance?	

The organisation's Director of Procurement/Head of Purchasing (or equivalent) must be aware of all potential capital purchases and we require organisations to use best procurement practice when purchasing equipment with Wellcome Trust funds.

Equipment to be purchased
We expect you to consider the cost-effectiveness of the proposed purchase of equipment. The estimated price of the equipment must cover all aspects including delivery, installation, maintenance and training, where appropriate. We expect discounts to be negotiated and included in quoted prices. If there is a preferred manufacturer for certain items of equipment, you can explain this in the 'Type of equipment' field.

We expect that the equipment you request will be covered by the manufacturer's warranty for the first year after it is purchased. We will fund reasonable maintenance costs for four years after the initial period of warranty on all equipment (irrespective of the length of award made), where this is negotiated as part of the capital purchase cost. We will also consider requests for the maintenance of equipment over five years old if you can demonstrate that it is cost-effective .

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

Equipment

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

Equipment maintenance

We consider requests for maintenance of existing equipment if the grant that funded its purchase has ended. We only provide maintenance costs for equipment more than five years old if it is cost-effective to keep maintaining it.

Maintenance for existing equipment

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

Justification for equipment and equipment maintenance.
(500 words max.)

If you are requesting a piece of equipment which costs more than £100,000, provide details of:

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

Are you requesting a piece of equipment with a list price of £100,000 or more?

We require a copy of at least one formal quote for each piece of equipment with a list price of £100,000 or more. The discount that has been negotiated must be stated in the quote. We expect a contribution from the host organisation, or other source, if your application includes a substantial equipment request.

Upload a copy of at least one formal quote; if you have more upload these as a single PDF.

Synchrotron radiation sources

Will you need access to a synchrotron source?

We collect data on access to synchrotron sources for information purposes.

Apply directly to the synchrotron facility you want to use.

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

Specify:

Are you requesting costs from us relating to synchrotron radiation sources?

These facilities are normally free for researchers who are prepared to publish their results in the public domain. If this is not the case, you can request access costs in the 'Access charges' section. You can also request related costs for travel and subsistence in the 'Travel and subsistence' costs section.

Access charges

Are you requesting access charges?

You can ask for the cost of access to shared equipment or facilities if they're essential to your research project. These may include materials and consumables, plus a proportion of:

- maintenance and service contracts;
- staff time costs for dedicated technical staff employed to operate the equipment or facility.

We don't cover the costs of:

- estates and utilities;
- depreciation or insurance;
- other staff e.g. contributions towards departmental technical, administrative and management staff time.

If the facilities or equipment were paid for by a Wellcome grant, you can only ask for access charges if:

- the grant has ended;
- any support for running costs and maintenance contracts has ended.

Access charges

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

Justification for access charges.
(300 words max.)

Travel and subsistence

Are you requesting travel and subsistence?

Include here conference attendance and collaborative visits. Where necessary, please state the host organisation.

Conference attendance

The lead applicant and any research staff to be employed on the grant can request costs to attend academic/scientific conferences, including conference registration fees, up to the maximum annual amount specified on the scheme page. Specify the amount being requested per person.

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. Justify the need for the visit, and its duration, in your application.

Travel and subsistence

Description	Total

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

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 and Research Management costs); where they do not, select Other and type a description of the item.

Research management and support costs

Where research management and support costs are allowed and you are including these in your application, provide a letter from the Finance Director of each organisation requesting these costs. The letter must provide a breakdown of the costs requested and confirm that the request is a true representation of the costs incurred.

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. Further guidance can be found on the scheme webpage.

Miscellaneous other

Type	Description	Total

Justification for miscellaneous costs.
(500 words max.)

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

Summary of costs requested	
	Total
Total	

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 of your research proposal (£)? Include inflation in your costs at the percentage rate currently used by your administering organisation.	
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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."

Our policy position on research involving human participants can be found on our website.

We require ethical approval (usually from the appropriate National Health Service (NHS) research ethics committees) for all research we fund involving human participants, human biological samples or personal data. Personal data (as defined in the Data Protection Act 2018) is any information relating to an identified or identifiable living person i.e. a person who can be identified either directly from that information or indirectly by combining it with other available information. Any use of personal data or biological samples, relating to living or dead persons, should conform to MRC guidelines available at: http://www.highlights.rsc.mrc.ac.uk/PIHR/index.html#/?_k=opxohv and <https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/>.

