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Proportionality in health research

Proposals for a fresh approach

Policy brief

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Overview

This policy brief argues that a fresh approach should be taken to the role of proportionality in human health research. It highlights problems with how the concept is currently used by health research regulatory systems and suggests that it would benefit from broader and more flexible applications. It makes two recommendations to realise this fresh approach.

These recommendations draw on research by the Liminal Spaces Project at Edinburgh Law School, [a five-year Wellcome-funded project](#) that examined health research regulatory systems and how their operation might be optimised. This brief is further informed by a [study](#) we carried out with stakeholders working across human health research to capture their experiences of the regulatory system.

How does proportionality currently apply to health research?

In health research contexts, proportionality is, primarily, a concept used by research ethics committees (RECs) and other bodies with regulatory responsibilities to assess whether the expected benefits of research are sufficient to support risks to participants. If the balance between risk and benefit is deemed acceptable, then the research is likely to be approved. If the risks are assessed as disproportionate to potential benefits, then it is unlikely that the research proposal will be approved unless its protocol is changed. There may also be circumstances where a research proposal is assessed to have minimal risks, burdens, or intrusions for participants and therefore “[raise no material ethical issues](#)”. This might include research protocols that propose to carry out interviews or questionnaires [that do not touch on sensitive topics](#). In such cases, UK-based protocols can be eligible for an [accelerated REC review](#).

When is proportionality used?

The diagram below sets out a simple example of how research might develop across a trajectory.



Proportionality is usually considered at a single point on the health research trajectory – that is, when researchers submit their protocol to a REC with the hope of [receiving approval](#) to proceed with their research question(s). The REC can then call on proportionality as a tool which applies a brake to research if it assesses that risks outweigh potential benefits. Proportionality is not usually called on throughout the rest of the research trajectory. We suggest that **this narrow use of proportionality is problematic for two key reasons**.

What are the problems with current applications of proportionality in health research?

The complexity of risk

As noted above, assessments of proportionality depend on assessments of risk. But risk is itself a complex concept because it is **dynamic**, and because it is **subjective**.

UK regulators and researchers who contributed to our [study](#) told us that **the perceived riskiness of a research study does not remain constant throughout its lifespan**; it changes as more knowledge is generated. That is, risk is dynamic. Proportionality, which depends on risk, should therefore be similarly dynamic. At present, it is not – primarily because it is only really considered as ethically important when a research proposal is submitted to a REC.

Risk is also complex because it is subjective. During the course of our project we have seen, for example, that risk assessments of the same protocol [can be tackled very differently](#) by RECs located in different countries. Such examples suggest risk – and the proportionality assessments risk informs – is subject to highly variable assessments based on the preferences or concerns of the decision-makers who are involved. Assessments of risk and proportionality might, therefore, change as a protocol is developed over time.

Neglecting the big picture: realising social value

Elsewhere, we highlightⁱ how realising social value is paramount to the validity of human health research. This is the ‘big picture’ of all health research endeavours. However, **proportionality currently neglects this big picture** because it does not adequately address health research as a whole systemⁱⁱ in two key respects.

1. Focus on proportionality at a single point on the trajectory

As outlined above, proportionality is usually applied at a single point on the research trajectory – that is, towards the beginning, when researchers seek REC approval for their proposal or authority from a similar body to undertake research, for example, [with patients’ data](#). We suggest that **only using proportionality to consider ethical issues in research at a defined early point can seriously jeopardise the chances of realising social value in research**. This is because it fails to reflect that research is represented by a trajectory which can raise a variety of ethical questions across its life course, not just at its inception. As we explain in our social value paper,ⁱⁱⁱ all the types of social value that can arise from research cannot be anticipated from the beginning. New opportunities for social value can arise, as well as new risks and new ethical questions that must be navigated. Proportionality could be a helpful tool to use to navigate such ethical questions and to realise new forms of social value but at present research systems mainly focus on using it at the approval stage. In other words, **proportionality is not simply a risk management tool**. Many stakeholders in the health research ecosystem [see it as a fundamentally ethical exercise](#) about weighing all considerations when deciding whether and *how* to proceed with research or aspects of a research project. This includes not just the reduction of risks but also the examination of opportunities to bring about new social value.

