Advanced Research + Invention Agency ARIA

Programme Call – Full Proposal Guidelines

How to Format your proposal

- Page count: up to a maximum of 10 pages (including diagrams, excluding references)
- Format: single line spacing, standard character spacing (neither expanded nor condensed)
- Font: Arial. Colour: black. Size: 11-point font or larger
- Margins: At least 0.5" margins all around
- File Type: PDF

Applicants are required to provide a proposal no longer than 10 pages in length that outlines:

Section 1: Programme & Technical

The aim of this section is to gain in-depth, technical information about the project being proposed. This should include:

- A detailed explanation of the proposed idea/solution and how it supports the technical objectives of the chosen pathway.
    + This should be supported by visual aids, preliminary data and/or strong scientific rationale for why what you are proposing would work and how it meets the technical goals of the programme.
    + Please include any required technical information, as specified in sections 2 and 3 of the call for proposals document.
- A comprehensive list of the known technical risks/unknowns standing in the way of achieving the stated goals.
- How the proposed approach is differentiated from commercial or emerging technologies being funded or developed elsewhere.
- Description of the proposed activity of work, key metrics and milestones and any dependencies and assumptions.
- Estimated timelines - applicants should provide a Project Plan for the lifecycle of the project, showing what you plan to achieve for each period of the project.

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- A detailed description of any perceived regulatory, legal and ethical risks along with plans on how these risks might be managed.

Section 2: The Team

This section includes information about the proposed individuals or teams that will conduct the research and management structures. This must include:

- Details of the project team - we want to know who will be doing the work (not just the principal investigator or project lead) and what portion of their time will be dedicated to this project. You could include short bios about each team member (we discourage you from submitting CVs).
- If you intend to collaborate with or rely on any third parties, sub contractors/grantees, who they are and which elements of the project they will support/deliver.
- How you intend to coordinate and manage the teams including any collaborations with third parties.
- Any potential gaps in your core competency which would be required in order to achieve the overall goals.
- We also want to know what motivates you or the team to want to do this project and why you are the right person/team to work on this project.

Section 3: Administrative Response

This section includes information about the budget, intellectual property that you intend to rely on, any perceived conflicts of interest and for non-UK applicants how the proposed project may benefit the UK.

In completing your application you must also provide answers to the following questions. Answers to these questions are not included in the 10 page cap. You should complete these questions in the application portal so there is no need to format these in a specific way.

Application	Guidance
How much funding do you need?	*(Please provide a cost breakdown by completing the spreadsheet here.* *Prior to completing this template you should review ARIA's Eligible cost guidance here.* *The completion of a more detailed costing template will be required prior to contract/grant signature)*
Are you proposing to contribute funding?	*(Where you or your organisation are proposing to contribute funding to the project please let us know how much funding you plan to contribute, who is contributing the funding, is the funding already secured and any other relevant details.* *ARIA will fund 100% of project costs and contribution of funding is not essential however, we welcome proposals that contribute funding in cases when such funding will strengthen the potential success. In these cases, this funding contribution will be considered as part of the overall strength of the project proposal)*
Does your proposal depend on background IP (pre existing)?	*(If Yes, give us an Indication of: What background IP is required, Whether you currently have rights to that IP)*

Have you already secured funding for a similar project or are you currently in the process of seeking support from other funding sources for the same project?	*(If yes, tell us more about the funding you already have or are applying for)*
Any other factors or restrictions that might impact your freedom to operate and deliver the project?	*(Please provide a detailed description of any perceived conflicts of interest with the programme director, import/export or security restrictions that you are aware of)*
How do you envision commercialisation of the proposed project?	*(Please complete and upload a commercial hypothesis for your project using the guidelines here)*
Are you proposing to perform the majority of the proposed project outside of the UK?	Our primary focus is on funding those who are based in the UK. For the vast majority of applicants, we therefore require the majority of the project work to be conducted in the UK (i.e. >50% of project costs and personnel time). However, we can award funding to applicants whose projects will primarily take place outside of the UK, if we believe it can boost the net impact of a programme. In these instances, you must outline any proposed plans or commitments in the UK that will contribute to the programme within the project's duration (note the maximum project duration is 4 years). *Please provide a detailed description of any proposed plans (including a timeline) or commitments)*

Has a suitably authorised member of your organisation approved the submission of this proposal?	*(In the application portal, please select the option that best describes your situation and provide details where required).*
Do you intend to use animals as part of your proposed project (even if you don't intend for us to cover the costs of such research)?	*If yes, applicants will be required to answer the additional questions in the portal (also included in Annex 1 to this document).*
Are you planning on including a clinical trial as part of your proposal?	*If yes, applicants will be required to answer the additional questions in the portal (also included in Annex 2 to this document).*
Additional questions about you/your organisation that can be found in the application portal.	

