

Agenda item:	9
Attachment:	A

HRA Board paper

24 March 2020

Title of paper:	Proportionate review of research for educational purposes
Submitted by:	Helen Nolan (Wessex Institute) with input from Matt Westmore, Janet Messer (HRA).
Summary of paper:	This paper updates the Board on progress relating to the number of submissions of student projects to HRA as well as stakeholder engagement activities undertaken since the embargo on research for educational purposes was extended. It seeks approval to implement the previously agreed model in September 2021 in time for the next academic year.
Reason for submission:	For approval
Further information:	The Board agreed a new model for student research in September 2020, but it was not feasible to implement due to the pressure of the pandemic on the research system. The HRA is taking forward plans for a significant review of what is reviewed by RECs and how research is reviewed. The government has strong ambitions to embed research in the NHS and to develop researchers of the future within the NHS. In light of both of these, this paper proposes that we progress with implementing the model previously agreed by the Board. This will then enable further development to take place through the ethics review programme.
Budget / cost implication:	Cost saving
Dissemination:	Communication with stakeholders can take place quickly once we know the Board's decisions. The key audience is course leaders, but awareness will be realised more widely across stakeholders using multiple channels. Directly re-engaging with stakeholders we have already engaged with will be particularly important if board decisions deviate from their expectations.
Time required:	15 minutes

Proportionate review of research for educational purposes

1. Background

- 1.1. The Wessex Institute at the University of Southampton was commissioned to support HRA and the devolved administrations (DAs) to review their approach to study approval for student research. The aim of the review was to ensure students gain the best learning experience of health and social care research, and to reduce the time that HRA, DAs and NHS Research Ethics Committees (RECs) are spending advising on and reviewing poorly prepared applications.
- 1.2. During the project the context changed dramatically. COVID-19 and recovery from it in terms of research, health care delivery settings, and the wider economy became paramount. In March 2020 the review of applications for individual undergraduate and master's student projects was suspended. Initially, this was to apply during the crisis in order to free up resources to deal with COVID-19 research applications, but it also expedited some of the thinking that had already taken place during the student project.
- 1.3. In September 2020 we presented our recommendations for the long-term approach to student research to this Board and the Four Nations. We proposed an approach whereby alternatives to research requiring approvals were encouraged for the majority of students but that there was proportionate eligibility across health and care students. The Boards agreed to the principles but decided that the embargo on standalone student applications should be extended until September 2021 due to the ongoing impact of the pandemic on the NHS and research system. The Board requested that in March 2021 the feasibility of implementing the agreed approach is reviewed.

2. Context

- 2.1. In the course of this work we spoke to a large range of stakeholders, including students, regulators, professions and professional bodies, universities and colleges (course leaders and supervisors), NHS as a research setting, DAs, HRA staff and REC members. As discussed more fully in the paper submitted to the September 2020 Board meeting, we heard a number of important messages about research for educational purposes. Key points were:
 - Student research is an important part of the education of researchers of the future and current health and care professionals.
 - Student research is often well conducted, can provide high quality evidence for the health and care system, and good learning outcomes for students.
 - Students are often well supported by their supervisors and institutions. However, some students can have a poor experience and there is a significant burden for the HRA, DAs and the NHS.
 - Many students do not have time to complete the approvals process and so it becomes a stressful experience.
 - Student research places a significant burden on many parts of the system.
 - Some students find themselves doing research that requires NHS REC/HRA approval when they could have selected different types of research.

- Standalone and individual projects are not representative of modern research.
- Not all students and courses are the same, so the approach taken needs to consider a variety of learning requirements and contexts.
- Sponsors and supervisors have a key role in supporting students in achieving their learning outcomes, but course leaders are pivotal.

2.2. Before the embargo was put in place, approximately 40% of applications to IRAS were student projects. Of these, 8% were from undergraduates, 24% from Master's and 68% from PhD students. Between April and September 2019 280 non-doctoral applications were received (an average of 46 per month). These applications not only used up significant resource due to their number, but often required extra effort and handling from HRA staff and REC. Part of the reason for this is that over 25% of student applications are missing key information or documents.

2.3. Since the decision to extend the embargo in September, we have been working closely with stakeholders to promote alternatives to standalone student research projects. Our aim has been to instil a long-term culture change to how student research is approached. We have recently conducted a well-attended workshop for course leaders, as they were identified as key stakeholders for implementing any future changes to student research. Workshop attendees were enthusiastic in sharing their experiences, and feedback after the event indicated that the majority of attendees agreed that there are alternatives to standalone student research for undergraduates and masters' student (or equivalent) that can still meet student learning outcomes. In fact, half of respondents to our feedback survey agreed that these alternatives provide a better experience of modern research. 63% of respondents said that they had made or are intending to make permanent changes to how research education is delivered for their students as a consequence of the change in approvals policy.

3. Implementation

3.1. At the Board in September it was agreed that the HRA and DAs should adopt a new student research review model, which uses a number of different measures to improve the quality of student research applications and to reduce the resource needed to review this kind of research. These measures will ensure that master's and undergraduate students do not submit an application for standalone research, with very limited exceptions.

