Health Research Authority

Agenda item:	10
Attachment:	A

HRA Board paper
16 September 2020

Title of paper:	**Proportionate review of research for educational purposes**
Submitted by:	Matt Westmore, Helen Nolan and Katie Meadmore (Wessex Institute), with input from Janet Messer, Teresa Allen and Juliet Tizzard (HRA).
Summary of paper:	This paper presents recommendations for the HRA Board to consider in relation to when/if the embargo on approvals for research for educational purposes is lifted and what it is replaced by. The recommendations were developed following cross-sector stakeholder engagement.
Reason for submission:	For approval
Further information:	Specific decisions for the HRA Board: 1. Agree policy that will apply irrespective of options below – see recommendations, page 5. 2. When/if the current embargo is lifted what should the new guidance and eligibility criteria be? See table 1 and 2, pages 6, 7. *Option A:* Proportionate eligibility across health and care students *Option B*: Health and care professionals, and doctoral students eligible *Option C*: Doctoral students only are eligible 3. When should the current embargo of undergraduate and master's (and equivalent) projects be lifted? See table 3, page 9. *Option 1*: May 2021 to align with wider transformation work *Option 2*: September 2021 to align with the next academic year and greater clarity on post-COVID priorities. *Option 3*: Never (subject to 1-year consultation-in-use)
Budget / cost implication:	Cost saving; the magnitude of savings depends on the options chosen.
Dissemination:	A draft communications strategy has been developed across the Devolved Administrations (DAs) which can be completed 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:	20 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 applications.

1.2. The scope of the project was agreed in November 2019. We consulted with a wide range of stakeholders on the premise that some students were likely to be ineligible to apply for approvals going forward but not that the majority of students would be ineligible. A more radical approach may be the right decision now – but current expectations of stakeholders needs considering when re-engaging with them.

1.3. 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 are now paramount. Department of Health and Social Care (DHSC) and Government priorities such as ending of the EU transition period and the R&D road map are now looming. These changes have resulted in more radical options being presented to the HRA Board for consideration.

2. Context

2.1. Research for educational purposes (herein student research) is an important part of the education of researchers and 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, this is not always the case. Some students can have a poor experience and there is a significant burden for the HRA, DAs and the NHS.

2.2. These are long standing issues that resulted in the 2014 HRA consultation, How we best support research in the NHS – Educational Research (http://bit.ly/2LBuFTu). Significant work had already been completed on many of these recommendations, but significant time has also elapsed, with much changing in the research and education landscape in the meantime.

2.3. Approximately 40% of applications to IRAS are student projects. Of these, 8% are from undergraduates, 24% from Master's and 68% from PhD students. These applications not only use up significant resource due to their number, but often require 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.

2.4. COVID-19 has placed unprecedented pressure on our health services, academic community, RECs, HRA and DAs. Consequently, HRA/the Devolved Administrations published a statement in March 2020, stopping students below doctoral level submitting applications. This embargo remains today.

3. Stakeholder engagement

3.1. We engaged with a range of stakeholders to gather views and experiences about student research and to seek views about particular future approaches. A full list is enclosed in appendix A, but in summary we spoke to; students, regulators, professions and professional

bodies, universities and colleges (course leaders and supervisors), NHS as a research setting, DAs, HRA staff and REC members. We asked for wide ranging views on the current situation regarding student research and discussed the following specific issues: how do different types of students and courses vary, why do students do research, how could we improve overall student experience and learning outcomes, what different approaches are institutions already using, what would be the impact of refusing applications from specific cohorts.

Student research is important – don't break a working system

3.2 We heard from across stakeholders that student research is an important part of the education of researchers and health and care professionals.

3.3 The key concern of all stakeholders was ensuring the best learning experience for students in order to develop the best research and healthcare delivery professionals for the future. All stakeholder groups said that prohibition was not the only option; burden can be reduced by improving the quality of student submissions as well as reducing the number of them.

3.4 It was noted, both by external stakeholders and HRA staff, that HRA's main objective (the Care Act 2014) is to protect and promote the interests of patients and the public in health and social care research. Stakeholders suggested one way to do that is to ensure health and care student research in the NHS is possible. Student research must also be appropriately conducted and proportionate to the risks and benefits it poses to participants.

Not all students or courses are the same

3.5 Some students 'stumble' into health and care research that requires NHS REC or HRA approval; the majority select their research project based on clinical relevance to their area of expertise, training or future career plans.

