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How can health research regulatory systems strengthen their trustworthiness?

Policy brief

March 2021

www.law.ed.ac.uk/research/research-projects/liminal-spaces

Overview

This brief takes as its starting point that trust is a vital element of ethical health research. Because of its importance, we argue that health research regulatory systems must continue to strengthen their trustworthiness to support the future of the research they govern. To do this, systems must respond to challenges to their trustworthiness head-on. We propose four recommendations for how this might be achieved.

This brief draws on research by the Liminal Spaces Project at Edinburgh Law School, [a five-year Wellcome-funded project](#) which examined health research regulatory systems and how their operation could be improved.

What do we mean by ‘trust’ and ‘trustworthiness’ in health research?

Whether people give their trust in health research contexts depends on them finding researchers and their institutions to be trustworthy. But trustworthiness cannot be achieved by ticking off a list of defined aims and objectives. Instead, as [others have observed](#), it requires researchers and their institutions to act with goodwill towards the people whose trust they seek. Such goodwill can be shown, for example, by researchers being open and transparent about how their research could contribute to the public good. It can also be shown by being honest and forthright about challenges and mistakes and having plans in place to correct wrongs when they occur.

Why are trust and trustworthiness important in health research regulation?

Each day we are asked to trust in institutions, the services they provide, and the promises they make. Trusting is a big part of our lives. But when we are asked to trust health research and health researchers – either as participants or as citizens whose health and wellbeing could be affected by the results of the research – the request seems particularly powerful. One reason for its power is that health research is an activity characterised by risks and uncertainty.ⁱ Where guarantees are simply not available because of such uncertainties, trust becomes a facilitator of research progress. Indeed, without trust research simply cannot happen. **Trust therefore has real power in health research.**

And because trust and trustworthiness are so closely connected, when people are asked to take part in health research, **the trustworthiness of researchers and their institutions plays a significant role in whether they decide to take part.** If potential participants feel that researchers or their institutions are untrustworthy, then **the research might stall before it starts** – for example, where [participants are put off from engaging with the project](#).

Why can trustworthiness be a challenge for health research?

Our work suggests that there are at least three reasons why trustworthiness can be a challenge for health research.

1. Trust and trustworthiness are fragile

As others have [observed](#), trust is “difficult to gain, easy to break, and tough to repair once broken”. In other words, **trust is fragile**. For example, if one person working on a research project is deemed untrustworthy, trust in the whole research proposal can be jeopardised. Flashpoints for trust being jeopardised include a lack of communication between researchers and participants; not enough, or unclear, information about what the research is doing; or perceptions that researchers have a conflict of interest, for example a concern about “profit over people”.

2. Health research is an uncertain enterprise

We have observed elsewhere that uncertaintyⁱⁱ cuts across every health research endeavour. Such uncertainties put trust – which is already fragile – under further pressure. For example, **the perceived trustworthiness of a researcher or their research might change fundamentally throughout the course of research**, especially when unforeseen consequences arise precisely because research is an uncertain endeavour. This challenge might be especially acute during health research emergencies, such as the COVID-19 pandemic. As an example, whereas previously vaccines took many years to develop, the speed with which COVID-19 vaccines have been developed has led to concerns about the public [doubting the quality of the research](#) and [safety of the vaccines produced](#). Even if the science is sound, such concerns must be addressed. If too many people do not trust the vaccines and refuse, then the whole programme and public health are in jeopardy.

3. Health research regulatory systems can be inflexible

In another briefⁱⁱⁱ we have raised concerns about health research regulatory systems’ inflexibilities and their often-rigid approach to regulatory structures and rules. **Such inflexibilities do not fit well with the trustworthiness of research** which can shift and change over time and according to the context of research. Systems therefore need to be able to adapt in response to those changes.

How can these challenges be addressed?

There are, of course, established mechanisms which can help to show that health research systems are trustworthy. These mechanisms might include accountability, processes that protect people’s privacy (for example, [data safe havens](#)), or public engagement where participants’ voices become part of the research endeavour. However, we propose a broader reflection on how the whole system of research can strengthen these established indicators of its trustworthiness. Specifically, **we focus on how the trustworthiness can be strengthened through developing a learning regulatory system across health research**.

