



PROTECTING AND  
PROMOTING:  
CAN REGULATORY  
STEWARDSHIP LEAD THE  
WAY IN HEALTH RESEARCH?

A ROUNDTABLE DISCUSSION

29 March 2019

# Roundtable report

## *Protecting and promoting: Can regulatory stewardship lead the way in health research?*

### *A roundtable discussion*

#### **Executive summary**

On 29th March 2019, a roundtable of research ethics committee (REC) members, research managers, regulators, patient advocates, and scholars was convened at Edinburgh Law School to discuss ‘regulatory stewardship’, a potentially novel regulatory model of health research oversight that could improve regulatory interactions among different stakeholders. A key aim of this roundtable was to consider a reimagining of regulatory spaces in health research to optimise their effectiveness in delivering productive regulation. Research from the University of Edinburgh’s Liminal Spaces Project suggests that regulatory stewardship involves different actors—RECs and others involved in the regulation of health research—helping researchers and sponsors navigate complex regulatory pathways and work through the thresholds of regulatory approvals. 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 if a framework delineates how and when regulators and regulatees should communicate with one another and makes clear who has what responsibility and role to be played (if any) at each stage in the research lifecycle.

Using hexagon shapes to thematically group responses to several high-level questions posed to them, roundtable participants helped identify the key challenges and opportunities associated with regulatory stewardship. For example, several participants commented on the difficulty in teasing out the conceptual and practical difference between stewardship and gatekeeping, and considered whether there are aspects of health research regulation that can be researched more in-depth to see whether stewardship is observed or can be implemented as a pilot project. Participants also discussed the importance of patient and public participation in regulatory stewardship, and the link between stewardship and proportionality: stewardship is partially about streamlining regulatory pathways, helping to avoid researchers and sponsors and getting bogged down in unnecessary paperwork or duplicative processes. Overall, participants supported the potentially beneficial impact of regulatory stewardship in health research. The next step for the roundtable participants is the construction of a short policy brief that outlines the ways in which a regulatory stewardship approach might be implemented in health research.

## **About the Liminal Spaces Project**

The Liminal Spaces Project is a five-year initiative that began in October 2014. This Wellcome Trust Senior Investigator Award in Medical Humanities led by Prof Graeme Laurie seeks to provide the first-ever integrated, interdisciplinary and cross-cutting analysis of health research regulation (HRR) as it impacts on, and often impedes, the Wellcome Trust vision of realising extraordinary improvements in human health. The research confronts the gaps between documented law and research practice – i.e., liminal regulatory spaces – and promotes a holistic approach thus far absent in HRR.

## **About the Regulatory Stewardship roundtable**

This Roundtable arises from one of the key findings of the Liminal Spaces Project, viz, that in a range of areas of regulation in health research, a phenomenon exists that has hitherto been largely unrecognised: the practice of regulatory stewardship. This happens within regulatory environments when certain actors emerge to help researchers and others to navigate the complexities of regulation and research approval. The project team have characterised regulatory stewardship as the practice of “...guiding others with prudence and care across one or more endeavours – without which there is risk of impairment or harm – and with a view to collective betterment.”

The Liminal Spaces team has already published work in which an argument has been made that this role of regulatory stewardship must be more overtly acknowledged and understood. The Roundtable arose as a means to test the contours of the proposed model, and to ask whether and how regulatory stewardship might better operate as a key feature in health research regulation.

A particular instance of regulatory stewardship can be found in and around the practices of Research ethics committees (RECs). RECs occupy a critical position in the governance of health research. In the UK, 85 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. Through their discretionary power to input to and potentially influence an applicant’s research design, RECs can impact what knowledge is produced and can significantly affect the relationship between researchers and research participants. They make, therefore, for a fascinating object of investigation, particularly in light of recent regulatory changes. This roundtable, which convened on 29 March 2019, sought to uncover RECs’ workings and relationships within a network of connected actors in health research, with a view towards charting a novel regulatory model (or models) for health research oversight in the UK that could improve regulatory interactions between different stakeholders.