3.2. We heard during the project, and in subsequent engagement, from some health and care professionals in less research-active settings, that their course was the only mechanism that enabled them to set aside time in their job for research. We heard that certain health and care professional bodies embed research into professional courses. We heard from research-active NHS organisations that appropriate and relevant inclusion of research in Master's courses is crucial to their ambitions to increase research activity and awareness. The new model allows for standalone student projects where these are relevant to the NHS organisation in which they are conducted, and the student's professional development. The model therefore diverts the vast majority of student research to new methods of learning, whilst enabling properly supported research activity that reflects the needs of the NHS. The new UK Vision for Clinical Research aims to embed clinical research at the heart of patient care across the NHS, and sets the ambition for all health and care staff to feel empowered to support research. Implementing this new model will be a key contribution from the HRA to achieving the vision.

3.3. In summary the exceptions permitted are:

- Students on health and care master's courses (or equivalent) will be able to undertake research that require HRA (or DA equivalent) staff review, providing that they are on a course in a university department that is active in health and care research requiring NHS REC and/or HRA approval.
- Student projects requiring proportionate REC review would be permissible if other learning alternatives had been discounted, there was adequate justification and the student had sufficient supervisor support.
- Health and care professionals (or trainees) working in the NHS studying for master's (or equivalent) courses in research active university departments, and doctoral students would be able to submit applications requiring any level of review.

Case study: MPharm degrees form part of the professional training for registered pharmacists (being accredited by the General Pharmaceutical Council), and include a requirement for training in research and research methods using novel data. Medway School of Pharmacy has adopted a group project model with the academic designing the study with input from students, wherever possible designing studies so that they can be managed through the institution's ethics committee and don't involve the NHS. Where research projects involve the NHS they are spread over several years with students being brought in at appropriate points, with significant collaboration with the NHS.

- 3.4. This approach is intended to balance the professional development needs of health and care professionals, the need to embed research in the NHS, and the importance of developing researchers of the future. A continued blanket exclusion would be likely to have unintended consequences and would need significant reputational handling by the HRA with the university sector, professional bodies and the NHS.
- 3.5. During the period in which all non-doctoral research was stopped, the drop in such applications equated to a reduction of 462 applications per year compared with the previous year. This roughly equates to a saving of 10.5 FTE effort in HRA alone over a full year. Implementation of the agreed plan would allow limited exceptions to take place, but those that are accepted would have to meet higher quality criteria. Our aim would be to free up the equivalent of about 8 FTE per year in HRA through implementing this model (equivalent to about £300k per year), in order to focus on new priorities.
- 3.6. We have the opportunity through the Research Ethics Review Programme to further refine the proportionality of review and can therefore use this student model as a platform to enable further changes that further reduce the burden on the HRA and our DA colleagues.
- 3.7. We are promoting a continued focus on the alternatives to standalone research applications by supporting the building of a community of interest, particularly for course leaders. We found that at the workshop they were very receptive to the idea of an ongoing mechanism for sharing ideas about the best ways of conducting student research. We have been liaising with the R&D Forum and ARMA to discuss how this might be approached with their support. A workshop is being planned for the summer, which could then potentially lead to a longer-term community of peers, supporting each other with minimum involvement of the HRA. We are also developing case studies from the examples we heard at the workshop to be used for other communication activities.
- 3.8. When considering timelines for communication it needs to be taken into account that the community are uncertain what will happen after September. Some are assuming all will return to normal and so are deferring decisions and preparation. Some are fearful the full embargo will hold, which would be particularly controversial amongst professionals coming back into education for CPD. If we can provide advance warning of the nature of the eligibility/ineligibility rules, course leaders will have sufficient time to prepare for the changes,

including designing alternative learning solutions. Therefore, we suggest communicating with stakeholders as soon as possible:

- the HRA and DA's expectation is that the agreed approach will be the position from September 2021 onwards.
- there are still uncertainties around how and when the health and care sector will recover from the current pressures of COVID-19 and so the position may change.

Summary

The Wessex Institute has been working with the HRA and DAs on this work since autumn 2019 and have been able to engage a wide variety of stakeholders through individual conversations, workshops and focus groups. Through this consultation and in collaboration with HRA and the DAs, we have established a proportionate approach that ensures students gain the best learning experience of health and social care research, without putting unnecessary burden on HRA, DAs and NHS Research Ethics Committees (RECs). Taking forward the model now will avoid risks of unintended consequences and reputational damage in light of the current interest in embedding research in the NHS.

The unprecedented nature of COVID-19 has had a large impact on the focus and timelines for this work, however, we have now reached the point where the agreed approach can be implemented. This will be taken forwards in the capable hands of HRA and other stakeholders, and further developments in proportionate handling of applications will be incorporated into the ethics review programme. Notably, we hope that these stakeholders will include the R&D Forum and ARMA, who can provide support in shaping a community of interest for course leaders.

Next steps

Given the pre-election period, the plan would be to communicate a decision to proceed with the new model immediately. This would allow further follow up with the relevant communities in the period through to May, including advertising a workshop that ARMA and R&D Forum have scheduled a workshop for late May. We have direct channels with many of the relevant stakeholders as a result of the engagement work through the project.