



THE UNIVERSITY of EDINBURGH
Edinburgh Law School



Regulatory stewardship

Concept note

What is ‘regulatory stewardship’?

All health research must follow regulations. However, many of these regulations are complex and can change quite often. Their complexity and changing nature can mean that researchers (and their sponsors) may find it difficult to understand and carry out what regulations require of them. In such cases, they may need some help.

Sources of help for researchers and sponsors include people or organisations who are more familiar with what regulations require. They might include organisations who can guide researchers on how to follow the rules, or other researchers who have more experience with navigating the regulations. For complex research that needs to follow multiple rules and regulations across different fields, assistance in navigating the landscape is crucial. The help that such people or organisations offer to researchers and sponsors is what is called ‘regulatory stewardship’.

When might researchers need regulatory stewardship?

In health research, there are several complex regulatory requirements where stewardship can help researchers. Here are three examples:

- 1) Where researchers are required to submit research proposals to a committee which reviews them and gives an opinion about whether they are ethical. Here, a research ethics support service might be a regulatory steward that helps to identify which issues might be a problem and should be addressed before going to a committee.
- 2) A requirement of researchers to ensure that the outcomes of their research are accessible to everyone and published ‘openly’. For this requirement, a regulatory steward might be another researcher who has written an open access publication and can advise on how to proceed.
- 3) The need to navigate complex data protection and confidentiality regulations. Here, a regulatory steward could advise on how these regulations apply to the research project, and how they might be complied with in a way that supports the research objectives. A Data Protection Officer performs this role.

Why is regulatory stewardship important in health research?

The aim of all health research is to improve people’s health and wellbeing. The aim of regulatory stewardship is to help clear the path to such improvements. It does this in several ways, including through:

- Offering support and reassurance to researchers (and sponsors) who may feel burdened by regulatory requirements.
- Addressing concerns about an [‘them vs us’ mentality](#) between researchers and regulators through illustrating how everyone in health research depends on everyone else.
- Enabling projects to get underway more quickly, while still ensuring systems protect research participants. This means that regulatory stewardship can help to make health research systems more efficient.

How can regulatory stewardship be put into practice?

Regulatory stewardship depends on people working together across the whole health research system, and forming a mutually-supportive network. To do this effectively, everyone who is a part of the system needs to know what role they play across the different stages of research. This helps them to identify whether they need regulatory stewardship (and from whom), or whether they could offer it to others. To help with this exercise, the Liminal Spaces project at Edinburgh Law School has [suggested](#) that law and policy need to (1) acknowledge the role of regulatory stewardship more clearly than at present and (2) support the creation of regulatory stewards to better assist researchers and others who promote health research.

Read more:

- [Can regulatory stewardship lead the way in health research?](#)
- [Charting regulatory stewardship in health research: making the invisible visible](#)
- [Regulatory stewardship in health research: policy brief](#)

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