Recently, one of the Liminal Spaces team members (Edward Dove) undertook an empirical investigation of the roles and practices of RECs in light of recently implemented health research legal regulation that explicitly seeks to promote health research in the UK, in part by streamlining regulation itself. It was unclear how these recent regulatory changes, stressing efficiency and maximisation of UK competitiveness

for health research and maximisation of return from investment in the UK, might affect the substantive and procedural workings of RECs. It was also unknown whether or how the modification of research regulation at the level of legal architecture to promote research—seen, for example, in the Care Act 2014 and in the mandate of the Health Research Authority (HRA)—might ‘trickle down’ to the day-to-day practices of RECs.

The research findings from that empirical investigation aim to serve as a basis for further assessments of RECs and health research regulation, thereby opening the potential to inform policy decisions and policy reform. Indeed, a key aim of this roundtable was to consider a reimagining of ‘regulatory spaces’ in health research to optimise their effectiveness in delivering productive regulation. Core questions include:

- How might participant protection and research promotion work together in a regulatory framework, if at all?
- Is there a need for a deliberative space within which RECs can both negotiate the risks relevant to a research application and also work with researchers to get to a point where the application can be deemed ethically acceptable?
- What range of actors needs to be involved, with which responsibilities, and towards which ends?
- How might a regulatory deliberative space be protected to capture and promote the fluid, processual nature of REC deliberations and effective health research regulation?

As outlined above, research from the Liminal Spaces Project suggests that regulatory stewardship involves different actors—RECs and others involved in the regulation of health research—helping researchers and sponsors navigate complex regulatory pathways and work through the thresholds of regulatory approvals. 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 if a 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 (if any) at each stage in the research lifecycle.

To this end, in this roundtable we considered whether a regulatory framework for health research could chart different kinds of regulatory stewards with distinct roles, such as state stewards, institutional stewards, operational stewards and ethics stewards. If so, seen in this way, the example of the REC serves as an illustration of a potentially much wider contribution to policy, regulation, law, and theory in the health research context.

The tangible objectives of this roundtable were:

- To bring together research ethics committee members, policymakers, regulators, and other stakeholders from across the UK to discuss current challenges in health research governance, to facilitate knowledge exchange, by exploring recent research findings on health research regulatory practices in action;

- To encourage stakeholders to contribute to policy development in health research by co-developing a model or models that aim to integrate regulatory stewardship in health research in ways that both protect research participants and also facilitate ethical and socially valuable research;
- To develop further a regulatory model for health research oversight in the UK that integrates regulatory stewardship and improves regulatory interactions between different stakeholders in health research;
- To facilitate future collaborative research and co-designed regulatory practices that improve health research regulation in the UK and internationally; and
- To explore ways to enable health research to become more responsive to political and societal developments, in local and global contexts (particularly in the context of Brexit).

This report, co-authored by the roundtable participants (see Appendix 1), summarises the discussion. It also lays out next steps for the group.

### **Session 1: Introductions and context setting**

This first session consisted of introductions and context setting. Participants suggested several learning objectives they hoped to get from the roundtable, including learning how:

- regulation can be more efficient and more effective;
- research can be presented so that it is in the best shape possible by the time it goes to a REC;
- researchers can better navigate through various regulatory processes;
- patient perspectives can be adequately heard and integrated into processes;
- ethics can be better embedded into the entire research process rather than being seen as an add-on;
- regulatory stewardship can be better and/or further embedded into the work of regulatory authorities; and
- we can lessen the ‘us versus them’ mentality that sometimes exists between researchers/sponsors and regulators.

Several participants thought that a form of regulatory whether stewardship already exists in health research, even if it is not labelled as such; others expressed the view that elements of stewardship may exist, but not across the health research regulatory space as a whole and in a joined-up way.

Formal presentations were then made by two of the participants.

