

<b>Agenda item:</b>	13
<b>Attachment:</b>	A

## HRA Board Cover sheet

### 24 March 2021

<b>Title of paper:</b>	HRA Risk appetite statement
<b>Submitted by:</b>	Steve Tebbutt
<b>Summary of paper:</b>	To seek Board approval of the HRA's proposed risk appetite statement. This incorporates comments and feedback from the January 2021 HRA Board seminar and has been approved by the HRA Audit & Risk Committee at its meeting in February 2021.
<b>Reason for submission:</b>	For approval
<b>Further information:</b>	Following Board approval, a learning and development programme will be taken forward with teams across the organisation to discuss the appetite statement and consider the risk categories which are relevant for that team and how the risk appetite translates to managing risk at that level. This will support the development of the HRA's risk culture and deliver a shared understanding of how we calculate and manage risk across the HRA.
<b>Budget / cost implication:</b>	N/A
<b>Dissemination:</b>	Published with March Board papers. Learning programme to follow for teams across HRA
<b>Time required:</b>	5 minutes

# Health Research Authority

## Risk appetite statement

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). Further work is required to develop more specific and granular risk appetite statements, measures and limits for individual risks. This work will be carried forward through articulation of the risk appetite statement with teams and working with individuals to understand how the risk appetite relates to the specific threats and opportunities they face, both internally and externally, as part of core business and programme / project activity.

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 our Research Ethics Committees (RECs), 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 making the UK an attractive place to do 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 business area

### Reputational

We rely on our reputation to influence and secure the engagement of researchers, funders, sponsors and other stakeholders. 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 and retain an overall **minimal / cautious** risk appetite with regard to our reputation.

However, we are prepared to take a stance which may be opposed by some of our audience where we believe it is necessary for the achievement of one or all of our statutory objectives. We are **eager** to increase our visibility and use our growing influence to promote our own policy agenda on key areas such as the use of patient data, research transparency and public involvement.

### Strategic policy

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 are therefore **open** to develop policy into areas which will encourage and facilitate research and promote transparency in research. We will continue to engage and work with a range of stakeholders to facilitate research and support the life sciences industrial strategy. 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.

### 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. In 2018 the HRA underwent a substantial organisational change process to bring together the assessment of governance and legal compliance with the independent ethical opinion to ensure our process better meet the needs of researchers. Based on this new structure we have a **cautious** risk appetite towards sustaining our operational processes, systems and controls to support delivery and meet our statutory timelines.

We have however operated differently as a result of COVID-19 with virtual REC meetings and virtual attendance by researchers required, which has supported our research community and we are keen to build on these improvements. We therefore have a more **open** risk appetite for the enhancement of our operational processes.

We recognise the fast track service we offer, provided recently for COVID-19 studies, has been welcomed by researchers and have an **eager** risk appetite to build on this. A fast track review pilot will run between January and March 2021 which will test whether the HRA, on behalf of the UK, can establish a sustainable model for providing rapid research ethics review. We will await the findings from this pilot before considering whether our appetite for our overall operational delivery should change.

### 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.

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 are however risk **averse** 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 are **open** 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 at present 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 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 more standard 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 financial related activity with value for money the primary concern when entering into any new contracts.

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 data recognising the balance which must be made between openness and allowing collaboration between partners whilst ensuring systems remain secure and access controlled.

## Risk appetite definitions

<b>Averse</b>	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.
<b>Minimal</b>	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 of inherent risk.
<b>Cautious</b>	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.
<b>Open</b>	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.
<b>Eager</b>	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