# **Application summary**

# Application title

This is the title of your proposed project.

# Proposed duration of funding (months)

Investigator Awards can last up to seven years (84 months).

# Proposed start date

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

You can change your start date if your application is successful. All grant expenditure and activities must be within the grant start and end dates.

# 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	То	Position	Organisation	

Education/training				
From	То	Qualification	Subject	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. Answer 'not applicable' if you are not currently employed.

Your source of salary may affect your eligibility - please check the relevant scheme page.

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.

# **Clinical status**

Do you have a medical, veterinary, dental or clinical psychology degree?

Specify

Are you clinically active?

# What is your specialty?

If your specialty is not on the list, select 'Other' and specify.

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.

# 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;
- 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 you may 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.

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.

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.

# Training record

Name up to five individuals you have trained, if any. State the dates of employment in your group, the position they held (for example, postgraduate student, postdoctoral research assistant) and their current position. Describe your contribution to their career development. (300 words max.)

This helps us assess your contribution to the career development of others. We take into account your career stage.

# **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.)

## **Summary of research over the last five years** Provide a summary of your research over the last five years. (300 words max.)

This helps us assess the progress you have made with the research support you have received. The research does not need to have been funded by the Wellcome Trust.

# Research group size

Indicate the number of people in your research group currently, and projected numbers over the duration of your award. If future numbers are not yet known, provide your best estimate. (300 words max.)

# Joint applications

Is this a joint Investigator Award application?

These awards are open to joint applications from two researchers whose complementary expertise is essential to deliver their shared vision. Both should contribute equally to the development and delivery of the proposed research.

A joint application only needs to be submitted and approved by one of the applicants and their host organisation. Either of the applicants can be the lead responsible for submitting the application.

Joint 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	From To Position Organisation				
Education/training					
From To Qualification		Subject		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. Answer 'not

applicable' if you are not currently employed.

Your source of salary may affect your eligibility - please check the relevant scheme page.

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.

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

# **Clinical status**

Do you have a medical, veterinary, dental or clinical psychology degree?

Specify

Are you clinically active?

# What is your specialty?

If your specialty is not on the list, select 'Other' and specify.

Specify

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# Provide details

# Do you wish to undertake this award part-time?

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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). 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.

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.

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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.

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(200 words max.)

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(350 words max.)

# Summary of research over the last five years

Provide a summary of your research over the last five years (300 words max.)

This helps us assess the progress you have made with the research support you have received. The research does not need to have been funded by the Wellcome Trust.

# Research group size

Indicate the number of people in your research group currently, and projected numbers over the duration of your award. If future numbers are not yet known, provide your best estimate. (300 words max.)

# **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.

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).

Examples of lay summaries:

#### Science:

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.

#### Humanities and Social Science:

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

# **Research vision**

### Describe your research vision

Ensure that this addresses the aims and key research questions, how this research will advance your field and the research approaches you will take (3,000 words maximum). Refer to guidance notes (blue question mark icon, above) before completing this section.

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 3,000 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.

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

#### Aims and key research questions

Describe the key questions that you will address through your proposed research programme. If your research is not driven by an underlying hypothesis, describe how the research will lead to progress in the field.

#### Research approaches

For Investigator Awards in Science, explain your approach to exploring your research questions by describing the key lines of enquiry you will follow, the rationale for your choices and how this plan will enable you to achieve your research vision. Highlight any potential problems and how you might address them. You do not need to include methodological detail; however, you must make clear what you intend to do and how you intend to do it.

For Investigator Awards in Humanities and Social Science, explain your proposed approach and the methodology that you intend to use. Describe the originality of your approach. Make clear how you intend to explore your research questions to achieve your research vision.

For Investigator Awards in Humanities and Social Science, if the research will require access to archives, provide a list of these. Indicate whether the intended archives have been catalogued and whether or not access is guaranteed. You can provide this as part of the allowed additional information.

### Additional information

You may provide up to the equivalent of two A4 pages of additional information. 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 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 require to consider your application. Do not provide additional information, such as letters of support, unless specifically requested in the form. For our Investigator Awards in Humanities and Social Science, you may include the list of the archives if your research requires access to them.

(3000 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 vision. 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.

For our Investigator Awards in Humanities and Social Science, if you need to access archives as part of your research, you may include a list of 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.

# Institutional support

Upload a statement of support on behalf of your host organisation. This must be signed by the most senior authority in the relevant Faculty, School or Division. Refer to the guidance notes to understand what this should cover.

You should discuss your application with the relevant individual(s) at your host organisation at an early stage.

We assess the environment in which you will undertake your research and the nature of the support promised by the host organisation. You must submit a letter of support on behalf of your host organisation. This must express:

- why your organisation considers that you, in particular, merit Investigator Award status;
- how your organisation will support you to achieve the ambitions of your research proposal; and
- how your research proposal complements and addresses your organisation's strategic aims and priorities.