Edward Dove presented on “Protecting and promoting: Can regulatory stewardship lead the way in health research?” He summarised key themes and findings from his empirical research on RECs in the UK, namely: 1) The black boxes of ethics review: RECs have their own ethics space where they deliberate, but do not necessarily know if they are doing the same thing as other RECs; 2) Regulatory connectivity: difficulties in separating out law and science from ethics; and 3) Regulators as stewards: a lot of REC

members view their committees (or members within them) as stewards of research. Dove also summarised other findings, such as the challenge of working through participant protection and research promotion, and the role that key actors, such as Scientific Officers, REC Chairs, and REC Managers play in helping researchers and sponsors navigate the demands of getting their research study up and running. The implication for health research regulation is the crucial role that stewardship may play.

Graeme Laurie then presented on “Regulatory stewardship”. The presentation sought to do three things: 1) provide an argument in favour of recognising this role (which, as discussed by several of the participants in the introductory rounds, seems to be already occurring); 2) provide an account of examples where it is already found (but perhaps hidden); and 3) provide a statement of the normative elements of the regulatory stewardship role – and to query whether these make sense to stakeholders. Several open questions remain, including: What principles underpin the stewardship role? What responsibilities does it involve, and upon who do/should they fall? How might we conceive regulatory stewardship? How would regulatory stewardship appear in law and regulation? And what might it mean for the health research community, broadly considered?

All participants had been furnished with a copy of the publication produced on the Liminal Spaces team, but the team emphasised they were open to – and indeed encouraged – revision of the model proposed therein ([available here](#)).

## **Session 2: Experiences and lessons learned**

Participants then engaged in a discussion based on the presentations from Dove and Laurie. Among the discussion points raised were:

- In context of data stewards, safe havens exist across Scotland. Part of their responsibility is to support access to NHS patient data. RECs have a specific role in the wider context of all these other actors who are also there to facilitate researchers; should the remit of RECs be expanded, or should we look to see what other actors exist in the broader landscape that perform stewardship roles?
- The need to consider in the analysis the example of clinical trials research units and improvement specialists. Less well-funded projects may not have access to regulatory stewardship processes, whereas for well-funded projects there may be an entire sector which performs stewardship.
- While there may be a distinction between being well-funded and having regulatory support and being poorly funded and lacking support, in terms of how one navigates regulatory spaces this challenge in itself might not be contingent on funding.
- Regulatory stewardship needs to be embedded much earlier in the process before an application goes to a REC, particularly at the point of funding and sponsorship.
- A distinction may need to be *made between stewardship and gatekeeping*. These might be linked roles, but they are not necessarily the same. A related question

that needs careful consideration is how to work out a suitable balance of stewardship, in other words, how much stewardship is needed or is suitable for a given study? If you ask most researchers about stewardship, they would probably say there's too much of it, and what guidance they get is conflicting or difficult to resolve. Researchers are trying to tread a path to both please gatekeepers and work with stewards. There is a sense of ownership at the moment that stewardship people think they provide, but there's a need for various stewards to link their work to avoid duplication or inconsistency and to encourage a seamless passing of the baton from one regulatory stage to the next.

- There is some concern that with regulatory stewardship, the responsibility of good ethical conduct in research gets shifted away from the researcher and to the regulatory steward. There was strong agreement that regulatory stewardship should not be seen as a means by which the researcher can absolve him- or herself from being ethical or dealing with ethical issues in research. Any value from a model of regulatory stewardship must be in addition to the responsibilities of all actors within a regulatory ecosystem to discharge their own ethical duties.
- RECs should not be seen as a problem in health research regulation. They are well managed, and the guidance is well defined. Other elements in the system may be sources of problems, such as NHS R&D permissions, funding, etc. The challenge is in making sure the governance processes that are in place are proportionate and effective, but also pragmatic. Certain criteria need to be set, and certain people need to be reassured before research happens.
- The question of *timing and sequencing of stewardship* across the research lifecycle needs careful consideration – which stewards step in and at what point? REC approval is only one point in the research lifecycle and questions about working through regulation appear before and after the ethics approval stage. There was a strong position voiced by some participants that RECs should *not* be seen as stewards, but rather as gatekeepers. The logical conclusion from this is that stewardship ought to occur prior to research applications reaching a REC.

### **Session 3: Challenges and opportunities with health research regulation**

In this session, participants were asked to consider and respond to the question, “If regulatory stewardship is a viable model, what are the key challenges to putting it in place?”