2. Looking to the risks of not undertaking research

Proportionality assessments currently usually focus on the risk of doing, rather than not doing, research. However, the success of health research systems does not just rest on what they *do*. It also rests on what they do *not* do. A participant in our [study](#) with regulators and researchers indicated, for example, that “**the risk of not conducting research is an ethical issue and therefore should be taken into account.**” Indeed, not conducting research could contribute to an incomplete picture of how a particular health condition should be treated. This has the potential to undermine the whole purpose of research: to bring social value.^{iv} It may also have consequences for the trustworthiness of health research systems.^v

How should these problems be addressed?

The problems we have identified suggest that **a fresh approach to proportionality across health research systems is needed**. The concept is currently used narrowly and broadening its application could, we suggest, better support health research and researchers. We propose that proportionality should play a part in a whole system approach^{vi} to health research regulation. For example, this reflects where research data might reveal important information that can affect the health or wellbeing of participants but a protocol might not have considered the need for a feedback policy. Proportionality can have a role to play in the necessary discussions, for example through helping to assess the relative merits or burdens of seeking to contact participants with information about which they know nothing at all.

Recommendation: Researchers should be encouraged to consider using proportionality to navigate ethical issues throughout the course of their research as part of a whole system approach.

Research is a process, not a single event. What is deemed proportionate at the beginning of the research process may change as the research progresses through its various stages. We suggest that this means that proportionality – and indeed other concepts that are used to support ethical research – needs to be considered throughout the course of research. Broadening the application of proportionality could also better support researchers’ assessments of the values and risks at stake at multiple stages in their research. This would strengthen the ethical integrity of research systems.

We do not, however, advocate that researchers should be told to ‘take a proportionate approach’ to ethical issues that occur during their research, and simply left to their own devices. This is because health research operates as an ecosystem. Everyone who works in health research depends on others to fulfil the overall aim of research: to generate social value. It therefore follows that if proportionality is conceived more broadly, those research actors who are affected by this change will need to be supported by others.

Recommendation: Support should be available to researchers on how proportionality can be used to navigate ethical issues throughout the course of their research. Such support might come from:

- **RECs** encouraging researchers to consider whether the proportionality of their research might change as the research progresses, and offering support for how such changes might be tackled.
- **Publishers and journal editors** supporting researchers to publish experiences of how they used the concept of proportionality during their projects.
- **Funders** offering financial support for researchers' training on ethical reflection and how to use proportionality.

We suggest that such forms of support would be beneficial to health research systems in at least two ways:

- Throughout the course of research, they could offer researchers multiple opportunities for identified risks to be reassessed across time.
- They could encourage different people working throughout research systems to share knowledge and experiences, therefore supporting researchers who need to tackle similar issues in the future.

Such support can be described as a form of regulatory stewardship – which we explored in a short concept note^{vii} and was supported by the researchers and regulators who took part in our [policy study](#). This would see researchers and their institutions being guided through existing and emerging regulatory requirements and practices, potentially giving them more consistent support for ethical issues they may face across the lifespan of their research.

Conclusion

Throughout the course of our five-year project, we have reflected on how health research regulatory systems are fluid, interconnected systems. We argue that conceiving systems as a collection of siloed activities and actors is unhelpful for a variety of reasons^{viii} and instead put forward the notion that **health research is best described as a whole system**.

One of our reasons for supporting a whole system approach to health research is that it allows core ethical concepts – such as proportionality – to be applied throughout the research endeavour, rather than just at a single point. **Proportionality has much to offer for health research systems, but at present it is limited by systems which only use it at single points on the health research trajectory and largely as a risk management tool**. To optimise its use more fully **it must be reflected on as an ethical stance throughout the course of research**. We suggest that using it in this broader way will contribute to stronger health research regulatory systems.

Acknowledgments

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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)

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

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

ⁱⁱⁱ See note i.

^{iv} See note i.

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

^{vi} See note ii.

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

^{viii} See note ii.