Advanced Research + Invention Agency

ARIA

Sustained Viral Resilience

Call for proposals

Date: 17 October 2025

V0.1

Advanced Research + Invention Agency ARIA

SECTION 1: Programme Thesis and Overview

This solicitation is derived from the published programme thesis Sustained Viral Resilience, which sits in the ARIA Opportunity Space Sculpting Innate Immunity. We strongly recommend reading both of these documents before proceeding.

Viral infections—both pandemic and endemic—remain a leading cause of health and economic burden in the UK and worldwide. While vaccines significantly reduced disease burden in the 20th century from viruses such as polio, measles, and smallpox, they struggle against viruses that comprise the majority of today's disease burden—including influenza, coronaviruses, HIV, and the next pandemic virus—which are either rapidly mutating, highly diverse, or unknown. As vaccines are most effective when directing the adaptive immune system toward a single, unchanging target, they are ill-suited to the challenge today's viruses pose. In contrast, the innate immune system has evolved to detect and respond broadly to viruses. Medicines that strengthen the innate immune system could therefore offer a more resilient defence against viral threats and transform the landscape of antiviral solutions.

This programme aims to create a new class of prophylactic medicines, termed "sustained innate immunoprophylactics" (SIIPs), that strengthens the innate immune system to confer durable, broad-spectrum protection against respiratory viruses. Tools and insights from innate immunology, synthetic biology, AI, materials chemistry, and systems immunology will be integrated to maximise **precision**, **accuracy**, and **durability**. This programme will include direct research and development as well as the creation and provision of shared resources, tools, and services that support the advancement of these medicines. If successful, this programme will demonstrate a step change in our ability to combat rapidly mutating, diverse, and unknown viruses, building on the legacy of vaccines to continue humanity's march against infectious disease.

Key definitions

Innate immune system – We take an expansive view of what constitutes the "innate immune system." In addition to conventional cellular (e.g., macrophages, dendritic cells, neutrophils, NK cells) and humoral (e.g., complement, interferon, antimicrobial peptides) mediators of innate immunity, we also include physical and chemical barriers, innate-like B and T cells, non-immune sentinel cells, and cellular stress and defence responses.

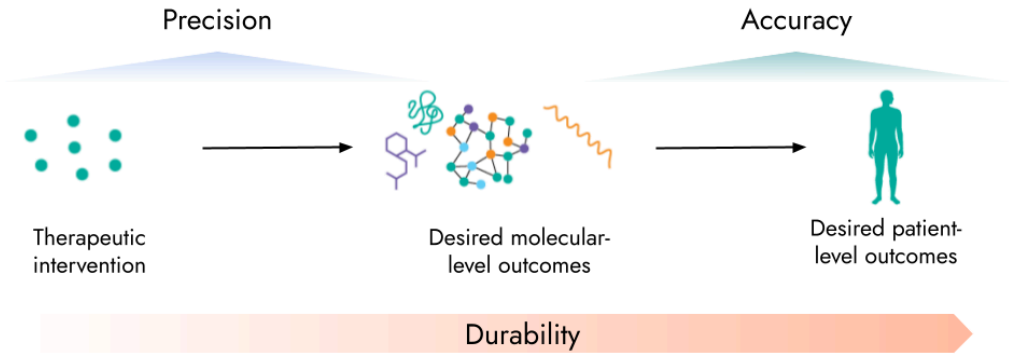
Strengthening the innate immune system – includes stimulating or redirecting pre-existing innate immunity, as well as introducing additional natural or synthetic components of innate immunity, with the aim of providing resilience against viral infection and/or disease.

Precision – the ability to map therapeutic intervention to desired molecular-level outcomes, and not others. Involves biological control, spatial control, and/or temporal control (e.g., drug A will cause a certain amount of upregulation of gene B within tissue C and at time D, with minimal other molecular-level effects).

- Biological control: control over the *nature* and *magnitude* of biological effects that are induced by a therapeutic intervention
- Spatial control: control over *where* the biological effects occur
- Temporal control: control over *when* the biological effects occur

Accuracy – the ability to map molecular-level outcomes to desired patient-level outcomes, and not others (e.g., a certain amount of upregulation of gene B within tissue C and at time D will effectively prevent viral infection with minimal patient-level side effects).

Durability – the length of time for which the therapeutic intervention yields the desired patient-level outcome.



SECTION 2: Programme Objectives

The goal of this programme is to create a new ecosystem of researchers and entrepreneurs dedicated to the development of antiviral sustained innate immunoprophylactics (SIIPs)—prophylactic medicines conferring protection against multiple viruses for months or longer by strengthening the innate immune system. Anchoring this goal is a central programme target: the demonstration of safe and effective prophylaxis for >3 months against respiratory viruses across at least 3 separate viral families with a single course of administration. This programme target should be the "north star" that Creators view their research as collectively enabling us to reach.

