## Taking a proportionate approach to approving research studies

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At the Health Research Authority, we review a wide range research in health and social care – around 5000 studies each year. Whilst it is right for some studies – such as drug trials - to go through a rigorous process of ethical review and research governance assessment based on a full set of information, this approach is not necessary for all research. Some studies are low risk and therefore need a lighter-touch review.

We have already introduced some processes to make HRA Approval more proportionate, but we know we can go further. As part of our service improvement programme, we have been looking at ways in which we can extend that proportionate approach to research regulation. We want to make it as straightforward as possible for new studies to obtain approval and focus our attention and resources where they are most needed.

In late 2017, we carried out interviews with 31 senior stakeholders in the research community and analysed our own data about research applications to inform our thinking about where we could enhance proportionality. We looked at the following types of research:

* Staff research
* Research using anonymised tissue and/or data
* NHS premises
* NHS-sponsored single-site studies.

### Extending proportionate review

One aspect that we have considered is whether we can speed up HRA Approval for some types of study.

We already have a process for proportionate ethics committee review which provides an accelerated, proportionate review of research studies which raise no material ethical issues (ones which have minimal risk, burden or intrusion for research participants). Each year, we consider around 1500 studies through our proportionate review process (about athird of all applications), in which studies are assessed by a subgroup of Research Ethics Committee (REC) members outside a REC meeting.

We have looked at developments in the USA and considered whether a fast-track review of low-risk studies by an appropriately trained staff member, rather than a member of the REC, would be appropriate here. This approach was popular with stakeholders.

We agree that we can take a more proportionate approach and that studies with no material ethical issues should not need review by an ethics committee. We have decided to pilot a refined process of this approach that involves both ethical review and assessment of low-risk studies being carried out by a member of staff. This desk-based approach would include:

* Staff-only studies
* Low risk data and/or tissue studies
* Basic science studies
* Surveys and questionnaire studies using a validated questionnaire with the intended audience
* Surveys with genuinely anonymised responses.

We are working up potential algorithms to quickly and easily identify studies that can reliably be categorised as having no ethical issues.

### A proportionate application package

Besides considering whether we could reduce the level of review or assessment needed for some studies, we have also looked at whether we can reduce the amount of information we ask for in support of an application for HRA Approval. Stakeholders were very supportive of this approach for low-risk studies. It would mean that applicants could complete a shorter IRAS form with a reduced dataset, tailored according to study type.

We agree that there is scope to reduce the amount of information collected in application forms for some types of studies. We are taking this idea forward in a pilot approach for staff studies, as described below. We will also keep this in mind for other study types as we review more generally how applications are made.

### A parameters approach: student research

We receive around 1800 applications for student research each year. Student projects are often of poor quality, have very tight timescales and receive inadequate support from supervisors.

We have been considering whether we can change the way we approve student research by exploring the concept of a parameter approach. This would involve a batched application made by the course leader where the research could fit within an agreed set of parameters:

* the students will do an identical research exercise (for example, all analysing the same dataset), or
* the students are expected to conduct similar research activity within an agreed set of parameters which can be deemed to be low risk (for example, students might have access to a range of identifiable tissue).

In each case, the course leader or supervisor would act as the Chief Investigator. This could be part of an extended proportionate review system for low-risk research and it would seem to lend itself to studies involving either data, tissue or simple questionnaires.

We are developing a communication plan targeted at supervisors so that best practice on the handling of student studies is widely understood.

### A parameters approach: platform trials

The parameters concept lends itself well to platform trials too. These are designed to be more efficient, testing multiple therapies and/or multiple diseases in one clinical trial and targeting treatment using advanced screening methods. The treatments or disease areas may change over time based on interim analysis.

In the past, researchers running platform trials had to submit many amendments to their approval to accommodate the changes made during the trial. We have been working with the MHRA to address this and have agreed that if researchers are clear upfront about what types of changes they intend to make during the trial – provided the single aim and endpoint is unchanged – this will reduce the number of amendments required. This approach reduces the administrative burden on both the applicant and the regulators.