Among the responses from participants were:

- Capturing the non-scientific view in a REC (i.e. if it cannot be understood by people in a REC, how are others in hospitals and elsewhere going to understand?).
- A proper understanding of what stewardship means; must distinguish between high-level stewardship (e.g. what the HRA was set up to do, to steward other organisations) and a key pre-requisite for the lower level (e.g. a sponsor

adequately supporting researchers to compile applications that are robust in ethical and regulatory terms).

- Providing resources to various actors to facilitate stewardship.
- Stewardship versus handholding. Who engages in stewardship and when?
- Getting stewardship embedded much earlier into the regulatory pathway.
- Culture change: if regulatory stewardship is to succeed, there needs to be a shift in culture and behaviour to make people more aware of the role, relative responsibilities and to be better equipped both to deliver stewardship and to take advantage of it.
- Putting structures in place in a way that does not create a sense of unfairness/frustration by researchers.
- Avoiding institutional compliance whereby language and processes become focused on getting through/box-ticking.
- Getting regulatory stewardship endorsed by researchers.
- Timing: regulatory stewardship needs to start early, from the conceptual stage of research design; if there is no stewardship before an application reaches a REC, it's too late. As mentioned above, a strong view was given that the role of a REC is more of a gatekeeping than stewardship one; stewardship may not be role of a REC in-committee, but out of committee it is. The end point should be RECs not having to do it at all.
- Danger of government bodies stifling creativity. If bodies dictate what the stewardship model is, then creativity may get stifled because of the top-down process.
- Guidance becomes interpreted through urban myth as rules; regulatory stewardship could play role here in dispelling myths.
- Avoiding the conflation between gatekeeping and stewardship, and not infantilising researchers and sponsors.
- Encouraging actors to trust regulatory stewards; and ensuring that stewards trust each other and work in a collaborative way (both with other stewards and other actors).
- Delineating a clear division of labour among stewards at different points in the research design and approval trajectory.
- Avoiding a sense of 'collusion' between regulators and regulatees.
- Ensuring sponsors are in a position to provide good advice as much as they can and as often as they can (this requires both resources and training).
- Building a system for metrics to ensure there is an evidence base on which regulatory stewardship can be built and assessed (questions of how you measure effectiveness, how you build up accountability, etc.).
- Demonstrating value of regulatory stewardship to those who have not already been 'converted' to it (i.e. viewing it favourably).
- Broadening the idea of regulatory stewardship to other forms of stewardship necessary in health research – for example, ethical stewardship (counterclaim is that regulatory stewardship is an umbrella term that captures other sub-forms of stewardship, including ethical stewardship that falls within the REC mandate).

- Avoiding putting too much work on RECs and turning them into mere governance managers.

Dove and Laurie made use of hexagons to group thematically the responses, as reflected in Figure 1 below. The responses were grouped into thematic questions of ‘Why’, ‘How’, ‘Who’, ‘What’, and ‘When’?