This programme seeks teams from across the R&D ecosystem that will be funded by ARIA across three Technical Areas:

TA1 — Explorers

Explorers will most directly aim at the central programme target, with **the overarching goal of providing compelling proof-of-concept evidence that SIIPs are possible**. Explorers will iteratively design, build, and test SIIP candidates for safety and efficacy across *in vitro* and *in vivo* models. We encourage integrated Explorer teams that incorporate all the expertise required to meet the programme target.

TA2 — Accelerators

Accelerators develop tools, platforms, models, standards, or datasets with **the overarching goal of broadly accelerating the process of bringing new SIIP candidates to strong proof-of-concept.**

TA3 — Translators

Translators conduct research that broadly facilitates the clinical translation and future commercialisation of SIIPs, with **the overarching goal of broadly smoothing the pathway from technical proof-of-concept to real-world impact.**

Programme Partners

In addition to the TAs identified above, we plan to solicit programme partners, who will provide programme-specific services directly to our Creators. Examples of this may include

in vivo testing services, computational data analysis services or regulatory consulting services. Applicants to TAs 1-3 will be given the option in their proposal to indicate where partnerships may be valuable to their project (this could be via ARIA's existing Activation Partners or programme-specific partners).

Selection of these programme partners will be subject to a separate solicitation to be completed once Creators for TAs 1-3 have been selected. Organisations interested in becoming a programme partner should not submit a proposal in response to this call. Applicants interested in participating in this element should register their interest by sending an email to clarifications@aria.org.uk and we'll notify you of next steps in late Summer 2026.

Budget

We expect to allocate £46m across this call for proposals, as outlined in the following table. We will consider proposals that fall outside these funding ranges, provided the requested amount is reasonable in relation to the scope of the proposed project.

Technical Area	Expected Budget	Expected Teams
TA1 - Explorers	£34 M	5 (£5 - 8 M each)
TA2 - Accelerators	£10 M	2 (£5 M each)
TA3 - Translators	£2 M	2 (£1 M each)

Interaction between the TAs

Each of these TAs contributes in a complementary way to the maturation of an ecosystem for SIIP development: Explorers by "scouting" pathways to the development of SIIPs, Accelerators by "building roads" from concept to strong proof-of-concept, and Translators by "building roads" from strong proof-of-concept to real-world impact. Overall, we see the Creator community of Explorers, Accelerators, and Translators as the initial seed for the ecosystem that this programme aims to launch.

We expect proposals to be submitted within a single TA. Applicants intending to complete projects in multiple TAs should submit separate proposals to each TA.

We expect our Creators to benefit from frequent interaction across TAs, but each Creator team is designed to be fully integrated and "end-to-end," meaning they contain all the necessary components to complete their project, without being reliant on the outputs of another Creator team.

SECTION 3: Technical Metrics

TA1 — Explorers

Creators in this TA should aim most directly at the programme target: the demonstration of safe and effective prophylaxis for >3 months against respiratory viruses across at least 3 separate viral families with a single course of administration. **To facilitate commercial development, one of these viruses must be either influenza or rhinovirus.**

Safety and efficacy are multifaceted concepts, and we do not wish to prescribe overly specific ways of assessing them. However, we offer the following as guidance on what might be considered as meeting the programme target:

+ **Safety:** A safe candidate has a well-understood mechanism of action and biodistribution pattern, does not induce clinically significant anti-drug antibodies, and is not associated with acute or chronic toxicity, including signs of autoimmunity or autoinflammation. Safety should be assessed a minimum of 3 months after SIIP candidate administration.
+ **Efficacy:** An effective candidate yields a >10-fold reduction of peak viral load in the lungs and/or a >50% increase in survival upon viral challenge compared to controls. Other parameters (weight loss, clinical signs, organ pathology, etc.) may also be measured to provide a fuller picture of candidate efficacy. Efficacy should ideally be assessed 3 months after SIIP candidate administration. Effective candidates may protect against viral disease and/or viral infection.

Since many Explorer teams will be starting at an early stage, we will not require, nor necessarily expect, that proposed Explorer projects advance to first-in-human trials by the end of the programme (although some may). Nevertheless, we believe the programme's impact will largely depend on the confidence it generates in the future clinical success of SIIPs. Thus, while we do not specify the models to use for demonstrations of safe, effective, and durable broad-spectrum antiviral prophylaxis, ideally teams should aim to gather data

that is expected to be as predictive of human clinical outcomes as possible. Explorer teams may choose to select different models to meet this criterion, and may consider a combination of various small animal, large animal, and in vitro and ex vivo tissue models. We encourage the use of in vitro and ex vivo tissue models when possible to add scientific value, e.g. to complement animal studies with an assessment of candidate safety and efficacy in a human biology context. Note that ARIA-funded research must comply with ARIA's policy on research and innovation involving animals, ARIA's policy on research involving human tissue, and ARIA's policy on clinical trials.