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Annex 1 - Additional questions for projects that include animals

Note: You can find more information on ARIA's policy on funding animal testing here.

Applicants should design their proposals in line with the above, the NC3Rs guidance and NC3Rs 'Experimental Design Assistant' for experimental design support.

1: Need - Describe (i) the need to use animals as part of your proposal, (ii) the use and current limitations of replacement technologies or non-animal methods in the research area, and (iii) how the proposed animal use is proportionate in light of your research objectives and the potential breakthrough that might be achieved.

2: Location - Specify the location of the proposed animal use (including details of the establishment where that information is available).
(Please note that the appropriate additional NC3Rs questionnaire must be provided alongside your application if (a) the location is outside of the UK and (b) the animals involved are one or more of the following: rodents; rabbits; sheep; goats; pigs; cattle; xenopus laevis and xenopus tropicalis; or zebrafish.)

3: Species - Indicate the choice of species to be used, the rationale for this choice, and the decision making process used.
(Please ensure that you address why the animal species and models being used can address the scientific objectives of your proposal and the relevance to human biology.)
(If you are you intend to use non-human primates you will be required to answer some additional questions be can be found here).

4: Animal characteristics - Indicate the characteristics of the animal(s) to be used, for example, strain or substrain, sexes, age or developmental stage, weight range, genetic modification status, pathogen status, and the rationale for this choice and the decision-making process used.

(Both sexes should be used throughout the research pipeline unless appropriately justified. If the use of only one sex is proposed, please provide a scientific justification for this.)

5: Experimental procedures - Outline the planned experimental procedures, including the frequency, duration and timing of all procedures. Include details of the maximum prospective severity rating (and, for activity undertaken in the UK, with reference to the Home Office severity ratings). For moderate or severe procedures, detail the percentage of animals expected to reach this classification. Provide details of the refinements in place to reduce the pain, suffering and harms to the animals and give information on the expected clinical signs and humane endpoints that will be put in place.

6: Experimental design - Outline the total number of animals required and how this number was reached. Provide details of the (i) control and experimental groups, (ii) the experimental unit, (iii) sample size per group, including a justification for the chosen sample size, and (iv) the methods implemented to reduce confounders during the conduct of the studies (e.g randomisation and blinding strategies). If randomisation or blinding is not used, provide rationale for this. For research generating inferential statistics, provide details of any power calculations used to determine the sample size.

7: Licences and ethical approval - Where the proposed research is to take place:

A. In the UK, please provide details of the Home Office licences in place in respect of the proposed research, researchers, and venue. If the necessary licences under the Animals (Scientific Procedures) Act 1986 are not yet in place, please outline your plans to ensure that such licences are acquired and estimated timelines; OR
B. Outside of the UK, please provide details of any relevant licences in place in respect of the proposed research, researchers, and venue to the extent applicable. If licences or other approvals are not yet in place but will be required, please outline your plans to ensure that such licences are acquired and estimated timelines.

(Please note that it is the responsibility of all applicants to ensure that the appropriate licences and approvals are obtained where this is required. This includes the approval by a

local ethical review process (and, where UK based applicants are undertaking research outside of the UK, additional approval from any relevant UK institutional Animal Welfare and Ethical Review Board). Licences (or amendments to existing licences) do not have to be obtained before your application is submitted to us, but if your application is successful you must have the necessary licences in place before any animal experimentation begins.)

8: Outcomes and analysis - Outline primary outcomes to be assessed and describe the planned statistical analyses.
(Provide details of all the outcome measures taken during the conduct of each study and indicate the primary outcome measure, that is the outcome measure that is used to determine the sample sizes. Provide a description of the statistical analysis methods that will be used, explaining how they relate to the experimental design used and the experimental unit (that is, there is a difference between N samples from one animal, as distinct from one sample from each of N animals, or combining samples from multiple animals), and showing that they are appropriate for the types of data that will be collected. Applicants should consider whether and how to access statistical support.)

Non-human primate questions *(to be answered if you answer yes to use of non human primates in question 3)*

Before answering the questions, please read the NC3Rs guidance on 'Non-human primate accommodation, care and use' and 'Responsibility in the Use of Animals in Bioscience Research'.

1. Provide the name and location of the supplier from where non-human primates will be sourced. State the approximate journey times and the measures in place to minimise transport stress.

2. Will the non-human primates used in this study be the offspring of animals born in captivity (i.e. F2 generation or later)?

3. Provide the name and location of the establishment where the animal work will take place.

4. Provide details of the housing for non-human primates. Include the following:
    a. The enclosure size, including vertical space and space allocation per animal in metres/centimetres.
    b. The flooring type, stating whether the floor is solid and covered with substrate. Note that if the use of solid floors is not feasible due to study restrictions provide the scientific rationale for this.
    c. Representative photographs of the monkey enclosures.