3.6 Student courses vary significantly from undergraduate, different types of master's, through to doctoral programmes. There are other relevant courses that are considered equivalent to undergraduate/master's/postgraduate (e.g. City and Guilds, apprenticeships etc.). Students vary in experience from those on non-health related courses with no experience themselves and learning in departments with limited experience of health and care research; students on health related courses progressing through conventional further and higher education pathways; experienced health care professionals coming back into education as part of continuing professional development. A blanket prohibitive approach would cause significant disadvantage to the learning opportunities of some students.

3.7 No one spoke strongly of the need to allow undergraduates (or equivalent) to conduct standalone research that required its own NHS REC or HRA approval – in fact it was commonly commented that this was not appropriate. Undergraduates are not sufficiently experienced nor do they have the time to complete the approvals process. It was felt unfair to put them in that position or risk receiving an unfavourable opinion.

3.8 It was noted that doing health and care research was a fundamental learning outcome for Master's students on health and care courses, especially Master of Research (MRes), within research active departments, e.g. medical schools. However, time restrictions and the potential for undertaking alternatives routes were acknowledged.

3.9 Of particular concern were experienced health care professionals coming back into education for continuous professional development and to improve their own clinical practice, health care professionals on accredited training programmes. It was put to us that it does not make sense for these students to do alternative types of research outside of their clinical practice.

3.10 We heard PhD and other doctoral level research project should continue to be reviewed. Whilst not without problems these students tend to be better supported in their research, have more time to navigate the complex system and are more likely to become researchers in the future. That said, increases in quality for all student research could reduce NHS REC and HRA burden.

Need for greater clarity

3.11 In our discussions with DAs the importance of maintaining alignment across the UK was confirmed. It was agreed this should be a joint project with the same rules across nations (albeit they may be operationalised/communicated differently).

3.12 We heard from course leaders that the biggest challenge with the current embargo is the uncertainty over what the new rules for student research will ultimately be and when they will come into force. This prevents them planning for future cohorts of students and managing expectations of and supporting the current. It has also led some students to defer by one year in the anticipation that they will be eligible.

3.13 A number of course leaders felt that the guidance would be a useful tool for demonstrating to students the type of research that would be realistic for them to undertake. A number of course leaders already actively encourage master's and undergraduate students to carry out research projects that do not require research approvals.

3.14 There is a need for clarity on existing processes, with HRA staff questioning whether certain processes could be made simpler, such as amending the student's name on a long-standing project. This is also echoed by course leaders, who feel that if alternatives to research requiring approvals is being encouraged, these should be made more straightforward to do.

3.15 There was a lack of understanding of what projects needed NHS REC or HRA approval. Even when HRA staff felt a project clearly did not require an IRAS submission, some institutions were insisting on one. There was a lack of awareness of the different approvals routes; staff, proportionate and full review. Course leaders and students acknowledge the difficulties of completing projects in a limited time and said it would be helpful to have the process clearly set out with indicative timeframes so that an informed decision could be made.

The role of sponsors and supervisors

3.16 Students experience varying levels of support, with some having dedicated co-ordinators and finding the process straightforward, whilst others are unclear who to reach out to when they need help. NHS colleagues highlighted that there can be issues when supervisors are not given the support they need from their institutions. The responsibility of supervision falls to NHS clinical and R&D staff. HRA staff indicated that the role of institutions needs to be made more explicit and that working with universities to improve supervision would lead to better applications.

3.17 We heard different views and confusion over the role of the sponsor and who therefore is best placed to be the sponsor. Some argued that it should be the university because they have responsibility for the education of the student, whilst others argued it should be the research site (e.g. hospital) because they have the clinical expertise and is where much of the research activity happens. HRA were clear that it should be the educational institution. When discussing what would constitute 'sufficiently experienced' in relation to the chief investigator, some suggested indicators such as 'had submitted an IRAS application as CI within the last 3 years'; others highlighted that it's not just about the CI – some institutions have departmental support to ensure high quality applications and well supported students.

