

Health Research Authority

Risk appetite statement

September 2023

This risk appetite statement sets out how the Health Research Authority (HRA) balances threats and opportunities in pursuit of achieving its strategic vision to enable high quality health and social care research that improves people's health and wellbeing.

Understanding and setting a clear risk appetite statement is a key element of our overall risk management and assurance framework. Establishing and articulating the risk appetite statement helps to ensure that the HRA is able to manage and respond to risks consistently across the organisation. A shared understanding of how we manage risk supports the development of the HRA's risk culture and allows our teams to understand how the risks they are taking relate to the overall strategic objectives and direction of the HRA.

This document will provide a high-level risk appetite statement along with more specific risk appetite statements for different business areas (e.g. financial risk appetite).

It is important to note the risk appetite statement and its framework will change and develop as the environment affecting the HRA changes and also as the risk culture of the HRA matures. This statement will therefore be reviewed by the Board on an annual basis as a minimum.

Overarching risk appetite statement

One of the HRA's fundamental roles is to protect participants involved in research and a key focus of the HRA's strategy is therefore to enable high-quality research which is in the interests of patients. We accept that the very nature of research involves an element of risk or potential risk.

The HRA, through HRA Approval, our Research Ethics Committees (RECs) and the Confidentiality Advisory Group (CAG), endeavours to balance the risks of taking part in research with the potential benefits to the public, both those participating in studies and the wider public benefit as result of any research findings. It is therefore fundamental to the ethical conduct of trials that research participants are given clear information to enable them to make an informed choice about participation, including making a choice to accept any associated risks.

The HRA also has a duty to encourage and facilitate research therefore as an organisation we must ensure our processes and systems meet user needs and support our ambition for the UK to be the easiest place in the world to do trustworthy and high-quality research. We recognise therefore that in pursuit of our strategic objectives and delivery of our statutory responsibilities some risk taking will be necessary.

The HRA is not averse to taking risks however recognises that we must accept different levels of risk dependent on the area of business. Some areas we may be risk averse as the perceived benefit of taking the risk is minimal or the consequences of taking such a risk are too high, whilst there may be other areas where we can be more open or eager in our approach to taking risk. We therefore have identified and articulated our risk appetite for a number of key areas.

Risk appetite level by category

Reputational

We rely on our reputation to influence and secure the engagement of researchers, funders, sponsors, participants, and the public. The support of these parties is essential to achieving our goals and we therefore hold a strong commitment to being seen as a proportionate and respected regulator which can be trusted. We retain a **minimal / cautious** appetite for risk taking, seeking to limit the chance of any significant repercussions for the organisation.

Our appetite for risk taking is slightly greater (**cautious / open**) in taking decisions to increase our visibility and use our growing influence to work with others on key areas such as the use of patient data, research transparency and public involvement.

Strategy

The HRA recognises the importance of the successful delivery of its core remit and responsibilities as set out in the Care Act 2014 and we therefore have an **open** approach to risk taking, within a clear governance framework, in support of the delivery of our strategic objectives. To support this approach, we will refresh our organisational strategy at approximately 3-year intervals.

We will continue to engage and work with a range of stakeholders to support our strategic ambition for the UK to be the easiest place in the world to do trustworthy and high-quality research and our appetite for risk taking will reflect this. We will continue to listen to feedback and use intelligence to better understand the future of health and care research and technology to enable the HRA to stay ahead of user need and support innovation where there are clear benefits.

We are committed to making research inclusive and transparent, being a visible and trusted advocate for, and partner of, people in research and will listen to and involve patients and the public in the HRA and will take the necessary opportunities, through collaborating with others, to support the delivery of this ambition.

Operational

The HRA is required, under the Care Act 2014, to ensure that our research ethics committees provide an efficient and effective means of assessing the ethics of health and social care research.

We have a **cautious** risk appetite for our operational delivery, ensuring that appropriate controls and procedures are in place to support our decision making however will take opportunities to champion innovation when there is a clear benefit or improvement to be offered.

The HRA has an **open** risk appetite to working with other stakeholders to support our strategic priority to make the UK the easiest place in the world to do trustworthy and high-quality research. Combined Review, a single application submission and co-ordinated review leading to a single UK decision for Clinical Trials of Investigational Medicinal Products (CTIMPs), is an example of this. The HRA has worked with others, notably the devolved administrations, the Medicines & Healthcare Product Regulatory Agency (MHRA) and the National Institute for Health & Care Research (NIHR) and the HRA has an **open** risk appetite to undertake more initiatives which can offer tangible benefits to the research community.

The Research Ethics Service is a UK wide service and the HRA, alongside the devolved administrations has an **open** risk appetite to taking opportunities to improve the UK wide compatibility and making the UK an attractive place to conduct research, whilst maintaining appropriate standards.

Regulatory

As detailed in our overarching statement, all research carries the potential for risk and we will support our RECs in facilitating research whilst protecting participants by seeking to take a **cautious** approach to ethical review. We will ensure any decisions carefully consider the benefits vs risks with governance and assurance arrangements in place to manage the REC decision making process.

We will however operate a more **open** approach for the review of well defined, lower risk studies and look to take the opportunity to support a review which is proportionate to the risks involved in the study. A clear regulatory framework will remain in place.

The HRA recognises there may be types of research activity which generate strong and divisive opinions between members of the public. We will ensure the independent nature of the REC decision is maintained with decisions based on the merits of the research versus the risks involved as opposed to any public pressure.

We however have a risk averse appetite with regard to any activity where there is a deliberate breach of protocol which has or could potentially lead to the harm of participants. Any concerns raised by a participant or member of the public regarding the conduct of a third party, such as a sponsor or researcher, will be investigated thoroughly and action taken as required.