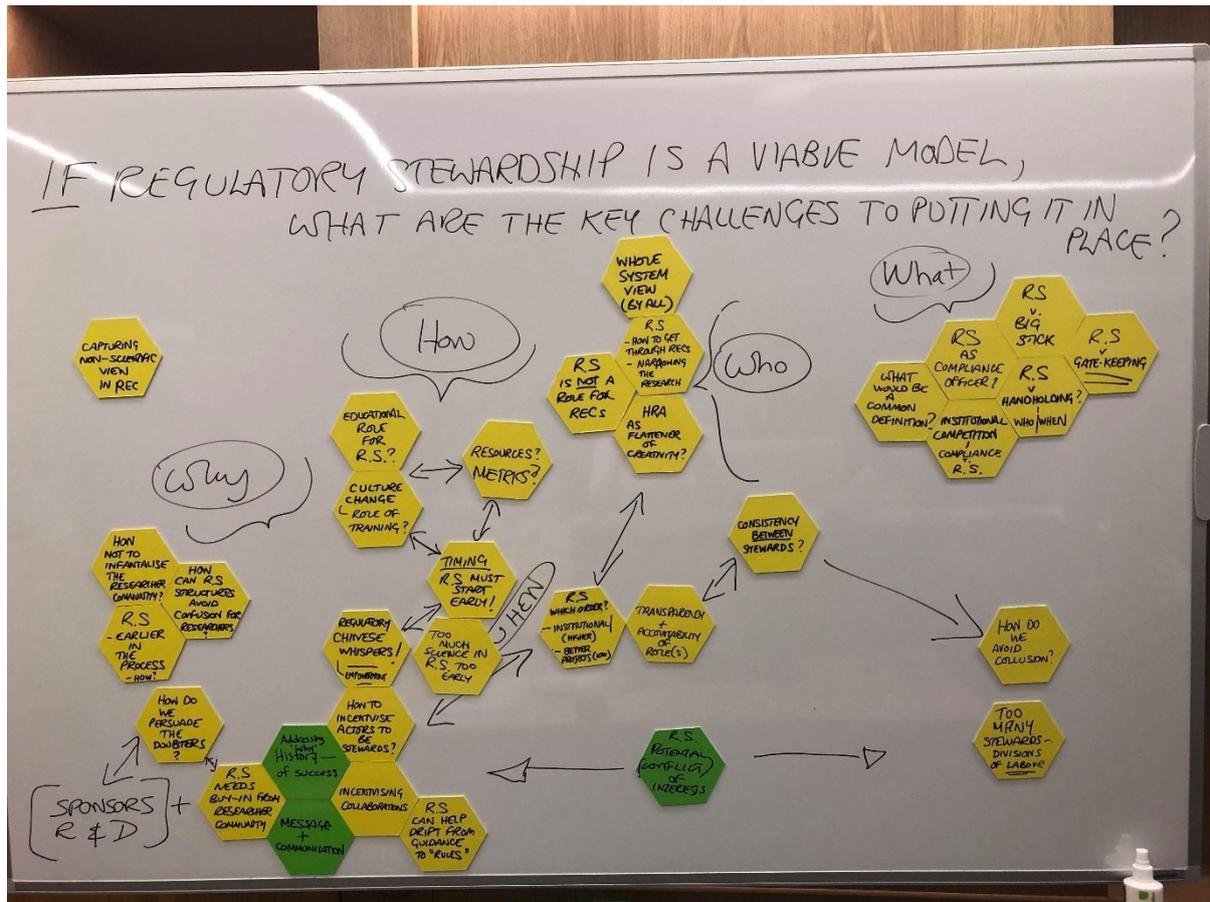
The messages captured in the hexagons were:<sup>1</sup>

- Capturing non-scientific view in REC
- Too much science in RS too early
- Regulatory ‘Chinese whispers’ – empowerment
- Educational role for RS?
- Culture change- role of training?
- How can RS structures avoid confusion for researchers?
- What would be a common definition?
- RS – earlier in the process. How?
- Timing: RS must start early!
- How to incentivise actors to be stewards?
- Incentivising collaborators
- Institutional competition- compliance v RS
- How to not infantilise the research (and wider) community?
- RS needs buy-in from research community
- Whole system view (by all)
- RS v Big Stick
- Rs v gate keeping
- RS v handholding? Who/When?
- RS as compliance officer?
- Consistently between stewards?
- RS – how to get through RECs and – narrowing the research
- Transparency and accountability of role(s)
- Resources?
- HRA as flattener of creativity?
- How do we persuade the doubters?
- RS – which order? Institutional (higher) // Better projects (low).
- RS can help drift from guidance to ‘rules’
- How do we avoid collusion?
- RS is NOT a role for RECs
- Too many stewards- division of labour
- Addressing history –of success
- RS potential of conflict of interests
- Message and communication

---

<sup>1</sup> Regulatory stewardship is shortened to ‘RS’.

Figure 1. Hexagon grouping of Question 1.



After the morning Sessions 1-3, three key questions emerged:

1. What is the difference between a gatekeeper and a regulatory steward?
2. Where does regulatory stewardship fit into the research trajectory?
3. Does regulatory stewardship already exist, and if so, where? Are we 'pushing an open door?'