4. Recommendations

4.1. We recommend that the HRA and Devolved Administrations adopt a new student research review policy 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. Those measures include:

- Discouraging applications by suggesting alternatives to leading projects which require NHS REC and/or HRA approval. This could still be health and social care related research.
- Discouraging applications for individual student projects and suggesting course group applications instead or students are involved in other research projects whose primary purpose is not education.
- Limiting the types of student research which the HRA/DAs will review (for example, excluding undergraduate research) (see options for eligibility below).
- Limiting applications to those that meet certain criteria relating to the supervisory environment; e.g. CI must be an experienced health or care researcher, there is significant departmental support, and sponsors adequately reward and recognise high quality supervision.
- Providing clear advice and guidance to those that meet the application criteria through a dedicated student help desk and triage service
- Establish a feedback mechanism for sponsors, course leaders and supervisors to support and share good practice

5. Options for the Board to consider: Eligibility to submit standalone applications

5.1. If after all alternatives have been considered it is still necessary for the CI to submit a standalone application certain eligibility criterion should be adopted. The HRA Board are asked to choose between or amend the following options:

Option A: Proportionate eligibility across health and care *students*

5.2.1 Students on health and care master's courses (or equivalent) are able to submit applications that require staff review, providing that they are in a department that is active in health and care research requiring NHS REC and/or HRA approval. These students would not normally carry out a project requiring proportionate review, however, this would be permissible if there was adequate justification and the student had sufficient supervisor support. Health and care professionals (or trainees) studying for master's (or equivalent) in research active departments and doctoral students would be able to submit applications requiring all levels of review.

Option B: Health and care professionals, and doctoral students eligible

5.3 Health and care professionals (or trainees) studying for master's (or equivalent) in departments active in health and care research requiring NHS REC and/or HRA approval, and doctoral students, would be able to submit applications for any level of review.

Option C: Doctoral students only are eligible (in effect this is continuing the COVID-19 embargo).

5.4 As has been the case during the COVID-19 pandemic, students at master's or undergraduate level would be unable to conduct standalone projects requiring NHS REC and/or HRA approval. Doctoral students would remain eligible.

Student type	**UG or equiv'**	**(Masters or equivalent) Students on non-health and care courses or in university departments not active in health and care research**	**(Masters or equivalent) Students on health and care courses in health and care research active university departments**	**(Masters or equivalent) Health and care professionals or trainees on courses in health and care research active university departments**	**PhD/ doctoral level**
Option A: *Proportionate eligibility across* health and care *students*					
Can be CI?	X	X	X	X	✓
Staff review	X	X	✓	✓	✓
Prop' review	X	X	✓	✓	✓
Full review	X	X	X	✓	✓
Option B: *Health and care professionals, and doctoral students eligible*					
Can be CI?	X	X	X	X	✓
Staff review	X	X	X	✓	✓
Prop' review	X	X	X	✓	✓
Full review	X	X	X	✓	✓
Option C: *Doctoral students only are eligible (in effect this is continuing the COVID-19 embargo).*					
Can be CI?	X	X	X	X	✓
Staff review	X	X	X	X	✓
Prop' review	X	X	X	X	✓
Full review	X	X	X	X	✓

Table 1: Options for eligibility for standalone applications

Table key: UG = undergraduate. Red = not permitted, Amber = in most cases students should seek alternatives but if there is justification for proceeding, strong supervision is required, Green = permitted

6. Options appraisal: policy for the review of student research (see attachment B for notes on data used)

6.1. *Pre-COVID-19 Resource implications for comparison*

- 2038 applications per year
- 79 undergraduate; 501 master's; 1457 Doctoral;
- For non-doctoral % REC slots: 12% REC slots (5000 applications in total/year)
- For non-doctoral additional HRA staff FTE: Circa 0.8 additional HRA staff FTE (on average 2-3 hours extra HRA staff time per application compared to non-student research)

Option	***A: Proportionate eligibility across health and care students***	***B: Health and care professionals, and***	***C: Doctoral students only are eligible***

