Application summary

Application title This is the title of your proposed project.

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	**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 scheme webpage.

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.

Current/last appropriate salary details
If you are currently unemployed give salary details from your most recent employment.

Salary grade

Basic salary (per annum)

Currency

Date of last increment	

Proposed starting salary for Fellow (£)

Clinical status Are you a healthcare professional?	

Indicate your healthcare profession

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

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

Provide details

Do you wish to undertake this award part-time? If you wish to undertake this award part-time, either from the start or part way through the grant, your host organisation must employ you on a part-time basis during that 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.)

Personal statement
How will this Fellowship further your research and career aspirations?
(300 words max.)

Research outputs
List up to 20 of your most significant research outputs; at least five of these must be from the last five years. For 10 of these outputs, provide a statement describing their significance and your contribution (up to 50 words maximum per output).

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

- Peer-reviewed publications and preprints
- 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 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.*

Recommendation by applicant's present sponsor/supervisor Upload a letter of support from your current sponsor/supervisor (500 words maximum).
If your current sponsor or supervisor is not in a position to make such a recommendation (for example, if you have only recently joined the department), then you can use an alternative. This should be someone you have worked with in the past twelve months. *If your current sponsor/supervisor is also your proposed sponsor for your Fellowship, they can write two separate letters or provide all the details in one letter.* *You should upload the letter of recommendation to the system. It must show clearly the sponsor's or supervisor's name, position and address.*

Sponsors

The sponsor must be based at the administering organisation.

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

Title of current post

Date of appointment	

Expected date of termination	

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

Recent publications List up to five publications that you consider the most important and relevant to this application.

Current and recent research funding (including Wellcome 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.

Recommendation Upload your letter of recommendation. As a guideline, this should be a maximum of 500 words.

The sponsor should give an assessment of the calibre of the applicant and why he/she is a suitable candidate for one of these awards.

Are additional sponsors required for your application?	

You will require a sponsor in every additional research environment that you are proposing to work in. This includes different research groups within the same organisation. The sponsor should be a person you are proposing to work with (e.g. the group leader or the principal investigator). Your sponsors should guarantee you access to space and resources and provide relevant scientific guidance for the required period.

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

Title of current post

Recent publications
List up to five publications that you consider the most important and relevant to this application.

Current and recent research funding (including Wellcome 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.

Recommendation
Upload your letter of recommendation. As a guideline, this should be a maximum of 300 words.

This should include an assessment of the value of the visit for the development of the applicant's research programme. We ask that you carefully consider the relationship of the proposed research to the abilities and career aspirations of the applicant. Please also give brief details of how the proposed work relates to other research carried out in the department.

Mentors

Details of proposed mentor
Your mentor should be an experienced researcher, normally based outside your research environment(s). They will provide independent support and advice during your fellowship and be committed to helping you achieve your career aspirations.

1

Name, including title (e.g. Professor, Dr)

Title of current post

Department

Organisation

Country

Supporting statement from proposed mentor
Upload a letter of support from your proposed mentor (300 words maximum).

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.

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 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. If your application is successful, this summary will be automatically uploaded, without editing, to our website. Take care not to include anything confidential or commercially sensitive.

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

Example of a lay summary
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

Detail:
(a) Aims and research questions;
(b) Work which has led up to the project;
(c) Approach and how you will address challenges;
(d) Key stages in your research plans, indicating location and timelines.
Do not exceed **1,400** words.

*The word count must not exceed **1,400** 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 proposal, the uploaded document must be in 11 point Arial font and portrait format.*

Additional information

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

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

Research questions
State what you consider to be the key question(s) that you are addressing. For research that is not driven by an underlying hypothesis, state the impact of the proposed studies.

Approach and methods to be used
You should provide details of experimental design for animal studies as part of the justification for animals in the 'Proposals involving animals' section of the form.

For epidemiological, demographic, case control, cohort and related studies, give a full and detailed analysis of the study design. Include details of any validation already undertaken or rationale for using standard protocols. You should give particular attention 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.

(1400 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 more information read Wellcome's clinical trials policy.

If your proposal involves more than one clinical trial, contact Wellcome for advice.

