

**Ethics Review Decision Making Tool**

**Criteria for Research that must go to the BSMS Research Governance and Ethics Committee, a BSMS School Research Ethics Officer, or the Health Research Authority (HRA)**

**No.s 1-8: Research activity that requires review by the BSMS Research Governance and Ethics Committee (RGEC).**

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| ***Non-clinical (non-NHS) projects that involve any of these criteria must be reviewed by the BSMS Research Governance and Ethics Committee (RGEC) or BSMS School Research Ethics Officer (SREO):*** |
| 1. | Research led by BSMS staff/students involving human participation, biomaterial, or personal data, either: * Directly: e.g., questionnaires, surveys, interviews, focus groups.
* Indirectly: Studies involving the generation of new data or samples from human participants who are not NHS patients (e.g. through access to their data or donation of biological samples).
* Observational studies involving methods of observation of humans (either openly or covertly).
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| 2. | Research recruiting patient populations exclusively via non-NHS recruitment channels in the community: e.g. publicly available online forums, Facebook groups, third sector voluntary and community organisations and charities.  |
| 3. | Research conducted outside the UK: BSMS-led research projects conducted by BSMS staff and/or Postgraduate Research and Taught students undertaken outside the UK. Affiliated academics, such as external collaborators undertaking or involved with funded research in connection with, or as part of, the University of Sussex also fall under the scope of BSMS RGEC review. |
| 4. | Social care research that excludes NHS staff and/or patients that is not funded through the Department of Health or National Institute of Health Research (NIHR): research that solely involves staff working in social care settings (such as nursing homes), or families and carers of individuals under the care of social care professionals. (Excludes review of integrated services research (NHS health and social care) primarily involving NHS patients and/or NHS staff; research involving anyone lacking capacity to consent; and social care research that is funded through the Department of Health or National Institute of Health Research (NIHR See: See: [HRA Resource Pack for Social Care](https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/research-governance-framework-resourc.pdf)  (p110 ‘Research Ethics Decision Tree for Social Care Research’).  |
| 5. | Co-Production/ Patient and Public Participation research activity led by BSMS staff and/or Postgraduate Research and Taught students which is funded or where the intention is to submit material for publication in journals. (Please see No. 12. for a definition of Patient and Public Involvement (PPI) activity that is not research and does not require ethics review).  |
| 6. | Research involving data collection gathered through online resources, such as groups or websites, or social media platforms, even those that do not collect or store identifiable data or where data is gathered without the explicit informed consent of each individual. |
| 7. | BSMS Curriculum Evaluation (including course evaluation, teaching evaluation): If the evaluation projects constitute primary research (e.g. evaluations of current or innovative educational techniques) and involve the participation of undergraduate medical students (and do not involve NHS Staff) or where the intention is to submit findings for publication in journals.  |
| 8. | Service Evaluations and Audits (involving non NHS services and patients) asking sensitive questions or involving vulnerable people or where the intention is to submit findings for publication in journals. Please Note: Regardless of whether the work is research, audit, or service evaluation, any study where the results are to be published externally is subject to ethics review through the University's governance procedures. |

**No.s 9-12: Research activity that does not require review by the BSMS Research Governance and Ethics Committee (RGEC) or BSMS School Research Ethics Officer (SREO).**

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| ***Non-clinical (non-NHS) projects which are exempt from BSMS Research Governance and Ethics Committee (RGEC) review:*** |
| 9. | Audit of Data/Secondary data analysis: Datasets can be shared so long as the research projects received ethics approval and the data to be shared has first been anonymised and the Principal Investigator is able to provide explicit consent from the data controller to access the data and prove that the data will be used for a purpose which falls within the remit of the original consent provided by data subjects. These studies are exempt from ethics review unless there is an intention to publish, in which case prospective publishers may require evidence that ethics review has been achieved. |
| 10.  | Research involving anonymised records and data sets that exist in the public domain. E.g., datasets available through the Office for National Statistics or the UK Data Archive where appropriate permissions have already been obtained and it is not possible to identify individuals from the information provided. Research involving public data sets that are not in the public domain and can only be accessed by accredited researchers (e.g. ONS data) which falls under the Digital Economy Act 2017. Research ethics review is not required if the PI has already obtained approval from the UK Data Authority but evidence of approval is required. |
| 11. | Projects requiring BSMS Gatekeeper Approval:Externally led research projects seeking to recruit either BSMS students or staff will require BSMS Gatekeeper Approval, ‘light touch’ review of the approved ethics application and survey/research tools.  |
| 12. |  Ethics review is not normally required for PPI activities providing certain criteria are met. For example, that: * Vulnerable or dependant groups are not included;
* There is no risk of possible disclosures or reporting obligations;
* The data is not considered to be sensitive or confidential in nature;
* And publication is not an intended outcome.