		doctoral students eligible	
Objectives in relation to resource implications	25% of master's students are now ineligible or seek alternatives 0 undergrad apps' 376 master's apps' 1457 doctoral apps 8% REC slots (non-doc) 0.5 additional FTE (non-doc)	50% of master's students are now ineligible or seek alternatives 0 undergrad apps' 251 master's apps' 1457 doctoral apps' 5% REC slots (non-doc) 0.4 additional FTE (non-doc)	100% of master's students are now ineligible or seek alternatives 0 undergrad apps' 0 master's apps' 1457 doctoral apps' 0% REC slots (non-doc) 0 additional FTE (non-doc)
Advantages	Matches engagement with stakeholders to date – has had positive feedback. Some flexibility, number of master's students can conduct research requiring staff or proportionate review (if they have time and support) – less chance of unintended consequences. Professionals and trainees can do research matching their area of expertise/ interest (developing the quality of professions).	Those students who are likely to have the least experience and support for conducting this type of research will be unable to submit (and can achieve learning outcomes through other projects). Experienced healthcare professionals can do research that matches their area of expertise/interest (developing the quality of those professions).	Clear, straightforward message, continuing as it has been during COVID. Reduction of 580 applications being submitted (28% of student applications).
Disadvantages	Students cannot lead a project and cannot shape one around their interests. Students on an MRes or clinical master's (e.g. MSc Allergy) cannot do standalone projects requiring full review. Eligibility criteria not clearly defined – there will be some nuance and interpretation needed by HRA staff, e.g. it is difficult to define non-health and care course and research active.	Students cannot lead a project and cannot shape one around their interests. Master's students on non-health courses cannot do standalone projects – it is difficult to define non-health and care courses and research active departments so there will be some anomalies. Students on an MRes or clinical master's cannot do standalone projects (e.g. MSc Allergy student wanting to do a patient facing study) unless they are a practicing clinician doing a master's for CPD. Eligibility criteria not completely clearly defined – there will be some nuance and interpretation needed by HRA staff.	No students (below doctoral level) can do standalone projects. Students cannot lead a project or shape one around interests. Particularly impacts experienced healthcare professionals doing CPD MSc. Likely reputational risk/ high level of discontent from stakeholders. Would not be expected given our engagement to date and would require extensive re-shaping of courses – especially for professionals doing master's. Potential reduction in quality of healthcare research and innovation in future (health and care master's students unable to do this research). Potentially health care professionals will not get the experience needed for progression and to create a quality taskforce in future (often they do master's over a number of years as

			have no time to do a PhD or stop working).

Table 2: Appraisal for options for eligibility for standalone applications. See Appendix C: Notes of data used in the options appraisal.

7. Options appraisal: decision about when (and if) to return to receiving student research applications (see attachment B for notes on data used)

7.1. In March 2020, the HRA and DAs suspended reviewing applications for individual undergraduate and master's student projects until further notice, while urgent review of COVID-19 studies was prioritised and significant pressure on the NHS/HSC limited their ability to participate in research studies unrelated to COVID-19. HRA has seen a reduction of 30% in applications for new studies and amendments during the pandemic – a significant fraction of these will be due to the embargo on student research.

7.2. Whilst the immediate emergency phase of COVID-19 has eased we are still operating under difficult conditions and with shifting priorities. The focus now is on restarting the non-COVID-19 paused portfolio and wider recovery of the research, and health and care delivery settings; this is at a time of continuing difficult working arrangements for staff and with the potential disruption of local and regional lock downs. Beyond COVID-19 there are growing priorities such as ending of the EU transition period and the delivery of the R&D road map.

7.3. When/if to lift the current embargo therefore requires careful consideration. The HRA Board are asked to choose between the following options:

1. May 2021 to align with wider transformation work.
2. September 2021 to align with the next academic year and greater clarity on post-COVID-19 priorities.
3. Never (subject to a review following consultation-in-use).

Option	Advantages	Disadvantages
1) May 2021 This would align with the findings from the wider HRA review of proportionality.	Course leaders would have sufficient time to prepare for the new academic year if it is clearly stated who will be eligible/ineligible. Any residual uncertainty in who would be eligible/ineligible could be resolved in the context of the wider proportionality review. Restarting paused projects should be complete. The nature of new priorities and pressures as the EU transition period comes to an end should be known. It would allow early learning from consultation and monitoring in use.	Many COVID-19 pressures may still remain, and local lockdowns/spikes could cause further disruption at research sites. The implications of new priorities and pressures as the EU transition period comes to an end may not be fully addressed.
2) September 2021 This would align with the 2021/22 academic year and greater clarity on post-COVID-19 priorities.	If advance warning could be given of the nature of the eligibility/ineligibility rules soon, course leaders would have sufficient time to prepare for more radical changes. Any internal changes within HRA could be implemented as part of wider changes. COVID-19 pressures may have fully lifted, and local lockdowns/spikes may be less likely. Restarting paused projects should be complete. The implications of new priorities and pressures as the EU	Impact on students who in the end would be eligible.

	transition period comes to an end should have been resolved.	
3) Never (subject to consultation-in-use). This is Option C but the narrative needs to change from COVID-19 to the long-term rationale.	Very clear cut. Advantages as set out in option C above.	Disadvantages as set out in option C above.

