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Realising social value as an objective for health research regulation

Policy brief

March 2021

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Overview

This policy brief argues that social value should play a more prominent role as an objective of health research regulation. At present, social value is mainly a point of focus when health research studies begin. We propose a series of recommendations that aim to broaden the application of social value so that it threads through the entire lifecycle of health research studies.

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.

Challenges to realising the social value of research

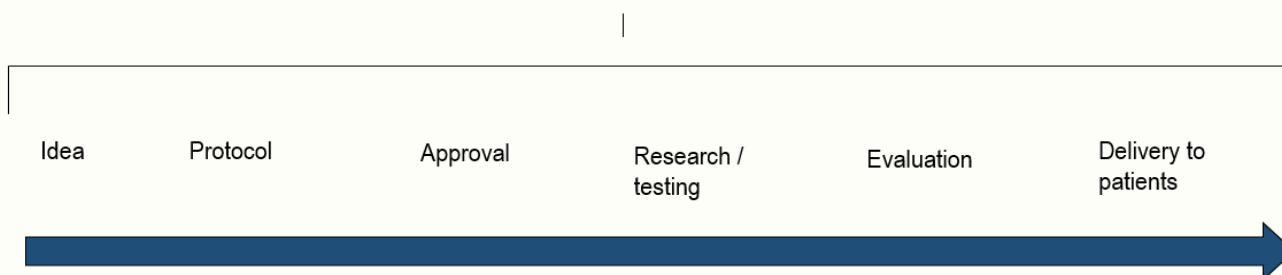
Describing what social value ‘means’

Social value is recognised as a centrally important guiding principle for health research, as shown by its prominence in [international guidance](#). Indeed, the idea that ‘social value’ must come from health research is surely unquestionable. However, social value is like an elephant: more easily recognised than described. This causes problems in regulation because two things quickly become unclear: how this ethical principle can and should be translated into practice; and how it can become an objective for regulation.

Some clarity can be achieved by looking at the many forms that social value might take. Obvious examples are new treatments, drugs, or vaccines. But less obvious examples of social value include research that returns negative results – that is, research which shows a new intervention does not work, or finds that the status quo remains the best course for medical treatments. And there are practical and funding problems associated with this kind of work – for example, researchers might not be interested in taking it on, they might not find journals to publish negative findings, and funders might want to put their money towards more ‘positive’ examples of social value that can create new markets rather than close off opportunities.

How social value is currently applied

We suggest that health research can be understood as a trajectory. For example:



Towards the beginning of this trajectory, research ethics committees (RECs) consider whether a research proposal has social value. However, at this early stage in the research trajectory, social value is only an ideal – albeit an ideal that all scientifically sound, ethically robust research sets out to deliver.

But how can we know if this ideal is realised? And who – if anyone – checks to see what social value actually results once the research is complete? The answers to these questions are uncertain. To make the answers clearer, we suggest that the **social value of research needs to be addressed more systematically than at present**.

Strengthening the role of social value as a research objective

Social value's dynamism across the whole research trajectory

Social value is likely to be addressed towards the start of the research trajectory. However, as stated above, at this stage social value is only a *promise* of benefit. As the research progresses the promised benefit may become unachievable, but this does not mean that social value has not been produced along the way. For example:

- **Initial hypotheses might be disproven and disregarded**: there is social value in finding ways to make this public to avoid future unnecessary research on the same hypothesis or in the same unfruitful area. Of course, such social value will not become apparent until after the research has concluded.
- From **participants' perspectives, research might reveal new information about them that can affect their health, wellbeing, and identity**: communicating such findings to participants – after ethical consideration and approval – could be an act of social value.

These examples of social value are in addition to the original promised social value presented to a REC in the research protocol. They show how **social value is not 'one thing' and nor is there necessarily one 'right' thing to do** to generate social value because it shifts and emerges throughout the entire research trajectory. Researchers and other stakeholders therefore need to **commit to social value throughout the lifecycle of research. We suggest that this is both an ethical and regulatory imperative**.

