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Health research project required advice or approval from 89 different people to get the green light

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Which health research projects involving humans are ethically justified, safe and legal? Who decides whether they should get the green light to proceed? In one case study, researchers at the Primary Care Unit, University of Cambridge, found that 89 different people were involved in approving a single small scale health research study for ethics and governance purposes.

The case study looked at ethics and governance communications before the implementation of the new UK Health Research Authority (HRA) approval process for England but the study suggests that problems of piecemeal activity and system complexity may still dog the research approvals process.

In the case study, 81 named individuals were required to approve the proposed research, for research ethics and governance approval purposes, and 8 unnamed individuals were mentioned in communications as having provided further advice. This corresponds to roughly two approvers for every person participating in the research. The study team recorded 491 exchanges with these 89 individuals, generating 193 pages of email text, excluding attachments.

These exchanges were conducted outside the supposedly "one-stop" Integrated Research Application System (IRAS) platform, expected to be the platform where all necessary documents are provided and

questions addressed. Importantly, the figures exclude the actual work of preparing the ethics documentation (such as the ethics application, information sheets and consent forms).

In one hospital, 10 individuals and 101 exchanges outside IRAS were needed, to allow researchers to interview 4 medical consultants.

The case study was based on an audit of approvals communications in relation to one interview- and questionnaire-based study conducted in England which used the National Health Service (NHS) procedures and IRAS. This was a relatively straightforward and small scale study of patient data sharing called "Prepared to Share?".

The approvals communications in the case study date from February 2013 to February 2016. Although some of the approvals were granted at a time when HRA Approval was already functional, the new system was phased in gradually and the Prepared to Share study was fully approved under the old system.

The researchers concluded that the size of the approvals machine and the nature of the work of its individual parts may still remain hidden, even to people working in it, including those working to reform it.

"Colleagues and reviewers from within the system have been struck by the figures, as we were. The scale of the work involved is largely invisible when done piecemeal", said Dr. Mila Petrova, Research Associate at the Cambridge Palliative and End of Life Care Group, Primary Care Unit and lead author of the paper about this research, published today in BMC Medical Ethics.

"Even though HRA Approvals seems to be achieving some improvements, we argue that more needs to change before researchers in England experience the system as "radically simplified", continued Dr.

Petrova.

The research team suggest six ways to further improve the research approvals system:

1. Support the development of a broad range of customised research ethics and governance templates to complement generic, typically clinical trials orientated, ones;
2. Develop more sophisticated and flexible frameworks for study classification;
3. Link with associated processes for assessment, feedback, monitoring and reporting, such as ones involving funders and patient and public involvement groups;
4. Invest in a new generation IT infrastructure;
5. Enhance system capacity through increasing online reviewer participation and training; and
6. Encourage researchers to quantify the approvals processes for their studies.

"Ethics and governance approvals are burdensome for historical reasons and not because of the nature of the task. The case study suggests that there are many opportunities to improve the efficiency and analytic depth of the process, in an age of innovation, increased connectivity and distributed working," said Dr. Stephen Barclay, University Senior Lecturer in General Practice and Palliative Care, Primary Care Unit.

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More information: Petrova and Barclay in *BMC Medical Ethics*:

"Research approvals iceberg: how a 'low-key' study in England needed 89 professionals to approve it and how we can do better"
bmcmedethics.biomedcentral.com … 86/s12910-018-0339-5

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