**Approval Pathway for BSMS Research Studies (Led by Staff or Students) Involving NHS Staff**

Research studies involving NHS staff in England (including those employed at our partner University Hospitals Sussex and Sussex Partnership NHS Foundation Trusts), should *not* be submitted for ethics review to either the BSMS Research Governance and Ethics Committee (RGEC), or BSMS School Research Ethics Officer (SREO) or University of Sussex C-REC.

Research projects recruiting NHS staff in England require Sponsorship from the University of Sussex and onward submission to the Health Research Authority (HRA) for HRA Approval. This applies to all NHS Staff research studies, whether led by a member of BSMS faculty, or by the Supervisor of a BSMS Postgraduate Taught student, or Doctoral student. The *UK Framework for Health and Social Care Research* sets out the required standards to be met for any such work[[1]](#footnote-1).

HRA Approval applies where an NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. HRA Approval for NHS staff research studies will solely cover the assessment of legal compliance and governance permissions aspect of review (and not involve parallel NHS Research Ethics Committee review).

To proceed, the Chief Investigator (CI) will need to:

* Apply for University of Sussex Sponsorship, before proceeding to the HRA for HRA Approval (this is solely for NHS governance approval and not NHS research ethics review).
* The documentation for both University of Sussex Sponsorship and HRA Approval is completed via IRAS <https://www.myresearchproject.org.uk/>. Projects require completion of an IRAS Form and supporting study documents for submission for both University Sponsorship approval and HRA Approval. The application will need to be sufficiently robust (it cannot be rushed due to limited time constraints).
* Refer to the information on University Sponsorship, which can be found here: <http://www.sussex.ac.uk/staff/research/governance/sponsorship>. It also involves an application to the[Pre-Sponsorship Review Panel](https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx)(PSRP) for onward submission to the [Sponsorship Sub-Committee.](http://www.sussex.ac.uk/staff/research/governance/sponsorship/ssc)
* Note that applications for BSMS staff-led research will need to demonstrate that they have been initiated by the lead NHS Trust, (usually either UH Sussex or SPFT) to receive Trust support for the study, OR be adopted onto the NIHR portfolio[[2]](#footnote-2), OR incorporate funding specifically to cover NHS set up fees. For clinical research governance advice, particularly within an NHS context, please contact: [Brighton and Sussex Joint Clinical Research Office (JCRO)](https://www.bsms.ac.uk/research/support-and-governance/jcro/brighton-and-sussex-joint-clinical-research-office.aspx).
* NHS Trust Confirmation of Capacity & Capability (R&D approval): Once a study obtains approval from the HRA, the CI must also seek confirmation that the NHS Trust has capacity and capability to host or run the study. Requirements will vary from NHS site to NHS site, broadly speaking the NHS Trust R&D office will assess the impact a study may have on day-to-day operations, staff time and costs.
* NHS Trusts may also refuse to assess a study if it is not adopted onto the NIHR portfolio. So you are advised to arrange early discussions with the relevant R&D office.
* Be aware that the approval pathway for ‘dual’ projects involving a cohort of BSMS staff and/or medical students, in addition to NHS staff, remains the same: The University of Sussex for Sponsorship followed by HRA Approval (for NHS legal compliance and governance permissions). RGEC will be involved in the review of the application at the Pre Sponsorship Review Panel (PSRP) stage, to maintain oversight of research involving BSMS staff and medical students.
* Be aware that standalone UG student research projects do not currently meet the HRA’s eligibility criteria and cannot be submitted: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/#september>
* Consider whether the research will add additional psychological burdens on front-line NHS staff at a time of heightened clinical pressures.

Please note that the BSMS Research Governance and Ethics Committee is a University ethics committee, and its review remit does not extend to the review of clinical research. Therefore, the scope of what is permissible to be eligible for RGEC review is severely limited and research which meets clearly defined criteria, described below, will require HRA review:

1. Participants: The study involves NHS clinicians, GPs, nurses, or other NHS key workers.

**AND**

1. Recruitment channels: Recruitment occurs via a NHS Trust channel such as a recognised staff intranet, HR department, or clinical care teams. The employing NHS Trust is undertaking the role of Gatekeeper to access the participant cohort and has a duty of care to its staff participating in the research.

The vast majority of research studies involving NHS Staff are anticipated to require University of Sussex Sponsorship and HRA Approval.

RGEC is only permitted to review research that will involve administration of an online survey or questionnaire tool solely via a suitable Gatekeeper that is external to the NHS, such as a:

* Recognised professional network (e.g. British Medical Association; Association of Breast Surgery, the Association of Cancer Physicians, the Royal Society of Medicine)
* Virtual network in the public domain: a public online forum and/or social media group (e.g. Autistic Doctors International).

Caroline Brooks, BSMS Research Ethics, Integrity and Governance Administrator (on behalf of the BSMS Research Governance and Ethics Committee)

June 2021

1. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ [↑](#footnote-ref-1)
2. https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm [↑](#footnote-ref-2)