

Uncorking the bottleneck in gaining sponsorship for clinical research

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Research is essential to advancing clinical treatment, improving treatment outcomes, and evolving healthcare services (NHS England, 2014; NHS England Innovation & Research Unit, 2018). This is recognized by the UK Department of Health, most notably by means of continued multibillion investment in the National Institute for Health Research (NIHR), to ensure the proliferation of applied and clinical research (Department of Health Research and Development Directorate, 2006; National Institute of Health Research, 2017). The focal aim of such investment is to support researchers to succeed in completing world-class research

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that benefits the public and those using the NHS, thus informing practice and policy. Nevertheless, long-standing issues in transforming research into practice persist, with an estimated lag of 17 years between publication and the introduction of an intervention (Morris et al., 2011). Partly in response to this lag, in November 2017, NHS England and the National Institute for Health Research released ‘Twelve actions to Support and Apply Research in the NHS’ (NHS England in partnership with The National Institute for Health Research, 2017). The goal of this joint statement was to highlight how both the NHS and the NIHR, in addition to other NHS-related bodies, could help tackle systemic and local inefficiencies that obstruct the timely production of research (NHS England in partnership with The National Institute for Health Research, 2017).

One such inefficiency, identified within the joint statement, pertained to delays in confirming multisite trials (NHS England in partnership with The National Institute for Health Research, 2017). In an effort to remove such obstruction, in June 2017, the Health Research Authority, the national entity responsible for overseeing the governance of ethical health research, relaunched a single research ethics and regulatory approval process (NHS Health Research Authority, 2017). Known as the Integrated Research Application System (IRAS), this system now merges all research ethics committees (RECs) and their affiliated research and development forms. As reported in the third quarter of 2017, such streamlining has reduced the time between application for ethical approval and first recruitment of participants from 231 days to 142 days (NHS England, 2017). This is a welcome outcome for health researchers in the UK and a significant step forward in reducing research delays. However, it targets just one area in which delays occur as it does not account for the barriers that researchers may face leading up to submitting their study proposal for ethical approval in England.

Researchers based at English universities seeking ethical approval are likely to be at an advantage. Unless the study requires access to an NHS patient or caregiver population, university researchers will typically have the option of submitting directly to in-house local university RECs (UCL Research Ethics Committee, 2018a). For non-NHS population studies, the universities at which the researchers are based are will generally take on the role of sponsor without it needing to be requested. Furthermore, if the studies are deemed not to involve vulnerable groups, intrusive interventions or sensitive topics, the researchers may have the option of submitting their application for expedited review, where it is reviewed by either the chair or a small group of members of the research ethics board (UCL Research Ethics Committee, 2018b). Contrastingly, researchers based at NHS institutions or researchers conducting NHS-interfacing research that is university-led typically cannot avail of such an expedited review, and cannot submit an application through IRAS unless they have acquired pre-agreed sponsorship (Health Research Authority et al., 2017). Yet, acquiring this sponsorship agreement can be lengthy

and arduous, as sponsors are responsible for the overall suitability of the research and research sites proposed, and can have the unwanted consequence of discouraging researchers and clinicians from conducting future research (Department of Health, 2017; Health Research Authority et al., 2017; Wellcome Trust, 2010).

Whilst some institutions review applications for research sponsorship internally, others outsource this task to local research management and governance support services. For example, some mental health trusts across London outsource this process to an external research support service tasked with reviewing all materials pertaining to sponsorship and preparation for submission to IRAS. Although such a service is valuable in centralizing local sponsorship requests and bolstering ethical applications prior to their submission, it can also pose significant issues for researchers. These services, though run by experienced teams, can add to research delays. This difficulty is acknowledged by the HRA who, in their published consultation, have noted serious delays in study start-up and a dearth of transparency in sponsorship procedure (Health Research Authority, 2014). In our recent experience, requests for sponsorship and research support tend to be accommodated on a first-come, first-served model, in line with REC allocations, rather than on the basis of the magnitude or urgency of the study. This can create an obstacle for studies which are not well-resourced or are time-sensitive, and ultimately may fail to launch. Anecdotally, we are also aware that this difficulty is also present in university-led NHS research which requires sponsorship from joint or translational research offices within their universities prior to submission to IRAS. In both scenarios, and in cases where the proposed methodology differs from standard clinical research methodologies, researchers may experience research delays (Swan et al., 2009).

Recognizing the breadth of knowledge that these support services can bring and the likely pressure that these are working under given their increased burden of responsibility, we recommend three key actions to reduce research delays. Firstly, we ask that research support services highlight the required documents needed for IRAS submission online or upon first contact with researchers, and formally clarify the circumstances under which these are required, with the HRA, to avoid discrepancies of opinion. Secondly, we suggest that these services restructure their public-facing divisions to reflect how the NHS serves its population, by catering to its users on the basis of the urgency and magnitude of the support needed. Finally, we emphasize that more experienced researchers are likely to require less input from these services. We ask that small study proposals submitted by experienced researchers be filtered separately from major grant-funded studies or those submitted by those who are new to research. Encouraged by the recent changes to ethical submission, we highlight these difficulties in the hope of continuing a national discussion on how to facilitate the production of high-quality and timely research which, despite significant governmental funding, is met with local hurdles. In light

of substantial funding pressures to the NHS overall, these suggestions may pose a more cost-effective solution.

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