Technological innovation

User-friendliness must be a key consideration for the HRA in the services and systems we provide to enable research and help support making the UK an attractive place to conduct research. We have an **open** appetite for risk taking with regard to technological innovation and development where investment is supported if there is a clear demonstration of benefit to the research community. Updating and improving our research systems is a key programme of activity with design and functionality, to meet the needs and expectations of researchers', key. On occasion, the HRA may have an **eager** risk appetite where there is the opportunity to implement technology which meets user needs which has a high likelihood of return from minimal investment.

The HRA's greatest risk at present is the delivery of its Research System Programme and has an **averse** risk appetite for any activity which would impact on the successful delivery of the programme. The HRA has strengthened its governance and control framework in this area to mitigate the associated risks.

The HRA will however operate a **cautious** approach for the systems which support our core services e.g. finance and human resource systems. Functionality is important however value for money and overall cost remain critical for these systems.

Financial

As a public body, funded by the Department of Health & Social Care and governed by the requirements of the HM Treasury's Managing Public Money, the HRA has a duty to handle public funds with probity and in the public interest. To ensure that the HRA helps the government maintain public trust the HRA has a **minimal** appetite for taking risks with regard to financial related activity with value for money the primary concern when entering into any new contracts. Social value must however also be considered during procurement with 10% weighting of scoring required to consider social, economic and environmental factors.

The HRA is however willing to make substantial investments, for instance in new technology to support our core business (e.g. research system development), when there is a sound business case for doing so and the benefits are sufficient to warrant the expenditure. The HRA must balance its minimal financial appetite with its more open technological innovation appetite when developing systems to meet the needs of the research community.

The HRA is risk **averse** with regard to budgetary overspend with control and measures in place to ensure we abide by the requirements expected of us as a public funded body.

Fraud, bribery and corruption

The HRA is **averse** to the risks of fraud, bribery and corruption and fraudulent behaviour and will maintain appropriately robust controls and sanctions to maximise prevention, detection and deterrence of this type of behaviour.

Information governance and security

Whilst we hold no patient data, the information we hold regarding research applications may be confidential and commercially sensitive. Information we hold on staff and our volunteers may also be sensitive. The accidental or deliberate wrongful disclosure of sensitive or confidential information has the potential to erode trust, damage both our reputation and that of the public sector as a whole, and ultimately prevent us from operating effectively. We therefore have a **minimal** appetite for information governance related risks. Whilst we recognise it is impossible to prevent these sorts of risk from occurring, we will ensure appropriate controls and mitigations are in place to limit their impact.

The HRA is risk **averse** to the growing cyber and information security risks which may potentially cause loss, harm or reputational damage related to the HRA's physical and technical infrastructure and assets, or the use of technology within the organisation.

We do however recognise the growing commitment to the sharing of data within and across government departments and are working with partners to enhance the interoperability of systems across the research system. The HRA has a **cautious** risk appetite regarding the sharing of research data recognising the balance which must be made between openness and allowing collaboration between partners whilst ensuring systems remain secure and access controlled.

Environment

The HRA is committed to reducing its environmental impact and has an **open / eager** risk appetite to consider opportunities with regard to sustainable practices which can be embedded into our daily business.

Culture

A key part of the HRA's strategy is to ensure we have the right culture and capability within the HRA. To support this the HRA has an **eager** appetite for looking at opportunities which will help deliver an innovative organisation which supports, develops and enables our staff to succeed, working towards a diverse and inclusive workforce.

Risk appetite definitions

Averse	Avoidance of risk and uncertainty in achievement of key deliverables or initiatives is the key objective. Activities undertaken will only be those considered to carry virtually no inherent risk.
Minimal	Preference for very safe business delivery options that have a low degree of inherent risk to the achievement of key deliverables or initiatives. Activities will only be taken where they have a low degree or inherent risk.
Cautious	Preference for safe options that have a low degree of inherent risk. Willing to tolerate a degree of risk in selecting which activities to undertake to achieve key deliverables or initiatives, where we have identified scope to achieve significant benefit and/or realise an opportunity. Activities undertaken may carry a high degree of inherent risk that is deemed controllable to a large extent.
Open	Willing to consider all options and choose one most likely to result in successful delivery while providing an acceptable level of benefit. Seek to achieve a balance between a high likelihood of successful delivery and a high degree of benefit and value for money. Activities themselves may potentially carry, or contribute to, a high degree of residual risk.
Eager	Eager to be innovative and choose activities that focus on maximising opportunities and offering potentially very high reward, even if these activities carry a very high residual risk

Risk appetite matrix (September 2023)

	Averse	Minimal	Cautious	Open	Eager
Reputational		Proportionate and respected regulator		Use growing influence to promote own policy agenda e.g. use of patient data, transparency, patient and public involvement	
Regulatory	Deliberate breach / third party complaint		Research approval - careful consideration of benefits vs risks	Proportionate approach to types of research	
Strategic policy				Research with and for everyone Accelerating UK research in the context of the life sciences vision	
Operational processes			Processes, systems and controls to support delivery / meet statutory timelines	Working with key stakeholders UK wide compatibility	
Technological innovation	Any activity with a detrimental impact on RSP			Innovation and development with investment supported (if there is a clear benefit to the research community and to patients and the public)	Innovation which meets user needs which has a high likelihood of return from minimal investment
Financial	Budgetary overspend	Procurement with value for money primary concern		Recruitment over establishment / vacancy factor	
Fraud, bribery & corruption	Fraud, bribery and corruption				

Information	Cyber attack	Breaches of information	Sharing of research data with other collaborators		
Environment				Embedding sustainability into HRA practices	
Culture					Supporting, developing and enabling our staff with an inclusive and diverse workforce