Processual regulation of health research

Concept note

What is a 'processual' approach to health research regulation?

Regulations create legal duties and responsibilities for actors across health research. However, these duties and responsibilities can be fragmented because they focus on isolated events in health research. These events include how participants' consent should be recorded before research can begin, what must be done with participants' data to ensure they are adequately anonymised before being used for research, and the securing of ethical approval before the start of the research.

But the actions, events, and people that make up health research systems do not operate in isolation from each other. Regulation that fails to recognise this is therefore a bad fit. This is where processual regulation becomes relevant.

Processual regulation considers health research as a joined-up system[i] and recognises that even if there are any identifiable 'events' or 'stages' in health research, these often overlap and influence each another. For example, these may be influenced by past, present, and future events; the actions or decisions of stakeholders; and the wider environment. A further aspect of processual regulation is the understanding that the interaction between these events and actors is constantly changing, that is, **regulation is part of a dynamic process that takes place over time**. Accordingly, to see health research as an example of processual regulation requires:

1) **A joined-up approach** based on the understanding that events within a process are influenced by a range of interconnected factors; and
2) **A fluid approach**, recognising that processes are dynamic and change over time requiring potential adjustments to original plans or approaches.

This methodology is regularly found in **social science**, **archaeology**, and **organisational management**, but is yet to be fully explored in health research regulation.

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The challenges of current regulatory approaches

The work of the Liminal Spaces project at Edinburgh Law School has shown that current regulatory systems are not processual, but instead regulate in silos. For example, 'personal data' are protected by data protection regimes; 'human material', or 'biomedical collections' similarly attract specific legislative attention; and embryo research is the subject of highly specific and restrictive regimes. For those who must adhere to regulation, this presents complex systems to navigate, particularly if their work straddles different types of health research.

We have suggested that isolating events in the health research process is unsatisfactory for a number of reasons:

- **Risk of duplication**: The creation of multiple siloed areas of regulation can result in the duplication of regulatory mechanisms that can slow down, hinder, or even halt, important research and innovation.
- **Risk of overlap**: Regulatory regimes will at times overlap, causing researchers to experience difficulty in interpreting, and thus complying with, their rules. This is especially evident for complex research which straddles a number of regulatory categories' boundaries, for example, integrated biotechnologies.
- **Risk of regulatory blindness**: There is no body with responsibility to oversee the research process as a whole to ensure that the regulatory objective(s), including social value, are in fact realised.

By viewing health research regulation as an interconnected system, processual approaches can avoid these difficulties.

Why might processual regulation be important for health research?

Health research operates in a highly-regulated environment. Across the entire lifespan of their study, researchers must respond to what regulation demands of them. However, as we have noted elsewhere[ii], health research is uncertain, setting out to discover as yet unknown information to improve human health and current treatments. But, in health research, uncertainty can also apply to how health research regulations should be interpreted. That is, there can be a degree of flexibility in how regulations are applied (without breaking the rules). Processual regulation tackles this particular type of uncertainty through **encouraging regulators and researchers to adapt as research studies evolve**. Through accounting for changeable health research processes, **processual regulation could therefore support the achievement of regulatory objectives, such as protecting humans in the research process and achieving social value[iii] and promoting a more efficient system**. Furthermore, if these learning moments are captured, they can teach future researchers and regulators how to approach new research in ways that build on these experiences – the regulatory ecosystem becomes a learning system.

How might a processual approach to regulation be put into practice?

Rather than promoting a series of steps to be taken, **processual regulation requires regulatory bodies to constantly revaluate the guiding principles and rules to understand if they meet the main regulatory objective: to achieve social value**. Regulators might, for example, implement feedback loops – that is, a continuous cycle of learning from uncertainties that affect research – to

examine how current regulations are experienced by those they regulate. Another example would be to capture and share the experiences of complex research protocols that have had to navigate multiple research regimes, developing lessons for the future. Liminal Spaces has done some work on this already as part of a policy study where researchers and regulators were found to favour a more flexible approach to regulation.

A core objective of the Liminal Spaces project was to 'reimagine' human health research regulation. Two examples of where a processual approach could improve regulation can be found here:

- Catriona McMillan's 'context-based' model for embryo research
- Annie Sorbie's processual approach to public interest

Read more:

- Liminality and the limits of law in health research regulation: what are we missing in the spaces in-between?
- Co-production and managing uncertainty in health research regulation: a Delphi study
- Beyond regulatory compression: confronting the liminal spaces of health research regulation
- Beyond categorisation: refining the relationship between subjects and objects in health research regulation
- Reconfiguring social value in health research through the lens of liminality

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[i] Liminal Spaces (2021) End of project vision statement: driving a whole system approach to health research regulation.
[ii] Liminal Spaces (2021) The challenges of uncertainty in health research: how can regulatory systems remain fit for purpose?
[iii] Liminal Spaces (2021) Realising social value as an objective for health research.

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