TA2 and TA3 – Accelerators and Translators

Accelerators should aim at broadly accelerating the process of bringing new SIIP candidates to strong proof-of-concept, and Translators should aim at broadly smoothing the pathway from technical proof-of-concept to real-world impact.

Due to the diversity of activities encompassed within TA2 and TA3, we expect to refine measures of success on a bespoke basis with each selected Creator. Generally, it is important that TA2 and TA3 projects are developed such that their outputs will be as useful as possible for SIIP development. Thus, Accelerator and Translator teams should be prepared to engage with stakeholders to the extent that this could help shape their research.

SECTION 4: What are we looking for/what are we not looking for

We expect to fund a diversity of approaches in order to foster a vibrant research community and maximise collective progress toward the programme target. We are primarily looking for proposals that may "change the global conversation about what is possible" and whose teams are dedicated to realising the programme goals. Typically, we expect proposals to involve newer approaches or radical (as opposed to incremental) extensions of pre-existing work. Preliminary data and results are not required, although providing in detail your reasoned basis for expected success is encouraged.

For further clarification of approaches within scope, applicants are encouraged to see the definitions in Section 1 of this document of "innate immune system" and "strengthening the innate immune system."

TA1 — Explorers

We expect that the development of SIIPs will require step changes in precision, accuracy, and durability over what is possible with existing innate immunoprophylactics. Key guiding questions that we would expect Explorer teams to consider in their application include:

+ **Precision:** Will the proposed plan deliver candidates incorporating elements of biological, spatial, and temporal control (ideally at least two out of three)?
+ **Accuracy:** Does the proposed development plan include rationale based on existing evidence or plans for experimental assessment for why the targeted innate immune profile would be expected to be associated with broad-spectrum antiviral protection?
+ **Durability:** Will the proposed plan deliver candidates that are in theory compatible with >3-month-long biological activity?

It may be that not all Explorer projects will be directly "translation-ready" by the end of the programme—in particular, because the complexity or cost of manufacturing may be too high. We believe that such projects still provide significant value to the ecosystem, either to provide additional examples to technically de-risk the broader concept of SIIPs, to become translation-ready in the future when manufacturing costs or other factors change, or to incentivise the development of cheaper or simpler alternatives that work by the same mechanism of action. As such, we will be interested in Explorer projects that could technically meet the programme target even if the proposed candidates would not appear to be immediately cost-competitive for further development.

Examples of approaches within scope include (but are not limited to):

+ *Modulation of innate immune cells at the epigenetic level*:
    - E.g., trained immunity inducers
    - E.g., epigenetic editing
+ *Modulation of innate immune cells at the genetic level*:
    - E.g., siRNA targeting negative regulators of innate immunity
    - E.g., gene editing of sentinel cells
    - E.g., DNA encoding natural or synthetic restriction factors or interferon-stimulated genes
+ *Modulation of innate immunity at the protein level:*

    - E.g., synthetic recombinant cytokines such as interferons or interferon mimetics engineered for biological specificity and longer half-lives
    - E.g., sustained release of small molecules targeting innate immune proteins
    - E.g., sustained release of engineered defensin-like antiviral peptides
- *Modulation of innate immunity at the cellular population level:*
    - E.g., induced expansion of innate-like T cells
- Both preclinical and clinical work are in scope.

Examples of approaches out of scope include:

- Traditional approaches to viral prophylaxis relying on adaptive immunity, e.g. broadly neutralising antibodies or vaccines where efficacy relies on the production of antigen-specific B and T cells
- Direct-acting antivirals
- Antivirals targeting host factors unrelated to innate immunity, such as host receptors
- Approaches that could only strengthen innate immunity for much shorter than the programme target calls for, even in principle (e.g., mRNA-encoded IFN)
- *Ex vivo* gene therapy approaches

TA2 — Accelerators

We are open to funding projects across diverse means of accelerating SIIP development to strong technical proof-of-concept. Examples of activities within scope include (but are not limited to):

- *Creation of multi-omics datasets to inform SIIP discovery:*
    - E.g., characterisation of human innate immune responses predictive of protection against symptomatic respiratory viral disease in a challenge or natural infection setting
- *Development of improved models for SIIP testing:*
    - E.g., development of in vitro tissue models that better recapitulate innate immunity in the respiratory tract over the long-term (air-liquid interface cultures, organoids, ex vivo tissues, and organs-on-a-chip with improved immunocompetence and/or long-term durability)
    - E.g., development of advanced in vivo models with humanised innate immune systems

- E.g., advancement of infrastructure for controlled human infection studies

Examples of research out of scope include:

+ Work that accelerates drug or vaccine development in general without distinct utility for SIIP development (e.g., developing foundation models for protein or genome design)
+ Fundamental research on innate immunology with only indirect ties to SIIP development
+ Proposals that strictly provide existing services to our Creators rather than develop something new (these may be better fits for partnerships)

TA3 — Translators

We are open to funding projects across diverse means of ensuring SIIPs have real-world impact beyond demonstrating strong technical proof-of-concept. Examples of activities within scope include (but are not limited to):

+ *Regulatory science and innovation:*
    - E.g., engaging with both SIIP developers and regulators to map regulatory pathways for SIIPs
+ *Health economics research:*
    - E.g., modelling the impact of SIIPs on healthcare systems and recipients, for either endemic or pandemic viruses
    - E.g., payer research
+ *Science communication:*
    - E.g., writing about the scientific and non-scientific challenges and opportunities associated with SIIPs to the general public or other stakeholder audiences

Examples of approaches out of scope include:

+ Work that facilitates the clinical translation or commercialisation of drugs or vaccines in general without distinct utility for SIIPs (e.g., general funding for a start-up incubator)
+ Proposals that strictly provide existing services to our Creators rather than develop something new (these may be better fits for partnerships)

+ Proposals that involve a large amount of laboratory experimental work (these may be a better fit for the Accelerator track)

SECTION 5: Programme Duration and Project Management

Project Duration

The maximum term of the programme is 4.5 years, and no project proposal should exceed this duration. We expect projects within each TA to have the following durations, but we are open to applications outside of these timeframes if reasonable:

+ TA1: 3–4.5 years
+ TA2: 2–4 years
+ TA3: 1–2 years

Project milestones and management

Each project's progress will be monitored using clearly defined milestones. Milestones will first be suggested by the applicant in their proposal. Applicants selected for an award will enter a negotiation phase with ARIA, where the programme team will work with applicants to further refine the project's milestones.

Milestones should:

+ Be specific, measurable, and signify a meaningful step towards reaching the goals of an individual TA as specified in Section 2.
+ Include details on methods used to achieve each milestone.
+ Be defined for the full duration of the project.
+ Be staged such that early experiments maximise the value of information gained to inform future iterations (specifically for projects that will involve multiple iterations of design-build-test cycles).
+ Include major "Go / No-Go" decision points, if applicable.

Progress reviews will occur quarterly and will consist of a written progress update from Creator teams as well as a site visit from the ARIA Programme Team. During each quarterly site-visit, Creators and the ARIA Programme Team will review the agreed upon milestones and discuss further details of each project. As part of that discussion, Creators will be encouraged to think through the following questions:

- Has the milestone for this quarter been met? If not, why not – and what might be mechanisms (possibly unconventional) to get back on track?
- What has been learned this quarter that may inform future stages of the project? E.g., is there a case to be made to pivot or scale up the project?
- Are there any additional resources, tools, or services that you've learned would significantly accelerate your progress?

Written and/or verbal feedback will be delivered to Creator teams following each quarterly review.

In addition to the above, each project will undergo a deeper mid point review, including a rigorous assessment of technical progress. Based on insights gained in the first half of the project, later milestones may be revised where appropriate.

Approach to intellectual property

TA1: Explorers

Explorers will use ARIA's standard approach to Intellectual Property (IP): creators will own any new IP generated as a result of the grant/contract, and will retain full ownership of any background IP they bring to the project.

TA2 and TA3: Accelerators and Translators

As Accelerators and Translators are meant to broadly accelerate SIIP development through the establishment of pre-competitive knowledge or resources, we will pursue a highly open approach to sharing outputs of Accelerator and Translator projects. As such, as a default we'll require any datasets and models to be made publicly available through open access publication.

However, where there is a case to be made for Accelerator or Translator projects to deviate from the above principle, applicants should indicate this in their proposal, and if successful, discussions can be had with ARIA during the negotiation phase. You should note that we will primarily consider exceptions where a commercialisation path is the most effective route to ensure the widespread availability and long-term maintenance of a tool or platform that benefits the entire SIIP ecosystem. In these instances, where Creators wish to patent Intellectual Property (IP) resulting from the projects, they commit to making the patented invention available for licensing to third parties for non-commercial research purposes. The

terms of such licences must be fair, reasonable, and non-discriminatory, reflecting prevailing market norms for non-exclusive research-use licences.

Collaboration between Creators

We expect each Creator team to be fully integrated and "end-to-end," meaning they contain all the necessary components to complete their project, without being reliant on the outputs of another Creator team.Nevertheless, we endeavour to enable all Creator teams to feel that they are a part of a greater whole: the entire programme team of all Creators. Therefore, we encourage collaborative sharing of non-confidential information between Creator teams throughout the programme, facilitated by our regular in-person creator events.

Creator events

In an effort to foster a collaborative research environment, we will host regular community events to allow the Sustained Viral Resilience Creator teams to exchange updates, ideas, and feedback on best paths forward. Creators for all technical areas will be invited to an annual Creator event lasting one or two days. All these events will be held in the UK and Creators are strongly encouraged to attend. Please include an estimation of costs related to attendance at these events in your budget proposals.

SECTION 6: Eligibility & Application process

Eligibility

We welcome applications from across the R&D ecosystem, including individuals, universities, research institutions, small, medium and large companies, charities and public sector research organisations.

Collaboration between Applicants

Many applicants may decide to apply as a consortium consisting of two or more organisations that are proposing a cohesive proposal to work collaboratively. Here, the application should be made by a single lead applicant, to whom the funding will be awarded if successful. Other members of the consortium will be subcontracted/granted by the lead applicant. Note that this does not necessarily mean that the whole consortium stands or falls together – at negotiation stage, we may indicate an intention to fund only certain workstreams or organisations.

Creators who apply as a consortium or otherwise indicate an intention to collaborate with other applicants will be expected to enter into a formal collaboration agreement. A signed term sheet must be executed by the date of the funding contract/grant, and a full agreement must be executed between collaborating organisations within the first quarter of the programme. The agreements must at minimum cover roles and responsibilities, treatment of confidential information, intellectual property and ownership of results, and dispute resolution. If helpful, we can refer applicants to established templates that can be helpful as starting points for these agreements.

Finding potential collaborators and teaming

For those seeking specific expertise to support their proposal, we have created a teaming request form to facilitate finding potential team members who have registered their interest in this programme. By following the link to the sign up form here you will be able to register, submit your details, and gain access to a list of other individuals seeking to find/share their expertise. All requests are screened via ARIA's internal team prior to access, after which connections will be made by individual users based on aligned expertise.

ARIA will also host an in-person event on **23 October 2025** for applicants who are interested in teaming to be able to meet each other in-person. To register your interest for this event, please follow the link to the sign up form here. You will then be able to submit your details and receive further information. Please note, this event is limited to 40 attendees, spaces will be allocated on a first come first serve basis.

Webinar

We are also hosting a webinar, on **22 October 2025**, to provide an overview of the programme's objectives, scope, and application process, and to give potential applicants an opportunity to ask questions to the ARIA team. Please register your interest and submit questions in advance for this event here. Applicants are welcome to register for both the webinar and the teaming event.

Application Process

The application process for Technical Areas 1, 2 and 3 consists of two stages:

Stage 1 - Concept paper

Concept Papers are designed to make the solicitation process as efficient as possible for applicants. By soliciting short concept papers (no more than three pages) ARIA reviewers are able to gauge the feasibility and relevance of the proposed project and give an initial indication of whether we think a full proposal would be competitive. Based on this feedback you can then decide whether you want to submit a full proposal. You can find out more about ARIAs review process here.

If you miss the deadline for submission of concept papers you can still submit a full proposal. However, we strongly encourage you to submit a concept paper. On average, 64% of applicants awarded funding submitted concept papers.

To ensure the process is quick and open we do not require your organisation's consent prior to submission of a concept paper.

You can find guidance on what to include in a concept paper here.

Following review of concept papers applicants will either be encouraged or discouraged from submitting a full proposal. For more details on the evaluation criteria we'll use, click here.

Stage 2 - Full proposals

This step requires you to submit a detailed proposal including:

- **Project & Technical information** to help us gain a detailed understanding of your proposal
- **Information about the team** to help us learn more about who will be doing the research, their expertise, and why you/the team are motivated to solve the problem
- **Administrative questions** to help ensure we are responsibly funding R&D. Questions relate to budgets, IP, potential COIs etc

You can find more detailed guidance on what to include in a full proposal here. **You can submit a full proposal even if you did not submit a concept paper.**

For more details on the evaluation criteria we'll use, click here.

Non-UK funding

Our primary focus is on funding those who are based in the UK. However, funding will be awarded to organisations outside the UK if we believe it can boost the net impact of a programme in the UK. In these instances, you must outline your proposed plans or commitments that will contribute to the programme in the UK within the project's duration (note the maximum project duration is 4.5 years).

If you are successfully selected for an award subject to negotiations this proposal will form part of those negotiations and any resultant contract/grant.

More information on the evaluation criteria we will use to assess your answers can be found later in the document here.

We have provided some additional guidance on non-UK funding in our FAQs including available visa options.

SECTION 7: Timelines

This call for project funding will be open for applications as follows (we may update timelines based on the volume of responses we receive):

Applications open	**17 October 2025**
Webinar	**22 October 2025**
We are hosting a webinar, to provide an overview of the programme's objectives, scope, and application process, and to give potential applicants an opportunity to ask questions to the ARIA team. Please register your interest and submit questions in advance for this event here.	
Concept paper submission deadline	**10 November 2025 (14:00 GMT)**
Concept paper review & notification of encouraged/not encouraged to submit full proposal sent	**11 November 2025 - 8 December 2025**
At this stage and based on your concept paper, you will either be encouraged/	

discouraged to submit a full proposal. If you receive feedback indicating that you are not encouraged to submit a full proposal you can still choose to submit a full proposal. You should note that this preliminary assessment/encouragement provides no guarantee of any full proposal being selected for award of funding.

Full proposal submission deadline	**22 January 2026 (14:00 GMT)**
Full proposal review	**22 January 2026 - 05 March 2026**

As part of our review we may invite applicants to meet with the Programme Director to discuss any critical questions/concerns prior to final selection — this discussion can happen virtually or we may seek clarification on certain aspects of your proposal via email.

Successful/Unsuccessful applicants notified	**11 March 2026**

At this stage you will be notified if you have or have not been selected for an award subject to due diligence and negotiation. If you have been selected for an award (subject to negotiations) we expect a 1 hour initial call to take place between ARIAs PD and your lead researcher within 10 working days of being notified.

We expect contract/grant signature to be no later than 8 weeks from successful/ unsuccessful notifications. During this period the following activity will take place:

- Due diligence will be carried out
- The PD and the applicant will discuss, negotiate and agree the project activities, milestones and budget details
- Agreement to the set Terms and Conditions of the Grant/Contract. Please note ARIA does not negotiate these terms. You can find a copy of our funding agreements here

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SECTION 8: Evaluation Criteria

Concept Paper and Proposal Evaluation Principles

To build a programme at ARIA, each Programme Director directs the review, selection, and funding of a portfolio of projects, whose collective aim is to unlock breakthroughs that impact society. As such, we empower Programme Directors to make robust selection decisions in service of their programme's objectives ensuring they justify their selection recommendations internally for consistency of process and fairness prior to final selection.

We take a criteria-led approach to evaluation, as such all proposals are evaluated against the criteria outlined below. We expect proposals to spike against our criteria and have different strengths and weaknesses. Expert technical reviewers (both internal and external to ARIA) evaluate proposals to provide independent views, stimulate discussion and inform decision-making. Final selection will be based on an assessment of the programme portfolio as a whole, its alignment with the overall programme goals and objectives and the diversity of applicants across the programme.

Further information on ARIAs proposal review process can be found here.

Proposal evaluation process and criteria

Proposals will pass through an initial screening and compliance review to ensure proposals conform to the format guidance and they are within the scope of the solicitation. At this stage we will also carry out some checks to verify your identity, review any national security risks and check for any conflicts of interest. Prior to review of applications Programme Directors and all other reviewers are required to recuse themselves from decision making related to any party that represents a real or perceived conflict.

Where it is clear that a proposal is not compliant, outside the scope and/or does not pass a quality assurance review, these proposals will be rejected prior to a full review on the basis they are not compliant or non-eligible.

Proposals that pass through the initial screening and compliance review will then proceed to full review by the Programme Director and expert technical reviewers.

In conducting a full review of the proposal we'll consider the following criteria:

1. **Worth Shooting For:**

    a. The proposed project uniquely contributes to the overall portfolio of approaches needed to advance the programme goals and objectives.

    b. It has the potential to be transformative and/or address critical challenges within and/or meaningfully contribute to the programme thesis, metrics or measures.

2. **Differentiated** – The proposed approach is innovative and differentiated from commercial or emerging technologies being funded or developed elsewhere.

3. **Well defined** – The proposed project clearly identifies what R&D will be done to advance the programme thesis, metrics or measures, is feasible and supported by data and/or strong scientific rationale. The composition and planned coordination and management of the team is clearly defined and reasonable. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed stage-gates and deliverables clearly defined. The costs and timelines proposed are reasonable/realistic.

4. **Responsible** – The proposal identifies major ethical, legal or regulatory risks and that planned mitigation efforts are clearly defined and feasible. Regulatory requirements (e.g., for animal testing or clinical trials) are clearly accounted for in the proposal.

5. **Intrinsic motivation** – The individual or team proposed demonstrates deep problem knowledge, have advanced skills in the proposed area and shows intrinsic motivation to work on the project and key individuals are dedicating sufficient time to the project. The proposal brings together disciplines from diverse backgrounds.

6. **Benefit to the UK** – There is a clear case for how the project will benefit the UK. Strong cases for benefit to the UK include proposals that:

a. are led by an applicant within the UK who will perform the majority (>50% of project costs spent in the UK) of the project within the UK
b. are led by an applicant outside the UK who seeks to establish operations inside the UK and perform a majority (>50% of project costs spent in the UK) of the project inside the UK and present a credible plan for achieving this within the programme duration.

For all other applicants we will evaluate the proposal based on its potential to boost the net impact of the programme in the UK. This could include:

c. A commitment to providing a direct benefit to the UK economy, scientific innovation, invention, or quality of life, commensurate with the value of the award;
d. The project's inclusion in the programme significantly boosts the probability of success and/or increases the net benefit of specific UK-based programme elements, for example, the project represents a small but essential component of the programme for which there is no reasonable, comparably capable UK alternative.

When considering the benefit to the UK, the proposal will be considered on a portfolio basis and with regard to the next best alternative proposal from a UK organisation/individual.

Proposal feedback

At the concept paper stage, applicants will be notified whether or not they are encouraged to submit a full proposal. If you are encouraged to submit a full proposal, we will provide detailed feedback to help inform your full proposal. For those applicants not encouraged to submit full proposals we will not provide feedback.

At the full proposal stage, applicants will be notified whether or not they have been successfully selected for an award. For those applicants not selected for award we will not provide feedback.

SECTION 9: How to apply

Before submitting an application we strongly encourage you to read this call in full, as well as the general ARIA funding FAQs.

If you have any questions, please use the chat function on the funding call page for the quickest response. It can guide you to the right information or connect you with the ARIA team if needed.

Clarification questions should be submitted no later than 4 days prior to the relevant deadline date. Clarification questions received after this date will not be reviewed. Any questions or responses containing information relevant to all applicants will be provided to everyone that has started a submission within the application portal. We'll also periodically publish questions and answers on our website, to keep up to date click here.

Please read the portal instructions below and create your account before the application deadline.

If you are disabled or have a long-term health condition, we can offer support to help you engage with ARIA, navigate our funding application process, or carry out your project, you can find more information here.

Application Portal instructions

APPLY HERE

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Concept Papers Guidelines

How to Format your proposal

- Page count: a maximum of 3 pages, including diagrams but 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 only

Section 1: Technical concept

Applicants are required to provide a concept paper no longer than 3 pages in length that outlines:

- Which Technical Area you seek to pursue (TA 1, 2 or 3)
- A brief summary of the scientific question you are setting out to answer, the proposed idea / solution, and how it supports the objectives of the technical area and the programme as a whole.
- A description of the approach or methodology that will be employed to address the research objectives. Including:
    - A description of the idea / solution proposed and why you have not been able to realise it previously.
    - Any data or scientific rationale to support your proposed concept - supporting data, journal articles, blogs, code or other materials may be referenced or linked to in the submission if they directly support your paper, but do not necessarily have to be your own work.
    - Identification of the technical challenges or obstacles that must be overcome to achieve the research goals. This includes potential risks and mitigation strategies.
- An overview of the proposed activity of work, any key metrics and milestones and any dependencies and assumptions

Section 2: Timeline, Budget and Additional questions

In completing your application you must also provide answers to the following questions. Answers to these questions are not included in the 3 page cap. You should complete these

questions in the application portal so there is no need to format these in a specific way.

Budget: How much funding do you need?

Please complete the table below providing an estimate in GBP (inclusive of VAT where applicable and all other costs) of what you consider a reasonable funding amount for your project. It's ok if you're not sure – give your best estimate.

Cost Type	Budget (£ Inc VAT)
Labour	
Materials	
Subcontract	
Equipment & Facilities	
Travel	
Other	
Subtotal	
Indirect Costs	
Total	

Timeline and additional questions:

Question	Guidance
Are you proposing to contribute funding?	*Where you or your organisation are proposing to contribute funding to the project please let us know. If yes, tell us how much funding you/your organisation plan to contribute.* *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.
How many months will you need to work on your proposed project?	*There is no minimum length for a proposed project. The maximum length is 4.5 years.*
Are you planning to give a portion of the work to external subcontractors?	*If yes, let us know what work you plan to give to a subcontractor. Subcontractors are any proposed third parties that you plan to enter into a contract or agreement with for services necessary for the delivery or management of the project.*
Do you consent to ARIA introducing you to other programme applicants to facilitate potential collaborations?	*The primary goal is to facilitate potential collaborations that can strengthen the applicants proposed projects.* *Please note that we will not share any information about your proposal.* *All personal data provided to ARIA will be processed in accordance with UK data protection legislation, including the Data Protection Act (2018) and the General Data Protection Regulation (GDPR). Further information on how we use personal data and how you can exercise your right as a data subject can be found in the ARIA Privacy Policy.*
Please indicate any programme wide partnerships that would be beneficial to your project?	*Please provide a brief summary of any additional expertise or resources that you believe could strengthen your proposal if provided via*

	partnerships (either via ARIA's Activation Partners or programme-specific partners).
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, what type of animal do you foresee using and roughly how many?* *Why do you think there is a need to use animals as part of your proposal?*
Are you planning on including a clinical trial as part of your proposal?	*If yes, please describe any expected timeline implications, required regulatory approvals, or other resultant dependencies which may have an impact on your proposal.*
Do you intend to use human tissue as part of your proposed project?	*If yes, please describe any expected timeline implications, required regulatory approvals, or other resultant dependencies which may have an impact on your proposal.*
Are there any conflicts of interest?	*Please provide a short description of any potential conflicts of interest.*
Are there any other factors or restrictions that might impact your freedom to operate and deliver the project?	*Please provide a short description of any import/export restrictions; security, ethical, legal and regulatory restrictions that you are aware of.*
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 4.5 years). *Please provide a brief summary of your proposed plans or commitments*
Additional questions about you/your organisation that can be found in the application portal.	

Advanced Research + Invention Agency ARIA

Full Proposal Guidelines

How to Format your proposal

- Page count: a maximum of 10 pages, (including diagrams, excluding references)
- 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, how it supports the technical objectives of the chosen pathway.
    + This should be supported by visual aids, data and/or strong scientific rationale for why what you are proposing would work.
    + 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, e.g. from commercial or emerging technologies being funded or developed elsewhere.
- A 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.

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.

In addition to the above the following table should be completed and attached as an annex to your proposal:

Individual	Role / expertise	Already in place? If not, how long after project kickoff are they likely to start?	FTE	Total time on project (months, rounded)
Sophia Fleissig	*Synthetic biologist, project lead (TA1.2)*	*Currently assigned to a different project but could transfer to this project with 6 weeks notice*	*80%*	*28*
Unknown	*Expert in plant tissue culture and transformation (TA1.3)*	*To be recruited, aiming to start within 3 months*	*100%*	*33*
Magnus Formaggio	*Plant geneticist advising on synthetic unit design (TA1.1)*	*Yes*	*40% during months 1-12, 20% during months 13-36*	*10*

Etc	*Etc*	*Etc*	*Etc*	*Etc*

Labour table to be completed for all individuals working on the proposed project (*filled here with hypothetical examples*).

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. In your proposal you may submit your budget using yearly, quarterly, or monthly phasing.* *Prior to completing this template you should review ARIA's Eligible cost guidance here.* *If your proposal is successful, prior to contract signature when the scope of work has been agreed, you will be required to provide a monthly cost breakdown.*
Are you proposing to contribute funding?	*If 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 4.5 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).*
Do you intend to use human tissue 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 3 to this document).*
Have you read and understood our funding terms?	*Our goal is to ensure your research can get going quickly, so we want to ensure a fast negotiation and award process. We aim to have agreements signed within 6 weeks, which we recognise can be much faster than standard at some organisations. Before proceeding, please confirm that you have read and understand our funding terms. If you are unsure which terms apply to you, you can find more guidance here.*
Additional questions about you/your organisation that can be found in the application portal.	

Advanced Research + Invention Agency ARIA

Annex 1 - Additional questions for projects that include animals

Note: You can find more information on ARIA's policy on funding animal testing here: ARIA's Policy on Research and Innovation Involving Animals.
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.)

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.

Advanced Research + Invention Agency ARIA

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?
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?

Advanced Research + Invention Agency ARIA

Annex 3 - Additional questions for projects that include human tissue

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 for the use of human tissue in your project:

1. Identify whether you will be using or storing 'relevant material' under the HT Act?
2. Will you obtain consent from donors for your use of human tissue?
3. If you do not think consent is required, what exceptions apply?
4. If you are using human tissue from deceased donors, have you confirmed with the tissue bank that the donor tissue was donated with appropriate consent for your specific use?
5. If you are using cadavers for your project, have you confirmed with the HTA licensed premises that consent for research was obtained for all cadavers to be used? Have you arranged with the HTA licensed premises for the use of cadavers on their premises as part of your project or have you obtained authorisation in writing for possession outside of the HTA licensed premises?
6. What stage of obtaining regulatory/ethical approval for use of human tissue, if relevant, have you reached?
7. Are you planning to analyse DNA or RNA from samples? If yes, will you obtain consent or utilise an exception for its use? If so, what exception will be used? If you are using human tissue from deceased donors, have you confirmed with the tissue bank that the donor did not exclude DNA analysis from their consent?
8. Where will the human tissue samples for your project be stored and does that location have an HTA licence? If not, when will that licence be in place?
9. Will you use samples from a registered tissue bank? Does that tissue bank have a generic approval in place and will this apply to your research?
10. Do you have a process in place for reporting of SAEs or SARs, if relevant for your project?

11. Will you apply for a licence from the HTA for storage of samples in your project?
12. Have you considered what will happen to human tissue samples after the project?
13. How do you plan to dispose of any remaining human tissue after the project? Do you have a system in place to inform donors?