Table 3: Appraisal of options on when to lift the current embargo

8. Next Steps

- Communications strategy will be completed based on the HRA Board's decision.
- Directly re-engaging with stakeholders we have already engaged with.
- If approved by the HRA Board, implement new approach through a one-year long consultation and monitoring in use process.

Appendix A: **Full list of stakeholders engaged (names redacted for data protection)**

We consulted through a range of 1:1 informal conversations, workshops and a student focus group.

Students

- Individual student feedback to HRA.
- Students 4 Best Evidence.
- Student focus group conducted online, including ten master's and doctoral students (see full account of the focus group in attachment B).

Regulators

- Health and Care Research Wales.
- Chief Scientist Office Scotland.
- HSC Public Health Agency.
- HRA (policy).
- HRA (communications and engagement).

Health and care professions

- Academy of Medical Sciences.
- Academy of Medical Royal Colleges.
- Health and Care Professions Council.

Universities and colleges

- UK Council on Graduate Education.
- Medical Schools Council.
- NIHR Academy.
- Research Ethics and Governance Manager and ARMA Special Interest Group chair.
- Head of Research Integrity & Governance.
- National School of Healthcare Science.
- Individual course leaders from the following institutions:
    - Cardiff University
    - De Montfort University
    - Kings College London
    - Manchester Metropolitan University (three different departments)
    - University of Bath
    - University of Edinburgh (two different courses)
    - University of Hull
    - University of Manchester (two different departments)
    - University of Nottingham
    - University of Oxford
    - University of Southampton

NHS and social care as settings of research

- NHS R&D Forum
- NIHR Strategy Board

HRA staff and REC members

- Associate Professor in Healthcare Ethics, Research Ethics and Governance Manager and REC chair.
- Workshop with HRA staff and representatives from England RECs, NRS Scotland and Wales RECs.

Appendix B: Alternatives to research that require NHS REC and/or HRA approval

Alternatives that do not require NHS REC/HRA approval:

- Research in other areas other than health or care.
- Health or care related research that does not involve patients, service users, tissue or data.
- Literature/systematic reviews.
- Service evaluations that whilst not research as HRA would define it do require research methods and skills and are conducted within clinical environments.
- Project protocol/proposal development (but not submission).
- Public/stakeholder involvement activities – for example research priority setting.
- Taught courses to develop understanding of research without doing research.
- Mock applications - including mock funding and REC panels, supported by experienced researchers but where students experience being both applicant and committee members.

Alternatives that still require NHS REC/HRA approval:

- Ensuring the level of review (staff, proportionate, full) is minimised in line with the learning objectives and requirements of the research question.
- Group student projects, led by an experienced health and/or care researcher, that support multiple students, potentially over multiple years.
- Projects that are being conducted for other reasons irrespective of whether students are involved but where students could become involved in a limited way. Such projects are particularly interested to give students access to larger, multi-disciplinary team science and a range of experienced researchers and clinicians

Appendix C: Notes of data used in the options appraisal

- Student applications take an additional two to three hours per application to support. This amounts to a total of around 0.8 FTE of additional HRA staff time. This would be a saving, although the biggest saving is from the reduced numbers of applications being processed by HRA/DA staff and going to RECs. Therefore the % of REC slots is used as a proxy for overall savings.
- The reductions in application numbers are just estimates. HRA staff have reviewed past applications against the proposed criteria and we have estimated reductions in numbers from steering students and course leaders towards alternatives to research requiring approvals.
- The data does not allow accurate predictions for the overall number, but we can make some assumptions to be monitored following implementation. If the assumed reductions are not materialising stricter controls may be required.
- Improving quality will also have an impact on time taken to manage student research by HRA/DAs and RECs.
- All records have been extracted on the basis of the applicant answering yes to the IRAS question “Is the study **or any part of it** being undertaken as an educational project?” This might include projects with minor student involvement. This makes it more difficult to predict the number of projects affected by our criteria.
- The data does not allow easy differentiation between types of master’s students. It shows non-health and care courses but not who were professionals. This makes it difficult to accurately show the effect of the different options.