### Session 4: Working better together

Following the lunch break, the roundtable re-convened to further discuss the responses from the question posed in Session 3. Some participants stressed that there is a messaging problem in trying to 'sell' regulatory stewardship to the research community. This is likely to arise because a lot of stewardship that is offered currently is on how to negotiate processes, which have been manufactured to demonstrate something or provide some physical safeguard. Often this turns into how to fill out the form properly, and we want to steer away from 'how to fill out the form'. Part of a better stewardship function may be about getting underneath the forms and exploring and answering why particular questions are being asked, rather than focusing on the questions themselves. In other words, a key role of stewardship might be to encourage and support deeper ethical reflection on the entire approvals process itself.

Another discussion point turned on considerations of downstream stewardship (i.e. what happens to research findings, etc.) and closing feedback loops, i.e. is one able to say, 'can someone steward back to make sure this gets fed upstream for the future'. Regulatory stewardship is not about removing the health research regulatory system but rather working within it to make the various component parts work smoothly and facilitate research across the lifecycle; it is also, ideally, about maximising the benefits that can rise from research (and not simply about getting research approved). In this sense, 'regulatory' in stewardship isn't referring to regulation in 'big stick' sense, but rather as a signal to the systems that govern health research across the UK.

### **Session 5: Testing regulatory stewardship and/or other models**

In session 5, participants were asked to consider and respond to the question, "If regulatory stewardship is a viable model (however labelled), what are the crucial next steps?"

Among the responses from participants were:

- Identify who would undertake the role of regulatory stewardship, who is going to organise it, and who is going to supply funding? If a steward is a specific person, how do they fit into an organisation?
- Revisit the IRAS form and the training associated with it.
- Identify which areas of stewardship we are talking about. What ethics or other practices are being stewarded at these various stages? How can we avoid duplication to get a more efficient system out of this?
- Promotion: engaging with regulatory stewards and the research community and understanding expectations.
- How we go about patient/participant and public engagement? If stewardship is already ongoing, how can we show example of where it is happening, and what's happening? How is it helping? We need to show examples and think about how there can be greater patient/participant and public participation in regulatory stewardship.
- Thinking about gaps in stewardship in terms of research topics, such as research on pregnant women.
- Consideration of whom we think will derive advantage from regulatory stewardship. What kind of advantage do we see, and who would deliver it?
- Division of labour amongst the various possible stewards.
- Getting the idea of regulatory stewardship embedded in policy documents. Universities UK may be a useful organisation for this.
- Encourage early thinking and support (with possibility of HRA secondment in the field).
- Consider whether this is a novel model or an attempt to rebrand a lot of disparate activities and become a key word. (Consensus at the roundtable was that regulatory stewardship is both a model and a bit of rebranding. We have normative basis. It is not about compliance or gatekeeping; it's about identifying examples of stewardship that already exist and tying the examples together

under a model – joining them as a system.) The next step here is to forge a common understanding of this term, identify where we are doing it and where we are doing it better.

- Embedding the idea of regulatory stewardship, and identifying the task description: is it person specification, and if so, what are the knowledge/skills of someone doing this?
- Understanding how stewards interact with each other; and getting the messaging and promotion right. We need to be clear on what stewards can and cannot do.
- Capturing the ‘complex’ or ‘odd’ research applications to learn from them. Regulators and RECs tend to operate in silos and do not learn from their deliberations. A next step would be to develop a system such that every deliberation is the foundation for the next, in no small part so as to keep to keep the quality of response the same.

Dove and Laurie made use of hexagons again to group thematically the responses, as reflected in Figure 1 below. The responses were again grouped into thematic questions of ‘Why’, ‘How’, ‘Who’, ‘What’, and ‘When’?