Social value: everyone's concern

We have argued elsewhereⁱ that health research regulation can be siloed, with regulators and their representatives taking up distinct roles at particular times. One of the reasons that such arrangements cause us concern is that **no one has overall responsibility for achieving the end goal of all health research: to realise social value**. But as we have noted, social value can occur across the research trajectory. This means that **everyone who works across that health research trajectory needs to focus on social value**, rather than just those who are involved when REC approval is sought. Although there are some existing examples – including **from some funders** – they are not abundant.

Recommendation: At each stage of the research trajectory, researchers, regulators, and others involved in carrying out research should ask: *‘is this research study on course to contribute social value?’* To answer this question, they might consider:

- Whether, and how, the research is currently promoting and delivering social value (i.e., value that includes, but also goes beyond, scientific value);
- The likely recipients of the potential range of social value that might be delivered by the research;
- Whether those recipients are different to those anticipated at the outset of the research;
- The actors – for example, citizens, policymakers, or government – who are likely to contribute to social value being realised or put into operation; and
- Whether, how, and by whom the social value can be delivered.

Such assessments should be carried out throughout the course of research. They could **change the nature of social value from an aspiration at the beginning of research to an objective throughout its lifecycle**. They could also form a feedback loop for regulatory systems: a cycle of continuous consideration, analysis, and improvement that supports future good practice.

Social value as an indicator of good practice

By revisiting the question – *‘is this research study on course to contribute social value?’* – we suggest that **research systems will continue to learn about what counts as social value, and how the social value of research can be strengthened**. This could yield examples of good or best practice which could benefit other researchers and regulators who aim to generate social value. Framed in this way, **social value itself becomes a potential measure of success for health research systems**.

Recommendation: Social value assessments and examples of good or best practice should be routinely published and offered as learning experiences for researchers, funders, and regulators alike.

Coming back to the question of whether the research is on course to contribute social value could also raise an alert for **research where social value is in jeopardy within a particular research project**. In such cases, research systems should be primed to respond and assist. This is an example of regulatory stewardship, which we have discussed elsewhere.ⁱⁱ

Recommendation: If assessments suggest that social value is not, or is unlikely to be, realised, regulators should step in to guide researchers through how they might re-establish the project’s social value. As part of this exercise, regulators should be open to forms of social value that were not previously foreseen or imagined.

When considering this recommendation, however, it is important to keep in mind two points:

- In some cases where wider social value is not going to be met, scientific value may remain even if this does not deliver on the original promise in the research protocol. In addition to considering whether new social value might emerge, researchers and regulators should therefore consider whether the study should continue because of its scientific value, in whatever form this might take.
- Jeopardy to social value should not be confused with research that generates negative results. As we have noted, such types of research can actually yield significant social value.

Recommendation: Social value is not only generated by ‘positive’ research. Research that generates negative findings can also offer social value. Funders should therefore consider supporting research that aims to prove negatives.

This should be in addition to increased efforts to support the open access publishing of negative results. Although these results may not be expected, they could add valuable knowledge to our understandings of human health.

Conclusion

Social value is at the heart of all health research, but at present its scope is limited to defined early points on the research trajectory. We suggest that it can be better identified and realised across the entire health research trajectory.

To strengthen its role in health research regulatory systems, researchers should be urged by funders and regulators to repeatedly come back to the question of social value throughout their research. In addition to better representing the fact that research is primarily about improving people’s wellbeing, it also demonstrates a more ethical and effective research enterprise.

Acknowledgments

We thank Dr Agomoni Ganguli-Mitra and Dr Rieke van der Graaf for reviewing an earlier draft of this brief. We also thank Professor Andrew Morris and Professor David Porteous for their input on experiences from a biomedical researcher perspective.

Read more about Liminal Spaces’ work on proportionality:

- [Co-production and managing uncertainty in health research regulation: a Delphi study](#)
- [The Cambridge handbook of health research regulation](#) (forthcoming, chapter 3)

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) End of project vision statement: driving a whole system approach to health research regulation.

ⁱⁱ Liminal Spaces (2021) Regulatory stewardship: concept note.