Work with REC members and stakeholders has shown this to be an acceptable approach and we are testing its feasibility using current systems and processes. We are taking this forward with stakeholders to ensure a system wide approach to ensure end-to-end benefit.

### Research on NHS premises

We receive around 50 applications each year for studies which take place on NHS premises but do not meet any other criterial for approval. This is despite the fact that we do not require these studies to have HRA Approval.

We have decided to maintain this position and to clarify our guidance to make it clear that researchers carrying out this kind of research do not need to seek HRA Approval.

### Staff research

We receive almost 500 applications each year for research in which the participants are NHS staff. Staff research projects do not need ethical review, but they do come to us for assessment against NHS standards. We considered whether we need to continue to assess staff research, or whether this type of study could fall out of HRA scope altogether.

Following stakeholder feedback and consideration of the impact of removing staff research from HRA scope, we have decided to continue to assess staff research.

This approach will maintain an assurance for local NHS R&D and make it easier for researchers to set up and run staff research in a consistent way across lots of NHS organisations. We know that it helps researchers when we clearly indicate that the study complies with NHS standards and whether or not NHS organisations are required to provide formal confirmation of capacity and capability, particularly because in most cases we can provide a clear message that NHS R&D offices do not need to undertake any local activity. We were concerned that, without HRA assessment, there could be a temptation to set up local systems, retaining R&D staff for this purpose and resulting in variation between sites.

However, we know that we could take a more proportionate approach to the application package that we require for academic-led funded research involving senior NHS members of staff. We are currently piloting an approach using a very much reduced question set, relying more on the protocol to make an assessment.

### Research using anonymised tissue and/or data

We receive around 350 applications each year for anonymised tissue, tissue and data or data-only studies. These studies do not need ethical review, but they do come to us for assessment against NHS standards. We considered whether we need to continue to assess anonymised tissue and data research, or whether this type of study could fall out of HRA scope altogether.

We agree that we can take a more proportionate approach. We are exploring the possibility of assessing biorepositories at an organisational level, rather than project by project. For example, assessment could give approval to the arrangements and compliance of a single tissue bank rather than the individual studies seeking to use anonymised tissue and data derived from the tissue bank.

We are working with stakeholders to agree standards for the assessment of biorepositories. In the meantime, there is no change to our current practice of assessing individual projects.

### NHS-sponsored single-site studies

We receive over 1100 applications (excluding clinical trials) each year for NHS-sponsored single-site studies. Stakeholders suggested that our assessment duplicates the assessment conducted by the NHS sponsor and we could remove this duplication. However, variation in the quality of local sponsor review means that it would be risky for us to stop the assessment of these studies, as the assurance provided to patients by consistent national standards is important.

During 2017 we worked with a large NHS sponsor to pilot a system where the sponsor provided assurance that the project met the standards. As a result of the pilot the NHS organisation strongly indicated that having two different pathways for single and multicentre sponsored studies would be unhelpful at the sponsor end.

We have therefore decided to continue to consider these studies for HRA Approval, but to also support sponsors to do a better job in ensuring the quality of their applications, so that we can reconsider the potential for a more light-touch assessment in the future. We are exploring with stakeholders (such as the MRC Regulatory Support Centre, the NIHR Clinical Research Network, the NHS R&D Forum and others) how this can best be achieved. We are reconstituting our non-commercial sponsor group to provide a forum for oversight of this work.

### Summary

By taking the approaches described above, we will be able to streamline the approval process for many types of research study, making it easier and quicker for researchers, and more efficient for us. This will mean that we can focus our resources and attention on higher-risk research, allowing low-risk research to start more quickly.

Our work to make regulation of health and social care research more proportionate is ongoing and we will publish further updates in future. If you have any ideas or feedback, please send them to hra.approvalprogramme@nhs.net.