**The Health Research Authority's (HRA) New Eligibility Criteria for Standalone Student Research**

The Health Research Authority (HRA) has introduced rigorous new eligibility criteria for standalone student research projects conducted in the NHS. The policy came into force on 1 September 2021.

The new eligibility criteria are published on the HRA’s website <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/#september> and introduce stricter rules governing the suitability of student research for NHS Research Ethics Committee (REC) review and NHS governance review (known as ‘HRA Approval’).

Standalone research at an undergraduate level requiring either NHS REC review and/or HRA Approval can no longer take place. (Standalone research refers to research where the student designs the study, submits for approval and conducts the project on their own under the oversight of a Supervisor). While from 1 September only Master’s level students who are either healthcare professionals or professionals in-training will be deemed eligible to apply for NHS REC review and HRA Approval. The arrangements for Doctoral research, however, remain unchanged.

The HRA’s new eligibility criteria mandates that:

* **Undergraduate level research:** Health and social care research applications from undergraduate students (including those enrolled on medical degrees) are no longer accepted for either NHS REC review or HRA Approval. (However, for medical students who are intercalating, the level of the intercalated course the research project is being undertaken at is the determining factor).
* **Master's level research:** Students should complete the HRA’s new ‘Student Research Toolkit’ to first check their eligibility. Some health and social care research applications from students working at Master's level are no longer accepted for NHS REC review or HRA Approval. At the Postgraduate Taught student level, there is clear prioritisation of standalone research primarily conducted by students who are otherwise employed as health care professionals in either NHS/Social Care (SC) settings, or are current trainees. A student on a health care course would include a student undertaking an academic course providing skills for provision of health care or health research in the NHS/SC. For example, pharmacy, psychology, speech and language therapy, pathology, and other professional courses. A health care professional would include all NHS/SC employed clinical staff and non-clinical NHS/SC professionals (for example those employed in health informatics and support workers) or those with recent NHS/SC experience. Trainees are individuals employed within the NHS who have not yet attained the level of qualification required for their vocation. Applicants must demonstrate current or recent experience in the NHS to ensure they understand how to undertake the research without creating undue burden on the NHS. There is an expectation that the research naturally falls within the scope of their discipline. The department running the Master’s course should be demonstrably active in health and care research with an expectation that Supervisors of Master’s level students themselves have recent experience of completing an IRAS application within the last 2 years.
* **Doctorate level research:** Applicants are eligible to complete health and social care research, subject to relevant approvals being in place. Doctoral applicants may find it useful to complete parts of the Student Research Toolkit to understand if HRA and/or NHS REC review is required.

However, the HRA has clarified that students at all levels may join research teams actively leading ethically approved clinical research in the NHS:

* Students can undertake delegated activities within an existing, approved research project without notification to the regulatory bodies. The Sponsor is responsible for determining whether the student's role is appropriate, and the Principal Investigator is responsible for the suitability of their research team members for the activity delegated to them.
* However, Sponsor representatives should not authorise any study that falls outside the eligibility criteria.

As part of the new policy, the HRA has launched a comprehensive [Student Research Toolkit](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/) which details the type of standalone clinical research projects that students will be able to undertake from September 2021. Crucially, students and their supervisors will now be required to complete the HRA’s toolkit before being able to submit an application through the Integrated Research Application System (IRAS).

The [Student Research Toolkit](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/) is an interactive PowerPoint presentation incorporating hyperlink access to 5 different HRA decision trees providing answers to the following questions:

* Is my study research?
* Is my research taking place in the NHS and will need NHS approval?
* Do I need NHS Research Ethics Committee (REC) review?
* What type of NHS ethics review do I need?
* Can I carry out my research?

The final decision tree specifically concerns the new eligibility criteria. To be eligible for a full NHS REC review, students will now need to demonstrate:

1. They are a Master’s level student or above (students working at undergraduate level are no longer accepted for either NHS REC review or HRA Approval);
2. The purpose of their research is to obtain a qualification;
3. They are enrolled on a health and care Master’s course (providing skills for provision of healthcare or health research in the NHS);
4. The University Department running the Master’s course is active in health and care research (with an expectation that Supervisors of Master’s students have recent experience of completing an IRAS application within the last 2 years and an understanding of the HRA’s approvals process);
5. The student themselves is either a healthcare professional (employed clinical staff and non-clinical NHS professional) or training to become one.

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**Appendix 1: HRA’s new eligibility criteria for standalone student research projects conducted in the NHS**

