



THE UNIVERSITY of EDINBURGH
Edinburgh Law School



End of project vision statement

Driving a whole system approach to health research regulation

March 2021

For over five years, the Liminal Spaces project at Edinburgh Law School has scrutinised the regulatory systems that support human health research. Here, **we present a vision statement** to mark the end of our project, and to highlight our aspirations for a more joined-up approach for health research regulation in the future.

What our project has led us to conclude

Our work has led us to conclude that regulatory systems are best described as trajectories that range from an initial research idea about improving human health and wellbeing, right through to delivery of that idea to patients. However, **there is a failure to consider this trajectory as a whole system in terms of how regulation currently functions. Instead, health research regulatory systems operate in fragmented siloes** which can hold them hostage to unnecessary duplication of regulatory requirements and to challenges in navigating the gaps between different and complex regulatory areas.

To better represent the realities of health research and to further build on incremental improvements that have been ongoing for decades, there must be a shift away from this fragmented approach to **more joined-up, reflective, and responsive systems of health research regulation.**

We are not suggesting that current regulatory systems have not made advances over the years. They have. But, equally, **there are good reasons to believe that more work can be done to support systems to operate optimally**, both to protect research participants and to promote health research and the considerable social value¹ it can deliver.

Why do we think a more joined-up approach is needed?

There are at least three reasons why regulatory systems that govern health research need to take a more joined-up approach.

1. They can operate with tunnel vision

Current regulatory systems focus mainly on identifying, assessing, and aiming to reduce risk to participants or patients. They do this through focusing on definitions and tightly-focused regulatory requirements – for example, regulating [personal data](#) differently from [human tissue](#), and creating specific regulatory regimes for research concerning a range of entities such as [embryos](#), [medical devices](#), or [advance therapeutic medicinal products](#).

Although systems' risk-aversion is sometimes based on good reasons, they can also create unlooked-for challenges. One of these challenges is that they encourage researchers and others to devote themselves to very narrow aspects of the system to ensure that they are adhering to regulations. **They are not encouraged to take a step back and see the big picture.** Instead, they are asked to toe the line at their own role in regulatory systems, giving them tunnel vision of the wider research context. This means that **no one has the role of having an overview or overall responsibility for achieving the end goal of research: to add social value.**ⁱⁱ A failure at one link of the chain of actions can threaten the entire research enterprise.

2. They can fail to see the 'human' in 'human health research'

People are at the heart of all health research, and it is important for regulatory systems to serve us all as effectively as possible. Current systems do not serve this aim as well as they might. This can be seen in how systems sometime adopt a 'job done' attitude. For example, consent and anonymisation are commonly-used regulatory tools that show a commitment to prioritising participants' interests. But systems' interest in these tools and what they mean often stops at the point where they are confirmed. This means that participants might no longer be sufficiently involved in the research process throughout the lifecycle of a research project. This **overlooks participants' continuing interests in the research process** and suggests **systems can at times be blind to the role of the human in human health research.** This may have consequences for people's trust in systems.ⁱⁱⁱ

3. They can be burdensome

A researcher who processes personal data will have to meet regulatory requirements that are quite different from a researcher who works with human tissue or embryos. Meeting extensive regulatory requirements within each of these areas is already challenging, but what about when a research study straddles all of them? Or more? Here, much is demanded of researchers who must navigate these regulatory boundaries and what they require of them. **Such burdens lead to serious consequences for the future of health research,** not least of which are stresses that might be experienced by researchers and potentially slowing down, hindering, or even halting important research and innovation. To address this complexity, our work has promoted the concept of regulatory stewardship which would support researchers to navigate regulatory requirements and therefore help to make the

system operate more efficiently.^{iv} Indeed, we have argued that developing and delivering research systems that are supportive to all their actors is a challenge that needs to be met head-on.^v

Our vision of the future of health research regulation: a whole system approach

Our vision of the future of health research is informed by our own research but also our work with others. This includes [a policy study](#) we carried out with stakeholders – including regulators and researchers – working in UK health research systems. This study supports our vision that **systems should continue to move away from strict, rules-based approaches, towards flexible regimes that promote the social value of research and which embody more examples of co-produced regulatory approaches and best practices**.^{vi}

A key part of realising a more flexible regime is to break out of the siloes that can operate in the health research system. Instead, **for regulatory systems to support health research endeavours optimally in the future, they need to take a whole system approach**. By ‘whole system approach’, we mean regulatory systems that capture the breadth and complexity of health research and the human values at stake across its lifespan. Indeed, **a failure to address underlying public values and concerns in health research can result in research stalling** because a social licence^{vii} has not been attained or public trust is undermined.^{viii} In short, it stalls, or even fails, because systems do not place people at the centre of their endeavours.^{ix}

Policy futures for the health research system

Drawing on our work over the past five years, [we have published](#) four policy briefs that offer a series of recommendations on how research regulatory systems might respond to better capture a whole system approach.

- How the whole system of health regulation can be reformulated as a learning process
- How systems can improve their responsiveness in times of crisis and change
- How the health research environment can better demonstrate how it is trustworthy across the whole system
- How social value can be better monitored and delivered across the whole system

Concluding note

Our vision aspires to health research systems that break out of their siloes and ease their inflexibilities. If they do this, we expect to see a whole system approach emerge to support what we think is the most important role that research plays: to offer social value to us all.

ⁱ Liminal Spaces (2021) End of project vision statement: driving a whole system approach to health research regulation.

ⁱⁱ See note i.

ⁱⁱⁱ Liminal Spaces (2021) How can health research regulatory systems strengthen their trustworthiness?

^{iv} Liminal Spaces (2021) Regulatory stewardship: concept note.

^v See: <https://www.cambridge.org/core/books/cambridge-handbook-of-health-research-regulation/6C0BD8EA72887CE20B6EC348D1BF148C> (afterword).

^{vi} Liminal Spaces (2021) Realising social value as an objective for health research regulation.

^{vii} Liminal Spaces (2021) Social licence in health research: concept note.

^{viii} See note iii.

^{ix} See note v.