‘PPI activities’ involve direct input from groups and individuals with relevant lived experience to provide useful assistance with either the design of research or content of participant facing materials. Such involvement is not the same as being a ‘research participant’. Examples of questions that could reasonably be asked during a PPI consultation would be: “Please can you look at our proposed Participant Information Sheet and Consent form?”; “What do you think about our recruitment strategy?”; “Do you think it will work?”, as well as other matters which will help the researchers that are distinct from being a research participant. However, where activity spills over into questions typically defined as qualitative research or involves an intention to publish, it would no longer be determined as a purely evaluative endeavour. If patients were asked about their experiences of accessing Mental Health services, an example of a research question might be: "How do we improve what mental health treatment you have received?" This question is research (and not PPI) since it attempts to derive generalisable new knowledge by addressing clearly defined questions and is concerned with answering research question/s themselves.   |

**No.s 13 – 17: Research activities that fall under the remit of the Pre-Sponsorship Review Panel (PSRP), University of Sussex Sponsorship Sub-Committee (SSC) and, the Health Research Authority (HRA).**

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| ***Projects that meet the following criteria must be reviewed by an NHS REC or the Health Research Authority (HRA) for governance and legal assessment:***  | ***Other approvals required*** |
| 13. | Research involving individuals identified as potential research participants because of their status as NHS patients, relatives or carers of patients and other service users of the NHS.  | University of Sussex Sponsorship + HRA Approval  |
| 14. | Research involving access to NHS patient identifiable data or tissue, organs or other bodily material of past and present NHS patients.  | University of Sussex Sponsorship + HRA Approval  |
| 15. | Research involving individuals under the care of social\* or community care professionals, local authorities or prisons. (\*See: [HRA Resource Pack for Social Care](https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/research-governance-framework-resourc.pdf)  (p110 ‘Research Ethics Decision Tree for Social Care Research’) | University of Sussex Sponsorship + HRA Approval  |
| 16. | Research limited to the use of previously collected anonymous NHS patient data or tissue may or may not require NHS REC approval. Please consult the HRA’s guidance on research using anonymous health information: <https://www.hra.nhs.uk/covid-19-research/guidance-using-patient-data/>  | University of Sussex Sponsorship + HRA Approval  |
| 17. | Research involving NHS staff recruited by virtue of their professional role.  | University of Sussex Sponsorship + HRA Approval (governance and legal assessment only) |

**No.s 18 – 19: Activities that are exempt from review by the University of Sussex Sponsorship Sub-Committee (SSC) and the Health Research Authority (HRA).**

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| ***Projects which are exempt from by an NHS REC review or the Health Research Authority (HRA) for governance and legal assessment:*** |
| 18. | Service Evaluations and Clinical Audits involving NHS patients (for example, retrospective case note review projects) do not usually need ethics review. However, they require registration at the NHS Trust at which they are conducted. Under clinical governance NHS organisations should have ownership and control of clinical audit and service review projects involving their patients, data, staff, equipment or facilities. They should therefore be responsible for considering any ethical implications and for ensuring each project complies with relevant NHS guidance e.g. confidentiality, consent, data protection, etc. It is recommended that staff gain NHS R&D management support for their proposals before proceeding. There may be a requirement to register the project in an appropriate database either with the Trust’s R&D department or elsewhere within the host organisation, as most NHS Trusts wish to keep a record of any service evaluations or clinical audit. An employee of the Trust should make this registration. The three levels of assurance in sign-off described below can be used as a general guideline: * To register the service review activity with the host organisation. (The Trust may require confirmation of the data required and likely data sources, information governance solutions – how data will be transferred and stored and who will have access to it).
* To comply with any local governance processes for Service Review Activity.
* To provide prospective publishers and educational establishments, if required, with evidence that ethics review has been achieved or provide evidence that a particular project has been classified locally as service review and not requiring ethics review.
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| 19. | Research limited to the use of previously collected anonymous NHS patient data may not require NHS REC approval. However, these projects still need to be registered with the R&D Office and reviewed for R&D approval. During the review process the researcher will be asked to complete the online HRA tools to confirm the project does not require NHS REC approval. Please consult the HRA’s guidance on research using anonymous health information: <https://www.hra.nhs.uk/covid-19-research/guidance-using-patient-data/>  |

If you have doubts or uncertainties concerning your project further advice may also be sought from Caroline Brooks, BSMS Research Ethics, Integrity and Governance Administrator: c.e.brooks@bsms.ac.uk