



[REDACTED]

18 December 2020

Dear [REDACTED],

**Freedom of Information request: FOI2020/00420**

Thank you for your Freedom of Information request received on the 30 November in which you requested the following:

**Your request:**

*RE: Approval times for research protocols submitted to IRBs in England and Wales*

*I am requesting data that UKRI, or one of its constituent bodies, holds on the duration of the research approval process for study protocols submitted to Institutional Review Boards in England and Wales.*

[REDACTED] *I am frequently astonished by the inefficiency and duplication of activity in the processes that support the review and approval of protocols for research studies conducted in the UK.*

*In a paper published earlier this year in BMC Medical Ethics, a UK site had the worst performance in Europe for approving a 66-site pan-European brain injury study.*

*The median time from protocol submission until the required IRB approval was obtained to start the study was 114 days (IQR 75–224). The fastest required IRB approval was obtained after one day in Serbia and Romania, whereas the longest time was found in a center in the UK (535 days).<sup>1</sup>*

*Research England's 2019 Delivery plan states that; "High-quality data and analysis is at the heart of what we do. Data, analysis and system intelligence drive all our policy and funding activities and underpin the critical monitoring and evaluation of all of our policy and funding interventions."*

*This gives me confidence that data is available on the relative performance of IRB approval process at the institutions you fund.*

**Our response**

I can confirm UK Research and Innovation (UKRI) do not hold the information relevant to your request.

The United Kingdom (UK) does not have Institutional Review Boards (IRBs) but an equivalent role for clinical or NHS-based research is performed by the Research Ethics Committees (RECs), which are overseen by the [Health Research Authority](https://www.hra.nhs.uk/)<sup>1</sup>. The [REC Directory](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/?query=&committee_region=&committee_type=&committee_flag=1)<sup>2</sup> provides information on [Research Ethics Committees](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/?query=&committee_region=&committee_type=&committee_flag=1)<sup>3</sup> (RECs) within the UK Health Departments' Research Ethics Service. Non-NHS research is reviewed by internal research ethics committees established by each Research Organisation. For information about the success rates and time to approval of studies reviewed by RECs, please contact the Health Research Authority<sup>4</sup> who may hold the information and for information about the time to approval of non-NHS related research protocols, please contact the individual Research Organisations. UKRI is not aware of any central body collecting this information.

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<sup>1</sup> <https://www.hra.nhs.uk/>

<sup>2</sup> [https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/?query=&committee\\_region=&committee\\_type=&committee\\_flag=1](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/?query=&committee_region=&committee_type=&committee_flag=1)

<sup>3</sup> <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/>

<sup>4</sup> <https://www.hra.nhs.uk/about-us/contact-us/>

If you have any queries regarding our response or you are unhappy with the outcome of your request and wish to seek an internal review of the decision, please contact:

Head of Information Governance

Email: [foi@ukri.org](mailto:foi@ukri.org) or [infogovernance@ukri.org](mailto:infogovernance@ukri.org)

Please quote the reference number above in any future communications.

If you are still not content with the outcome of the internal review, you may apply to refer the matter to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the review procedure provided by UKRI. The Information Commissioner can be contacted at: <http://www.ico.gov.uk/>

If you wish to raise a complaint regarding the service you have received or the conduct of any UKRI staff in relation to your request, please see UKRI's complaints policy: <https://www.ukri.org/about-us/policies-and-standards/complaints-policy/>

Yours sincerely,



Information Governance

Information Rights Team

UK Research and Innovation

[foi@ukri.org](mailto:foi@ukri.org) | [dataprotection@ukri.org](mailto:dataprotection@ukri.org)