The messages captured in the hexagons were:<sup>2</sup>

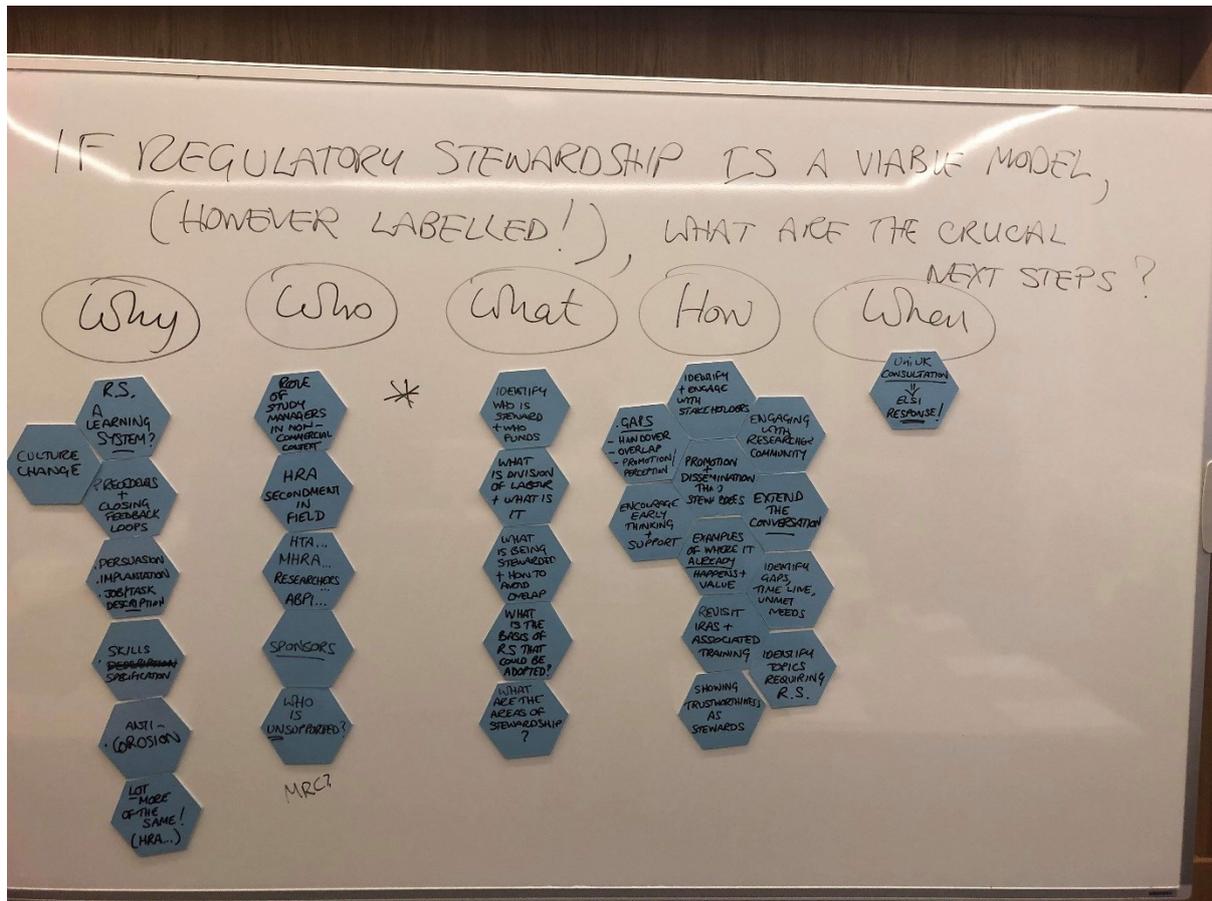
- Identify who is a steward and who funds
- What is being steward and how to avoid overlap
- Revisit IRAS and associated training
- What are the areas of stewardship?
- Identify and engage with stakeholders
- Examples of where it is already happening
- Engaging with researcher community
- Culture change
- What is division of labour and what is it
- Identify topics requiring RS
- Identify gaps, timeline, unmet needs
- Universities UK consultation and opportunity for a response to plug RS
- Lots more of the same (HRA)
- Encourage early thinking + support
- HRA secondment in field
- What is the basis of RS that could be adopted?
- Extend the conversation
- Persuasion, implantation, job/task description
- Skills specification
- Anti-corrosion
- Gaps (handover, overlap, promotion/perception)
- Showing trustworthiness as stewards
- MHRA + researchers + ABPI (+ HFEA + HTA, etc.)