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 limited 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). How will you allocate participants to study groups?
If your research includes a clinical trial you must also tell us:

- how you will comply with out policy on ensuring the inclusion of under-served groups and
- how your recruitment and retention methods will engage with under-served groups.

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

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

Additional information
Figures and additional information cannot exceed 2 A4 pages.

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

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, including 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 (e.g 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.

Are there any papers listed in your 'References' section as being "in press" that	

you wish to submit to us?	

Upload papers "in press" as a single PDF.

Outputs management and sharing

Provide an outputs management plan
All Wellcome-funded researchers are expected to manage their research outputs in a way that will achieve the greatest health benefit, maximising the availability of research data, software and materials with as few restrictions as possible. Our guidance on developing an outputs management plan, which includes a link to some good examples, is available here.
If an outputs management plan is not required, please briefly explain why below.
(700 words max.)

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

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

1) For data, software and materials outputs

I. What outputs will your research generate?
II. What metadata and documentation (e.g. the methodology of data collection and way of organising data) will accompany the outputs?
III. When will these outputs be made available?
IV. Where will you make these outputs available?
V. How will they be discovered and accessed by the research community? (e.g. via presentations/press releases)
VI. Are there possible restrictions to data sharing or embargo reasons?
VII. How will data and metadata be stored, backed up and preserved?
VIII. What resources (e.g. financial and time) will be dedicated to outputs management and ensuring all data is findable, accessible, interoperable and reproducible?

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

2) For intellectual property outputs

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

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

Research locations

Provide details of each research environment, including your sponsor/research sponsor there. This includes different research groups within the same organisation.

The proposed time spent at each research environment should total 48 months.

1

Name of sponsor/research sponsor You must invite the named research sponsor to participate in your application, under the 'Participants' section of this form.

Organisation

What work will you carry out here? Why did you choose this research environment? (350 words max.)

Proposed time to be spent at research location (months)

Start date (if known)

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 organisation and then select 'Edit' to add the country and percentage of funds. 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.

Research involving human participants, human biological material and identifiable data

Does your project involve human participants, human biological material, or identifiable/potentially identifiable data?	

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

We use the World Health Organization definition of research with human beings: "any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings:

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

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

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

- *human participants*
- *human biological samples*
- *personal data.*

The Data Protection Act 2018 defines personal data as any information relating to an identified or identifiable living person. For example, a person who can be identified either:

- *directly from that information*
  or
- *indirectly by combining it with other available information.*

Any use of personal data or biological samples, relating to living or dead persons, must comply with all relevant legislation where you are working.

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

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

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

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

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

Confirm that you have read our guidance on the feedback of health-related findings in research and

that you are in the process of considering your approach to this.

Who has, or will, review the ethics of the project and when? Detail any other regulatory approvals you have obtained, or will seek. We reserve the right to see relevant approval documents at any point during the grant and after it has ended. This is in accordance with our research involving human participants policy.

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

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

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

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

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

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

Which organisation(s) have agreed to fulfil this role? Wellcome 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 who fully understands the responsibilities and costs associated with assuming this role. This will usually be a university or NHS Trust. Wellcome cannot act as sponsor.

Confirm that the trial will be registered on one of the following:

- International Standard Randomised Controlled Trial Number Register (ISRCTN)
- ClinicalTrials.gov
- 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), see www.nc3rs.org.uk

Monoclonal antibodies
The use of ascitic animals for monoclonal antibodies (mAb) production in vivo should 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: https://www.nc3rs.org.uk/generation-and-breeding-genetically-altered-mice.

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 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?	

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.
Guidance on assessing the severity of a procedure is available from the Home Office website: http://www.homeoffice.gov.uk/science-research/animal-research/

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 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: www.nc3rs.org.uk/3rs-resources/housing-and-husbandry

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 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?	

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.
See the NC3Rs guidance on animal housing and husbandry for further details: https://www.nc3rs.org.uk/3rs-resources/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 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.org/funding/managing-grant/grant-conditions.

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

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

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

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

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

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

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

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

Synchrotron radiation sources

Will you need access to a synchrotron source?	

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

Applicants should apply directly to the synchrotron facility they wish to use.

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

Specify: