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How should the proposed Advanced Research and Invention Agency be regulated?

Policy brief

June 2021

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Overview

The proposal for an [Advanced Research & Invention Agency \(ARIA\)](#) has been met with [scepticism in some quarters](#) and although some [experts welcome](#) the introduction of such an agency, they have also shared [concerns on and suggestions for its operation](#). This policy brief identifies potential opportunities that the proposed agency has to support human health research (HHR) and offers recommendations on how ARIA should be regulated from the outset to help alleviate some of the concerns and scepticism. We argue that ARIA should adopt a principles-based regulatory approach and keep social value at the heart of its activities. The recommendations put forward offer an opportunity for ARIA's approach to be developed as an exemplar of how research regulation can operate as an effective and efficient whole system.

Potential opportunities of introducing ARIA:

- ARIA's agility, flexibility, and independence may lead to several benefits in research, thereby benefiting society.
- ARIA's culture of embracing risk and uncertainty is designed to fill a gap currently present within the UK research and innovation landscape.
- ARIA's financial flexibility and minimal red tape offers opportunities for research that might otherwise have been deterred by existing levels of bureaucracy and the timescales involved.
- ARIA's potential whole-system approach can lead to more co-production and collaboration.

To fully realise the benefits from such a whole system approach, ARIA should:

- Embrace a principles-based approach that governs the programmes from their initial to final stages, including feedback loops on learned experience of "doing regulation".
- Keep social value at the forefront and keep assessing the programmes against this ethical value throughout the programme trajectory.
- Seek and maintain a social licence for all of its activities.

These recommendations draw on research by the Liminal Spaces Project at Edinburgh Law School, [a six-year Wellcome-funded project](#) that examined HHR regulatory systems and how their operation might be optimised.

What is ARIA and how does this relate to HHR?

In [explanatory notes](#) to the [Bill](#) introduced to propose the establishment of ARIA, it is described as "*a new type of funding body for conducting, commissioning and supporting ambitious scientific research with a tolerance to failure.*" The Bill indicates that ARIA will operate as a body that can both undertake research itself and it can fund others to do so. However, its in-house research work has not been promoted as one of ARIA's key features, as shown by a [Government policy statement](#) which emphasises its funding functions. This raises some concerns over the remit of ARIA, namely this lack of consistent communication on what the agency is could lead to a risk of confusion and a lack of coherence in approaches to it. Concerns over the remit of ARIA do not end at this stage of muddled communication, but extend over the

entire purpose of ARIA. While it is said that ARIA will focus on projects that have the potential to result in a paradigm shift in science or lead to transformative technological change, it still lacks a clearly defined purpose, being referred to as [“a brand in search of a product”](#). This, again, leads to concerns of confusion, a lack of coherence and the risk of duplication with other regulatory agencies. Given this, it is crucial for ARIA to clearly and consistently define and communicate what its functions and purpose are. Since ARIA has the potential to promote two distinct objectives – funding and research – it is even more critical for it to adopt ethical, open, and transparent governance mechanisms for its operation. We expand on these suggestions in the recommendations below. Nonetheless, given the focus outlined, HHR would be captured as a potential funding or research opportunity for ARIA. The HHR that is carried out, or funded, by ARIA is an important issue to address prior to its inception. From what is publicly available on how ARIA could operate, it is possible to identify some potential differences between how ‘ARIA’ research might be regulated and how HHR is currently regulated in the UK.

Box 1: Potential differences in ARIA and HHR regulation

ARIA	<u>Health research</u>
A ‘whole-system approach’: it will operate throughout the life cycle whereby programme managers will be involved from start to finish of a programme	Fragmented, silo-based regulation centred around fixed objects based on their nature, e.g., data, tissue, embryos
Agile and flexible	Sometimes typified by a rigid rule-based approach with specific regulatory frameworks that do not always fully capture innovative research due to inflexible interpretation
Embraces risk and uncertainty	Often risk-averse and does not easily or effectively accommodate uncertainty within regulation
Potential for collaboration given design of smaller projects within an overarching programme	Need for more lessons learned across health research sectors, including in the field of experimental treatment

As we can see from this table, how ARIA might be regulated has the potential to address some of the pitfalls in HHR regulation. It has the potential to embody some of the [Liminal Spaces recommendations about improving regulatory efficiency and accountability](#) and to learn further from how ARIA operates in practice to improve research regulatory systems overall. As such, we must seriously consider what potential opportunities ARIA has to offer for HHR.

What are the potential opportunities of introducing ARIA for HHR?

ARIA’s design means that there are several opportunities for the health research landscape and beyond. We will focus on four: 1) agility, flexibility, and independence; 2) embracing risk and uncertainty; 3) Exploring funding models while minimising bureaucracy; and 4) what we promote as a [‘whole-system approach’](#).

Agility, flexibility, and independence

ARIA's proposed agility is a [key feature](#) emphasised by the UK Government. We see benefits of [such agility in funding and decision-making from the work of the Vaccine Taskforce and Rapid Response Funds](#). Thus, ARIA's ability to be agile could provide several benefits for scientific research and technology, and thereby our society.

[ARIA's flexibility and independence](#) is supported by its power to start and stop projects quickly and reallocate funding according to emerging research findings. It is also proposed that ARIA will have autonomy over what research and projects to undertake, its procedures, and its organisational culture. This flexibility and independence means it has the opportunity to capture some types of innovative research that may be missed by current regulatory frameworks. For example, an agency like ARIA might be able to find a way through the on-going concerns about [how best to support and regulate experimental therapies](#). However, where such agility, flexibility, and independence are not exercised in an ethical and accountable manner, trust in ARIA's activities may be impacted. Therefore, **to gain and promote trust in its activities, ARIA should demonstrate its trustworthiness by adopting open and transparent decision-making processes and acting in ways that are demonstrably accountable** (see recommendations below). Furthermore, **ARIA should identify ethical values key to its programme of work and embrace these values as guiding principles**. These principles should be reflected upon [throughout the life span](#) of all of ARIA's programmes – not just at their inception (see recommendation below).

Embracing risk and uncertainty

It is [proposed](#) that ARIA will embrace risk and uncertainty as part of its culture and embed “a *tolerance to failure in pursuit of transformational breakthroughs*”. As Box 1 indicates, regulation of HHR is generally risk-averse, a point recognised by the [House of Commons Science and Technology Committee](#). ARIA's proposed approach could therefore fill a gap present within this context. As we have [argued elsewhere](#), “embracing uncertainty – both as a human practice and a regulatory objective – may represent the brighter future for health research.”

Exploring funding models while minimising bureaucracy

ARIA will have the financial flexibility to experiment with a number of funding models. These models include: seed and programme grants, loans, investing in companies or prize incentives. It can also transfer property or other rights. These other rights can for example [include a patent](#). Importantly, the option of not seeking or enforcing a patent over highly-sought after interventions – such as COVID-19 vaccines – is also a valuable option. These different funding models with the added feature that ARIA will have “[stripped back red tape](#)” offer opportunities for research that would otherwise have been deterred due to the level of bureaucracy and timescales involved in making applications. However, the [UK Government has launched a review on reducing research bureaucracy for UK researchers](#), indicating reductions in bureaucracy may have wider application in the UK's research and innovation landscape. Nonetheless, as above, it is key for ARIA to demonstrate its trustworthiness, and what it funds and how it has used its funding is another aspect that it must be held accountable for. Thus, the demonstrated added

social value of this kind of agency becomes a crucial feature of its success and a measure of its worth in the regulatory landscape of the future.

A whole system approach

The [Government](#) has indicated that ARIA will operate “across the R&D life cycle from funding at the intersection of pure science and applied science; towards early technological development; and then exploring different avenues to commercial success.” ARIA’s design is therefore one of a ‘whole-system’ approach – a concept which Liminal Spaces has highlighted [elsewhere](#).

A whole system approach supports co-production and collaboration with others in HHR. However, to [promote such co-production and collaboration](#) and to fully realise the benefits of such a whole system approach, **ARIA should adopt a principles-based approach to its regulation and keep social value at its forefront, re-evaluating the research against this throughout the programme trajectory.** [Social value](#) from human health research can take many forms and close monitoring across the research lifecycle can help identify and disseminate this value more widely. We suggest further that ARIA can also adopt a pro-active [regulatory stewardship](#) approach given one of its functions according to the [Bill](#) is to offer advice to others.

How can ARIA operate as an effective and efficient whole system?

As shown above, ARIA offers several potential opportunities for the UK research and innovation landscape, one of which includes the potential to function as a whole system, [a key proposal of the Liminal Spaces Project](#). Taking a Whole System Approach – i.e., putting in place mechanisms for capturing the breadth and complexity of health research and the human values at stake across the entire lifespan of a research protocol – would allow us to trial this proposal and learn any lessons from how ARIA operates in practice. We offer three recommendations on how ARIA’s approach can be developed as an exemplar of how research regulation can operate as an effective and efficient whole system.

A principles-based approach

Given that ARIA is envisioned as a flexible agency, a [principles-based approach](#) would allow it to maintain this flexibility yet uphold ethical conduct. This is crucial given the nature of research ARIA will be involved in. ARIA’s joined-up system lends itself well to such an approach with the programme manager being able to act as a regulatory steward throughout the programme journey. To be effective, this principles-based approach requires regular reflection and review by all stakeholders involved. This engagement by all those involved allows for more co-production and collaboration throughout the programme journey thereby ensuring that different stakeholders are engaged in shaping and realising the final output, as well as the steps required to reach the final output.

Recommendation: ARIA and its stakeholders should collaborate to set [guiding principles](#) for its programmes of research. Once guiding principles are determined, they should reflect on and review these guiding principles at every stage of their research programme.

Social value

When conducting such transformative innovative research, ARIA and its stakeholders should ask: [what social value does this research have?](#)

The [Bill](#) currently requires that ARIA “must have regard to” exercising its functions for the benefit of the UK. The Bill provides a list of three benefits that can be realised in exercising ARIA’s functions. While this list goes beyond mere scientific outcomes, it is arguably too vague and broad and does not encompass some of the other values that could come from research. For example, social value would encompass benefit for a select group of people which is arguably not encompassed in the [“improving the quality of life” in the UK or elsewhere](#) benefit outlined in the Bill.

Recommendation: ARIA and its stakeholders should consider what [social value](#) comes from their research at the initial proposal stage and throughout the lifecycle of the research. They should continue to reflect on and evaluate their research against this objective so that the full range of social value has the optimum chance of being realised.

Social licence

What the [‘care.data’](#) project has shown us is that mere lawfulness is insufficient for the purposes of gaining support for a project. We need social legitimacy too. Given the innovative and transformative nature of the type of research ARIA will conduct and fund, it is important that ARIA seeks to secure and maintain a [social licence](#) to conduct, commission, and support such research for it to be successful. To do so, ARIA must meaningfully inform and engage stakeholders – including the public – throughout. It must also aim to maintain and promote [trust](#) in its activities by demonstrating its own [trustworthiness](#). This can be done in a variety of ways:

By adopting open and transparent decision-making processes

How programmes will be selected and how decisions will be made in relation to which research will be undertaken in-house, and which will be commissioned, must be communicated clearly and in an open, accessible, and meaningful manner. **Reasons for adoption or rejection should be a matter of the public domain.**

Clearly setting out what is the function and purpose of ARIA

As noted above, the Bill proposes that ARIA will operate as a funding agency that can also conduct and commission research. If it is perceived as a hybrid agency with a primary function of commissioning research, then this ought to be communicated clearly in all public facing communications as well as in advertising for recruitment for ARIA members. Furthermore,

ARIA's purpose is arguably vague and too broad. The [Government have said that this “open mission” is by design](#). However, in order to ensure that the boundaries between ARIA and UKRI are not blurred and result in unnecessary duplication and confusion, **it is key that ARIA's focus and boundaries are set and communicated clearly in an accessible manner** once this is set by ARIA's CEO. Having a clear mission and one that does not seem to duplicate present systems will help present such projects to the public in a clear manner. Nonetheless, to gain a social licence and to seek their trust, publics should be engaged and informed in an open, accessible and meaningful manner. Putting information 'out-there' is not sufficient. ARIA should ensure that all its communications and actions go beyond this: stakeholders and publics can play an important role in co-producing effective regulation – opportunities for this can and should be explored.

Acting accountably

ARIA will have some oversight in place such as needing to provide annual reports and reporting on its funding but, as currently sought, [it would be exempt from Public Contract Regulations and Freedom of Information Act](#). To maintain and promote public trust, **it is important that ARIA shows that it conducts itself in a responsible manner and can be held accountable for its conduct**.

Recommendation: To gain a [social licence](#), it is key to maintain and promote public [trust through demonstrated trustworthy actions](#). To do so, ARIA should meaningfully engage with the public by openly, accessibly, and meaningfully interacting on all key aspects of the work that ARIA will undertake.

Conclusion

The proposed ARIA has the potential to provide several opportunities for HHR and beyond. We suggest that by adopting the recommendations set out above, ARIA will have the best chance to fully realise its potential benefits. This is because, while a Bill purporting to set up a body like ARIA would provide sufficient legal basis and authority for this regulatory body, this is insufficient alone to garner social and ethical legitimacy. ARIA has attracted scepticism and concerns over how it may operate, and this must be addressed. The recommendations in this brief are designed to help allay some of the scepticism and concerns by setting out how ARIA could operate as an effective and efficient whole system. This would give an agency such as ARIA the best possible chance to function optimally for health research regulation.

Acknowledgments

We thank Ms Kate Harvey, Senior Research Officer, Nuffield Council on Bioethics, for reviewing an earlier draft of this brief.

Read more about Liminal Space's work:

More information can be found on the [Liminal Spaces project legacy website](#).

This project was supported by a Wellcome Trust Senior Investigator Award (Grant No. WT103360MA) entitled 'Confronting the Liminal Spaces of Health Research Regulation'.