You should seek 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, 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, you should seek this 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.

Confirm that you have read our guidance on the feedback of health-related findings in research (available on our website) 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 lifetime of the grant, in accordance with our policy position on research involving human participants.

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>. The Wellcome Trust cannot act as sponsor.

Do you propose to use NHS England facilities, staff or patients?

Have you completed a Schedule of Cost Attribution Tool?
This must be signed off by a local Clinical Research Network AcoRD specialist. Download a template SoECAT here. See our webpage on Excess Treatment Costs for more information.

Explain why you have been unable to complete a Schedule of Cost Attribution Tool. During NHSE's pilot phase (October 2018 – April 2019) 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. (100 words max.)

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?

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

Confirm you have in place or you will seek appropriate informed consent to use any potentially commercially exploitable results from tissues or samples derived from human participants.

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

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

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

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

Describe the oversight arrangements for the clinical trial (e.g. membership of Trial Steering Committee, Data Monitoring Board etc.)

Proposals involving animals

Select any of the following that apply to your proposed work:

The following notes relating to 'Proposals involving animals' 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.

Applicants must refer to the Wellcome Trust's policy on the use of animals in medical and veterinary research on our website.

In all animal experiments we support, the principles of reduction, replacement and refinement will apply. In all experimental

studies, applicants must actively consider:

- the complete replacement of live animals with tissues derived from either animals or humans;
- the possibilities of reducing the numbers of animals that need to be used;
- refining the experimental design in order to obtain the maximum amount of information from the minimum number of animals.

Refined methods in animal research are those which alleviate or minimise any adverse effects for the animals involved, and/or enhance animal welfare. Refinements may be applied at any stage in the life of an animal. Thus, refinement encompasses all aspects of a procedure, including:

- the source, transport, husbandry and environment of the animals involved;
- the experimental design (for example, the choice of species and the group size employed);
- the techniques applied;
- the end points of the procedures; and
- care of the animals before, during and after a procedure.

For further information regarding the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), see www.nc3rs.org.uk

Monoclonal antibodies:

The use of ascitic animals for monoclonal antibodies (mAb) production in vivo may only be proposed when in vitro attempts at mAb production have failed or the use of animals is considered justified for specific diagnostic or therapeutic products. You must give a full explanation if in vitro production methods are not considered to be suitable.

Select any of the following species you will use:
(Primate, Cat, Dog, Equidae, Pig, Genetically Altered Animals, Other animals)

The NC3Rs will review all applications involving the use of primates, cats, dogs and equidae animals, or their tissue/data.

All proposed research projects involving genetically altered mice are expected to consider the principles of welfare assessment set out on the NC3Rs website.

Select 'Add' to enter the animal species and total numbers required (this may differ from the number to be purchased, maintained).

Animal species	Strain (if appropriate)	Total number required to carry out proposed work
-		

Provide a justification of the proposed sample size alongside details of the planned statistical analyses. Describe the experimental design, including any plans to reduce bias such as blinding or randomisation if appropriate. You must include power calculations if appropriate. (1,000 words max.)

You may provide your answer to this question in the field provided (text entry format) or as a PDF attachment (upload format). If you are uploading your answer, the uploaded document must be in 11 point Arial font and portrait format.

For each species, you must ensure that adequate experimental detail is provided to justify both the use and number of animals. This should include:

- definition of unit of analysis (i.e. N referring to animal or sample number);
- means of avoidance of bias (e.g. blinding or randomisation);
- statistical analysis to be used and explanation of how sample and/or group size was derived;
- where repeated measures are used, the number of time points;
- an indication of number of replications of each experiment to mitigate spurious non-replicable results.

You may include tables and figures in this section to help justify animal numbers. You can find additional guidance on designing animal experiments through the NC3Rs Experimental Design Assistant.

(1000 words max.)

Why are the species to be used the most appropriate?
(250 words max.)

It is particularly important to justify the species when an animal is being used as a model for a human physiological or pathological condition.

Does your proposal include procedures to be carried out on animals in the UK which require a Home Office licence?
Your organisation must ensure that research involving the use of animals complies at all times with UK laws and regulations.

Is there a current Home Office Personal Project Licence (PPL) that authorizes the proposed procedures to be carried out in the UK?