Developing a learning regulatory system

We have argued elsewhere^{iv} that health research regulatory systems **should continue to move away from strict, rules-based approaches, towards flexible regimes** to promote a range of examples of the social value^v that can arise from research. A commitment to promoting whatever kinds of social value emerge from research – even if the original promise of a new treatment or intervention cannot be delivered – can go a long way in demonstrating trustworthiness. This is because there is openness and honesty about the fact that not all research can live up to its original promise.

But not only is flexibility important to realise social value; flexibility is also an important element of systems that can accommodate the fragility of trust. This arises because trust is not a rigid, constant value. It can flex and shift across the trajectory of every research project. Rather than expecting trust to follow from mechanisms such as accountability, systems instead need to embrace flexibility so that demonstrations of trustworthiness can be better accommodated if and when research itself must take a new course. **One way of embedding such flexibility into health research is to promote a learning regulatory system that applies meaningful assessments to the trustworthiness of research.** One method to realise such a learning regulatory system is to introduce self-assessments of trustworthiness for researchers throughout their entire project.

Recommendation: Researchers working across health research systems must constantly ask themselves if they are operating in a trustworthy way. To do this, mechanisms should be built in across the health research trajectory to pause and consider whether they continue to provide good reasons to be trusted. This might include ethics committees or other regulatory bodies:

- Requiring researchers to show how they propose to demonstrate their trustworthiness throughout the lifecycle of their research.
- Asking researchers to include in their proposal an account of how they will respond if their trustworthiness is called into question during their research.
- Reflecting on their own commitments to, and demonstrations of trustworthiness, i.e., the regulators must be trustworthy too.

We suggest that the more such self-assessments of trustworthiness are undertaken, the clearer the picture will be of what trustworthiness 'looks like' for researchers operating across various aspects of health research systems. This picture will only become clear, however, if assessments of trustworthiness are shared openly.

Recommendation: When researchers reflect on their trustworthiness, their observations should be shared openly so that health research systems can learn about, and better understand, what trustworthy research scenarios 'look like'. This exercise can be considerably enriched if examples of errors or missteps are also shared – showing how lessons were learned from mistakes.

As part of any assessment, however, **it is perhaps inevitable that there will be cases where the trustworthiness of researchers and their research are challenged.** This might be because research does not go to plan, or unforeseen circumstances arise. Where this happens, systems need to be prepared to respond to re-evaluate the trustworthiness of the research at hand. We suggest that regulators and funders should support such preparations. This is because **regulators themselves have a key role to play in maintaining the fragile web of trust that surrounds human health research.**

Recommendation: Regulators and funders should work together to establish how researchers can be supported to demonstrate their trustworthiness throughout their research, but particularly

when trust is found to be in jeopardy. This support might take the form of protocols which ask researchers to assess:

- Why their trustworthiness is being called into question at this stage of their research.
- What they might do to strengthen their trustworthiness, including what tools they can call on to help – for example, public engagement or increased openness.

How they can mitigate trust being jeopardised at a later stage of their research, including through setting out plans for subsequent assessments of their trustworthiness.

It is also important that regulators think creatively about how their systems of governance could support researchers to report instances of where trust might be in jeopardy.

Recommendation: Regulators should consider how they could create ‘safe spaces’ for researchers to report errors and mistakes that undermine trust. Examples might be drawn from the airline or pharmaceutical industries that support ‘blame-free’ reporting mechanisms.

Conclusion

The trustworthiness of researchers and the studies they undertake are important factors in any ethical research scenario. At present, however, research systems do not require researchers to consider explicitly how they will show that they are trustworthy throughout the course of their research. We suggest that using a learning regulatory system can support serious thought being given to this fragile concept, so that its application and demonstration can be strengthened in the future.

Acknowledgments

We thank Dr Angeliki Kerasidou and Dr Alessandro Blasimme for reviewing an earlier draft of this brief.

Read more about our work on trust:

- [Co-production and managing uncertainty in health research regulation: a Delphi study](#)
- [Data safe havens and trust: toward a common understanding of trusted research platforms for governing secure and ethical health research](#)
- [Expert perspectives on ethics review of international data-intensive research: working towards mutual recognition](#)
- Supporting the trustworthiness of health research: a novel framework for proxies of trust [*in development*]

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

ⁱ Liminal Spaces (2021) The challenges of uncertainty in health research: how can regulatory systems remain fit for purpose?

ⁱⁱ See note i.

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

^{iv} See note iii.

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