LiminalSpaces

Regulatory stewardship in health research: Policy Brief

A key finding of the Edinburgh Law School's Liminal Spaces Project is that in a range of areas in health research regulation (e.g. research ethics oversight, data protection, human embryo research), the practice of **regulatory stewardship** exists, even though it has not been explicitly recognised or endorsed to date.

What is regulatory stewardship?

Regulatory stewardship can be defined as the practice of designed entities (persons or organisations) guiding regulated entities (such as researchers) with prudence and care across one or more regulatory endeavours to help them navigate the complexities of regulation (e.g. putting a research ethics application together or obtaining an approval or complying with open access requirements for research results). Regulatory stewardship involves different entities serving to promote the pursuit of clearly identified ends, such as—in the health research context—ethically robust and scientifically sound research.

In this policy brief, we argue that **regulatory stewardship should be more overtly acknowledged in law and policy because it can help reduce regulatory burdens, achieve more proportionality in regulatory oversight, and create more opportunities for researchers to get their socially valuable research projects underway more quickly and ultimately to realise their social value.**

An example of regulatory stewardship in research ethics oversight

An example of regulatory stewardship can be found in and around the practices of research ethics committees (RECs). In the UK, 86 National Health Service (NHS) RECs review approximately 6,000 research applications each year that seek to involve potential research participants who are in the NHS systems. One of the tasks of NHS RECs is to ensure that any anticipated risks, burdens, or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society. Research from the Liminal Spaces Project suggests that regulatory stewardship involves Scientific Officers, REC Managers, and sometimes REC Chairs helping researchers and sponsors navigate complex regulatory pathways and work through the thresholds of regulatory approvals to get their health research project underway. **Collective responsibility**, as a component of regulatory stewardship, requires relevant actors to work together to design and conduct research that is ethical and socially and scientifically valuable and that ultimately aims to improve human health. This can only be accomplished, however, if a policy and practice framework delineates how and when regulators and regulatees should communicate with one another and makes clear who has which responsibility and role to be played at each stage in the research lifecycle.

Regulatory stewardship can be practised by a variety of entities, including both non-state actors and state actors. In the health research area, this can (and does) include the NHS R&D Forum, the MRC Regulatory Support Centre, and universities that may create regulatory knowledge and support programmes to support their researchers.

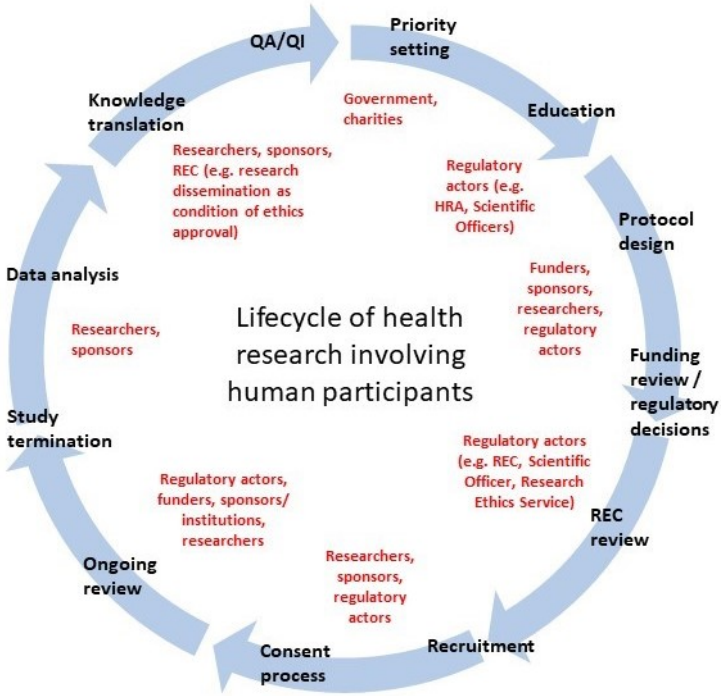
Based on our research that has revealed the importance regulatory stewardship, we advocate that **law and policy should provide pathways for designated entities to engage with regulatees in working through law, regulation, and regulatory approvals, or in other words, embed stewardship in regulation**. These pathways could include in health research, among other things,

enhanced online toolkits for researchers coupled with personalised online support and face-to-face meetings at key moments in research design, approval and conduct.

Regulatory stewardship also could be put on a legal basis, by declaring through statutory regulation that regulatory agencies are expected to bring a more systematic, comprehensive, lifecycle approach to the management of existing regulation. This would mean ensuring on an ongoing basis that regulations are: (1) proportionate; (2) fit for purpose; (3) enabling for stewards to work with regulatees in achieving their desired ends; and (4) requiring regulators to articulate how the public interest will be promoted through the regulated activity (e.g. research).

Such a legal footing would clarify the value of designed entities in enacting regulatory stewardship and specify the tasks for these entities. For example, in the health research context, these entities could be labelled as **state stewards** with relevant responsibilities (e.g. the Health and Social Care Directorate/Department of Health and Social Care and the Health Research Authority must act in a manner deemed to contribute to the public interest, and to demonstrate this); **operational stewards**, who would serve a complementary role (e.g. regulatory support centres, REC Managers, or Scientific Officers who help usher researchers through the complexity of established procedures such as sponsorship commitments and ethics application processes); and **ethics stewards**, who are self-explanatory (e.g. RECs that dialogue with researchers in ways to protect participants and promote research).

Regulatory stewardship has tremendous value to add to research (and other regulated activities). By stating clearly what roles each entity should play at the different stages in the research lifecycle, and how each entity should work with others to move from one stage to the next, health research regulation could achieve more robustly the twin aims of participant protection and research promotion. We illustrate the role of regulatory stewardship (and different entities) in health research involving human participants in the figure below.[1]



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[1] Used with permission from Edward Dove, *Regulatory Stewardship of Health Research: Navigating Participant Protection and Research Promotion* (Edward Elgar, 2020).