Detail your plans and timelines for acquiring the appropriate licence.

Provide the name of the licence holder and the PPL number.

If your proposal involves the use of animals, what would be the severity of the procedures?
You can find guidance on assessing the severity of a procedure on the Home Office website.

Provide details of any moderate, severe or non-recovery procedures
(250 words max.)

Does your proposal involve the use of animals or animal tissue outside the UK?

Confirm that the proposed animal work outside of the UK will comply with the principles of UK law. Animal research conducted outside the UK must, as a minimum standard, be carried out in accordance with the principles of UK law and regulation.

Law and regulatory standards often vary from country to country. If experiments are to be carried out on animals outside the UK, the experiments proposed must be performed to standards which accord with the principles of UK legislation. Furthermore, the housing and care of animals must similarly accord with the standards and principles of UK legislation.

You should refer to NC3Rs guidance on carrying out work abroad and choosing contractors.

Why is animal use necessary: are there any procedures of less severity that could be used?
(250 words max.)

Non-human primates If you are exclusively using already generated tissue or data in the proposed experiments answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and procedures. If a question is not relevant you can answer 'N/A', but we may request additional information if necessary for assessment.

Do the facilities and practices, and the proposed research comply with the principles set out in the 'National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) Guidelines: Primate accommodation, care and use' ?

Explain why not

Will it be necessary to transport the non-human primates (i.e. from breeding facility and within the host organisation environment)?

Indicate approximate journey times and the measures that will be taken to minimise the potential stress during transport.

Provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.

See the NC3Rs guidance on animal housing and husbandry for further details.

Will single housing of the non-human primates be necessary at any time?

Provide a justification for single housing, its duration, and explain what additional resources you will provide to the animals to minimise the impact on animal welfare.

Describe the experimental procedures involved and how any pain, suffering, distress and/or lasting harm will be minimised. Have the procedures been recently reviewed by the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and Animal Welfare and Ethical Review Body (AWERB)?

Will any of the experimental procedures involve food and/or water restriction?

Justify why this is necessary and outline what alternatives have been considered.

Will any of the experimental procedures involve restraint?	
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What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to avoid distress.

What prior experience and training in non-human primate use, care and welfare will you require of the staff named in the application? What provision are you making for continuing professional development in these areas?

Will any of the staff involved require specific training for any of the procedures concerned?	
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Provide details of the training needed and where it will be undertaken.

Cats, Dogs, Equidae and Pigs If you are exclusively using already generated tissue or data in the proposed experiments answer all relevant questions as thoroughly as possible, in particular the questions relating to housing and procedures. If a question is not relevant you can answer 'N/A', but we may request additional information if necessary for assessment.

From where will the animals be sourced?

Will it be necessary to transport the animals?	
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Indicate approximate journey times and the measures that will be taken to minimise the potential stress during transport.

Are animals to be imported?	
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Where animals are to be imported, what journey times have been agreed with the Home Office? Describe the conditions for the animals at the breeding establishment and how the potential stress during transport will be minimised.

Provide details of the housing for the animals, e.g. enclosure size, environmental enrichment.
<i>See the NC3Rs guidance on animal housing and husbandry for further details.</i>

Will single housing of the animals be necessary at any time?	
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Provide a justification for single housing, its duration, and explain what additional resources you will
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provide to the animals to minimise the impact on animal welfare.

Describe the experimental procedures involved and how you will minimise any pain, suffering, distress and/or lasting harm. Have the procedures been recently reviewed by the Named Veterinary Surgeon (NVS), Named Animal Care and Welfare Officer (NACWO) and Animal Welfare and Ethical Review Body (AWERB)?

What adverse effects might the animals experience? List the clinical and other signs that will be monitored, the frequency of monitoring and, where relevant, the humane endpoint criteria established for the study.

Will any of the experimental procedures involve restraint?

What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to avoid distress.

What prior experience and training in animal use, care and welfare will you require of the staff named in the application? What provision are you making for continuing professional development in these areas?

Will any of the staff involved require specific training for any of the procedures concerned?

Provide details of the training needed and where it will be undertaken.

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.ac.uk/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.ac.uk/funding/managing-grant/policy-relationships-between-trust-funded-researchers-and-commercial-organisations.

If you are satisfied that there are no issues, 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?

Specify