

**Ethics Review Decision Making Tool**

**Criteria for Research that must go to the BSMS Research Governance and Ethics Committee or an NHS REC** The below list includes research activity that requires review by the BSMS Research Governance and Ethics Committee (RGEC) or an NHS REC.

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| ***Projects that involve any of these criteria must be reviewed by the BSMS Research Governance and Ethics Committee (RGEC):*** |
| 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 that are not NHS patients (E.g. through access to their data or donation of biological samples). Or, 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. | Non-NHS social care research: 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, and exclude individuals under the care of social care professionals, and NHS Staff.  |
| 5. | Co-Production/ Patient and Public Involvement (PPI) research activity led by BSMS staff and/or Postgraduate Research and Taught students which is funded or where the intention is to submit findings for publication in journals.  |
| 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 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. |

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| ***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 were ethically approved and the data to be shared has first been anonymised and you are 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.  |
| 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. |
| 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.  |

**The following research activity must be reviewed by the 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:***  | ***Other approvals required*** |
| 12. | 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  |
| 13. | 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  |
| 14. | Research involving individuals under the care of social or community care professionals, local authorities or prisons. | University of Sussex Sponsorship + HRA Approval  |
| 15. | **Research limited to the use of previously collected anonymous NHS patient data or tissue. (Is this correct?)** | **University of Sussex Sponsorship + HRA Approval**  |
| 16. | Research involving NHS staff recruited by virtue of their professional role. | University of Sussex Sponsorship + HRA Approval (governance and legal assessment) |

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| ***Projects which are exempt from NHS REC review.*** |
| 16. | Service evaluations and clinical audits involving NHS patients Audits do not usually need ethics review. However, they do require registration at the Trust at which they are conducted: Most NHS Trusts want to keep a record of any audit so these should be registered with Trust R&D departments. An employee of the trust should be the one to make this registration. |