5. What environmental enrichment will be provided for the non-human primates to promote good health and psychological well-being? Include information on the following:
    a. The physical/structural, social, cognitive/occupational and sensory enrichment that will be available to the monkeys in their home environment.
    b. The food-based enrichment that will be available to monkeys to facilitate extended bouts of daily foraging behaviour.

6. Will single housing of the non-human primates be necessary at any time? If so, provide the scientific or veterinary rationale for this. State the duration of the single housing and what steps will be in place to minimise the impact on animal welfare.

7. List the procedures that the non-human primates will experience during this study. Include information on the following:
    - How often the procedure will occur, the number of occasions that the animals will undergo the procedure and how long each procedure will typically last.
    - How the procedures will be refined to minimise the welfare impact on the non-human primates on this study. Examples of welfare refinements include, home cage training for behavioural tasks (Tulip et al. 2017); protective cap for macaque cranial implants, Perry at al. 2020).
    - If the non-human primates will undergo blood sampling or dosing, include the blood volumes and routes of sampling or compound administration.

- If the non-human primates will undergo surgical procedures, include information on the anesthesia and analgesia that will be used and outline the welfare monitoring that will take place during the surgery and the post-operative period.

8. Will any of the experimental procedures involve food and/or water control? If so, include information on the following:
    a. The scientific rationale for why food/water restriction is necessary and what alternatives have been considered.
    b. The food/water restriction schedule and limits. State how these will be set for individual monkeys.
    c. The refinements in place to minimise the welfare impact on the non-human primates. Note that the NC3Rs guidance on Refining food and fluid control in macaques should be implemented.

9. Will any of the experimental procedures involve chemical or physical restraint? Has the use of positive reinforcement to train the animals to co-operate been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to minimise distress. Note that, if relevant to the species, you are encouraged to adopt the best practice recommendations in the handling section of the Macaque Website.

10. What adverse effects might the non-human primates experience? List the clinical and other signs that will be monitored, the frequency of monitoring and where relevant state the humane endpoint criteria established for the study. Note that this information should provide insight into the typical and worst-case scenarios for the welfare of the animals on this study.

11. When were the procedures last reviewed by the Animal Welfare and Ethical Review Body (AWERB), Institutional Animal Care and Use Committee (IACUC) or equivalent?

12. What prior experience and training in non-human primate use, care and welfare do those conducting the research have? What provision is made for continuing professional development in these areas?

13. Will any of the staff involved require specific training for any of the procedures concerned? Please provide details of the training needed, where it will be undertaken and the criteria used to assess competency.

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Annex 2 - Additional questions for projects that include clinical trials

Note: Applicants should design their proposals in line with ARIA's policy here.

Please provide answers to the following questions to assist ARIA in assessing your application for funding. If you cannot answer all of these questions please answer as fully as possible. You will need to complete all questions at a later stage within the project to enable funding of a clinical trial:

1. Which entity will be the intended sponsor?
2. Has the protocol (describing the objectives, design, methodology, statistical considerations, and organisation of a clinical trial) been finalised?
3. What stage of obtaining regulatory/ethical approval have you reached?
4. What is your regulatory strategy, if you have developed one? Do you intend to engage a regulatory consultant to assist with developing this?
5. Are any licences or approvals required to carry out the trial which need to be obtained in addition to regulatory approval of the trial itself?
6. What is the subject matter of the trial? For example:
    a. a new medical device;
    b. an Investigational Medicinal Product ("**IMP**");
    c. an Advanced Therapy Medicinal Product ("**ATMP**");
    d. an existing medicine or medical device for a new indication or use;
    e. an app or software as a medical device; or
    f. something else?
7. Where will the trial take place?
8. How long is the trial expected to take? Are there any factors that may affect this?

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9. Are there any factors that may affect the cost of the trial? Have any assumptions been made in developing the budget?
10. What type of trial is this? (for example - pilot/feasibility trial, trial of a form of screening or treatment, a cohort/cross-sectional study, decentralised clinical trial)?
11. Are there any unusual aspects to the trial design?
12. How many patients will be recruited and in what manner?
13. Who are the key personnel who will work on the trial?
14. How will patient confidentiality/data protection and patient safety (pharmacovigilance) be assured?
15. Will any of the work be subcontracted and has a contract research organisation ("**CRO**") been selected?
16. What will be done with the results of the trial in addition to publication? (Further research, commercialisation etc.)
17. How will any intellectual property in the results be protected?
18. Are there any obstacles (regulatory, logistical, etc) which need to be overcome in order for the trial to proceed? For example, does a drug need to be manufactured, specific intellectual property licensed in, or a key person recruited?
19. Are there any particular risks involved in the trial and how will you approach mitigating them?

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