---

<sup>2</sup> Regulatory stewardship is shortened to ‘RS’.

- RS: a learning system?
- Procedures and closing feedback loops
- Sponsors
- Who is unsupported?

Figure 2. Hexagon grouping of Question 2.



### Session 6: Where next?

In the final session, participants revisited several of the key questions raising during the day and discussed emerging themes that might be explored in the main output of the roundtable: a short policy brief on regulatory stewardship.

The first question revisited was the difference between stewardship and gatekeeping. Relatedly, it was queried whether regulatory stewardship is done (solely) by gatekeepers (i.e. regulators or those with a quasi-regulatory role, such as RECs), or is it something that needs to be separated?

There was discussion about whether aspects of health research regulation can be researched more in-depth to see whether stewardship is observed or can be

implemented as a pilot project. Some suggested observing regulatory affairs specialists to see whether stewardship is part of their job, even if not labelled as such. There is a research support infrastructure that already exists in health research, but it is not clear whether researchers, sponsors, and others perceive that infrastructure as supportive.

Within health research, there is a 'new' group coming in – statisticians, informaticians and engineers – who do not have biological sciences or medical science training. There is some concern that this group lacks the cultural experience of research involving health in humans and will need more stewardship and support than others. It might be fruitful to seek to engage with these new actors, especially since they will be unencumbered by some of the cultural 'baggage' of other stakeholders who have operated in the health research regulation environment for much longer.

There was also discussion of the link between stewardship and proportionality: stewardship is partially about *streamlining* regulatory pathways, helping to avoid researchers and sponsors and getting bogged down in unnecessary paperwork or duplicative processes.

Among some of the themes that emerged from the roundtable were:

- The importance of efficiency in regulatory process – how can stewardship drive efficiency?
- The interrelated questions of: what is regulatory stewardship, how can it be implemented, why should we implement it, when in the process should it be implemented, and who might be the stewards?
- Upstream and downstream regulatory stewardship (with feedback loops).
- Suggestions for 'new ground' to (pilot) test regulatory stewardship: 1) those who are newcomers to health research (e.g. informaticians, engineers); 2) social care researchers.

The immediate next step for the roundtable participants is the construction of a short policy brief that outlines the ways in which a regulatory stewardship approach might be implemented in health research.

**Acknowledgements:** The roundtable participants acknowledge and thank Wellcome for funding the roundtable through a Senior Investigator Award entitled "Confronting the Liminal Spaces of Health Research Regulation" (Award No: WT103360MA), and the College of Arts, Humanities and Social Sciences at the University of Edinburgh for supporting the roundtable through funding from a Knowledge Exchange and Impact Grant.

### Appendix 1: Roundtable participants

Edward Dove <i>(roundtable organiser)</i>	Lecturer in Health Law and Regulation, University of Edinburgh
John Buchan	Chair, Wales REC 7
Clive Collett	HRA Ethics Guidance & Strategy Manager, Health Research Authority
Hugh Davies	Chair, South Central – Oxford A REC, England
Alison Evans	Director of Policy & Impact, Alzheimer's Research UK
Phoebe Friesen	Post-Doctoral Fellow, Ethox Centre, University of Oxford
Judith Godden	Scientific Officer, West of Scotland Research Ethics Service
Simon Kolstoe	Chair, MODREC and Chair, Hampshire A REC; Senior Lecturer & University Ethics Advisor, University of Portsmouth
Graeme Laurie	Professor of Medical Jurisprudence, University of Edinburgh
Catriona McMillan	Senior Research Fellow in Law, University of Edinburgh
Lindsay Murray	Chair, South East Scotland REC 2
Helen Newbery	Scientific Officer, South East Scotland Research Ethics Service
Alastair Nicholson	Senior Development Manager, Health Research Authority
Fiach O'Mahony	Clinical Research Facilitator, University of Edinburgh
Rachel Smith	Programme Manager – Training and Partnerships, MRC Regulatory Support Centre
Charles Weller	General Manager, NHS Research Scotland Central Management Team
Sandra Wyllie	REC Manager, South East Scotland REC 1