The statement must also confirm:

- the nature of your employment contract and that it complies with our eligibility criteria for an Investigator Award;
- the source of your salary for the duration of the award that the necessary additional space, facilities and
- infrastructure have been agreed and will available to you for the award duration;
- details of any support (financial, administrative, technical or other assistance) that your organisation will provide; and
- for core-funded institutions, that the research is distinct from existing core supported activities, and if awarded would not replace or lead to a reduction in existing core support.

If a reciprocal arrangement is in place between your organisation and the Wellcome Trust, the statement of commitment must also include the required confirmations from the Director of the unit/institute under the reciprocal arrangement.

For Investigator Awards in Science, if you are requesting an international recruitment supplement (IRS), the letter of support must include confirmation that the organisation will match the IRS amount you are requesting from us.

# Outputs management and sharing

# Will your 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?)

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

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 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

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	
location when providing detailed costs in the 'Costs requested' section.	

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.

If you think that the currency may not be readily available, email grantpayments@wellcome.ac.uk. For more information see our website: www.wellcome.ac.uk/funding/guidance/currency-issues.

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

# 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.

Include the full employment costs for all staff requested.

### 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.

### Guidance specific to Investigator Awards in Science

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.

#### Guidance specific to Investigator Awards in Humanities and Social Science

Studentships - Wellcome Trust PhD studentships may be requested on Investigator Awards in Humanities and Social Science. The standard stipend scales are available on the scheme page. If you are requesting these costs you must make clear what the role of the students will be in the research programme.

Research leave ('buy out'/ teaching replacement) - we will consider requests to undertake a period of research leave if sponsored by the head of the department. Your institutional statement of commitment must contain an indication of support for your proposed research leave. We will provide the salary of a temporary lecturer (usually at a lesser level of seniority) and research expenses. This is normally limited to a maximum of 40% of the duration of the grant. Indicate clearly any costs that are associated with research leave.

# Salaries / Stipends

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

# Materials and consumables

Are you requesting materials and consumables?

# Materials and consumables

## Description

# 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.

If appropriate, costings can be clarified under 'Justification for resources requested'.

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 maintenance and procedures cost	Total

Animal associated costs Are you requesting animal associated costs?	
These costs cover specific and relevant training and environmental enrichment, including training for	or animal husbandry,

# welfare and associated training for animal technicians, and the cost of animal licences.

# Associated animals costs

Description

Total

Total

Description	Total

# Equipment

## Are you requesting equipment?

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 costs for the maintenance of equipment over 5 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

Are you requesting 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	current	Total cost of contract	% time on project	Total

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?

### Access charges

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

# Travel and subsistence

Are you requesting travel and subsistence?

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

## 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.

#### Guidance specific to Investigator Awards in Science

International recruitment supplement - if you are requesting an international recruitment supplement (IRS), provide a breakdown of the IRS costs. Do not include the contribution from your organisation For further information on the IRS, please see the scheme webpage.

#### Guidance specific to Investigator Awards in Humanities and Social Science

Conferences, meetings, workshops - you can request funding for symposia/workshops to disseminate research results and findings.

#### Miscellaneous other

Туре	Description	

Are you requesting research management costs under the miscellaneous costs heading? (for low- and middle-income country organisations only)

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.

### Justification for resources requested

Justify these costs under each of the above headings (for example, "Salaries"; "Equipment"; "Miscellaneous").

(1000 words max.)

Before completing this section, check the relevant scheme page on our website for more information on costs we will cover and disallowed costs.

If you are requesting funds for staff based in different locations, tell us where they will be working. If you are requesting funds to be awarded directly to more than one location, state in the cost breakdown where the funds are to be allocated.

Explain the need for any collaborative/overseas visits and their duration.

#### Guidance specific to Investigator Awards in Science

Provide a justification for all animal and animal associated costs. You do not need to justify animal numbers required here; you can include this in the 'Proposals involving animals' section.

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

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

# 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?

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).

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

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

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) has/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: (Proposal involves the use of animals, Proposal involves the use of animal tissue, Neither of the above)

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 (e.g. 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 about the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), please see <u>www.nc3rs.org.uk</u>

### 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 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: https://www.nc3rs.org.uk/experimental-design-assistant-eda

(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?

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

Detail your plans and timelines for acquiring the appropriate licence.

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: https://www.nc3rs.org.uk/news/choosing-contractors-animal-research

Why is animal use necessary: are there any other 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.

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?

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?

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 please 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?

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.

Please see the NC3Rs guidance on animal housing and husbandry for further details: https://www.nc3rs.org.uk/3rsresources/housing-and-husbandry

Will single housing of the animals 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 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

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