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Navigating multisite research set-up and approvals: helping researchers on the ground—a commentary

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Abstract

Confirming multisite studies presents an ongoing challenge for researchers based in England. Those wishing to set up a multisite study must undergo local Research & Development review, in addition to ethical review by a Research Ethics Committee. However, both the documentation required for multisite review and the length of time it takes to complete such a review can cause significant difficulty to researchers and add to research delays. This short article will examine the process of confirming multisite studies and the implications of current practice.

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The successful realisation of world-leading research is a key priority for the UK's Department of Health and Social Care (DHSC), which has significantly invested in the continued future of the National Institute for Health Research (NIHR) (Department of Health Research and Development Directorate, 2006; National Institute of Health Research, 2017; National Health Service (NHS) England, 2014; NHS England Innovation & Research Unit, 2018). Health research is viewed as playing a critical role in informing the NHS's ongoing clinical practice, service delivery and policy (Department of Health, 2017). It is also an important component of the NHS's long-term plan and is noted to be a key driver of future innovation and improved outcomes (NHS England, 2019). In an effort to support and facilitate such research, the Health Research Authority (HRA), tasked with overseeing the ethical governance of health research, in 2017, relaunched its long-standing Integrated Research Application System (IRAS) (NHS Health Research Authority, 2017). The purpose of this relaunch was to create a one-stop shop for researchers, where they could apply and present the necessary documentation for review by a Research Ethics Committee (REC) and various other independent bodies that expertly advise the HRA (such as the Confidentiality Advisory Group; CAG), or from whom special permissions must be obtained (such as Her Majesty's Prison and Probation Service; HMPPS), as part of one submission. A further aim, in streamlining this review process, was to reduce the time it took for proposed studies to begin and address a previously identified shortcoming pertaining to confirming multisite studies (NHS England in partnership with the National Institute for Health Research, 2017). Whilst the former aim was the subject of a previous editorial by the authors, who highlighted the presence of ongoing difficulties in acquiring sponsorship in light of reported substantial reductions in REC research delays, confirming multisite studies presents as an ongoing challenge (NHS Health Research Authority, 2017; Ranieri et al., 2018).

Researchers who wish to include more than one NHS site as a study site must gain the approval of each site's Research & Development Office, following the study's submission for formal ethical review (NHS Health Research Authority, 2019a). Obtaining multisite approval requires that researchers submit a 'local information pack' comprising a copy of the application submitted via IRAS, the proposed study's protocol, participants information sheets and consent forms, any certification from the HRA and additional documentation pertaining to whether the study is commercial or non-commercial in nature (NHS Health Research Authority, 2019b). Using non-commercial sites as an example, this additional

documentation consists of a Statement of Activities (SoA) and, more recently, a Schedule of Events Cost Attribution Template (SoECAT). These two documents are designed to help the sponsor and participating sites understand the support requirements for the study by clarifying which activities will be undertaken at each site and the cost of each activity (NHS Health Research Authority, 2019b). The SoA focuses on detailing planned recruitment figures, whether any support will be provided to the participating site by the sponsor and whether any human biological material or personal data will be processed and/or transferred between the sites. The SoECAT asks researchers to record the standard of care participants would receive during the course of the study, the site-level activities undertaken more generally and on a per-patient basis. The requirement to complete this form has been rolled out since October 2018 for new research studies using NHS resources, following a public consultation focused on simplifying arrangements for managing excess treatment costs (ETCs) (NHS England, 2018). Going forward, this will be a requirement for all clinical research studies even if these are not anticipated to involve ETCs. However, the mandatory use of such documents and the language presented within these can prove problematic to researchers on the ground and is indicative of a disjoint between the business and legal administrative world and the world of research.

In an effort to support researchers in completing these documents, the HRA provides some guidance (NHS Health Research Authority, 2018). Although this guidance indicates that researchers may choose to answer some of the questions, it fails to describe what the intention of the questions is or the impact of one's responses. For instance, within the SoECAT, researchers are asked to declare what their area of activity may be. Yet, there is no clear definition of what constitutes an area of activity within their guidelines. The requirement to select the option of 'non-tariff costs' rather than 'other procedures or activities' or 'other tests or investigations' when identifying the use of a questionnaire or assessment measure is not intuitive, particularly in non-medical disciplines. This presents particular difficulties as applications for ethical approval are often assigned to junior researchers emerging from universities where such language or procedure is not taught within their curriculum. Although researchers are asked to liaise with their sponsor in preparing this document, this process causes delays in itself and creates an expectation that the sponsor be sufficiently well-versed, which cannot be assumed.

Possible errors arising from researchers misunderstanding the content of these forms, and NHS sites' subsequent misperceptions regarding the researchers' intentions, are another regulatory hurdle likely to cause research delays. Such errors may also affect the extent to which sites will entrust researchers with access to their data, particularly if requesting access to personal or confidential information. Compounding these difficulties is also a lack of an enforceable timeline in which such approvals are to take place. Acknowledging that barriers pertaining to such

documentation are not the sole cause of difficulties in confirming multisite studies, simplifying and tailoring these documents to make them more research-friendly to both junior and senior researchers alike may reduce research delays and build confidence between participating NHS sites and those undertaking research. Finally, doing so may alleviate some of the burden experienced by many sponsors in approving and scrutinising applications for ethical review prior to submission via IRAS.

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