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**ETHICS AND EXTERNAL APPROVALS**

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| **Version** | **Date** | **Reason for Change** |
| 1.1 | 6 October 2020 | Updated to reflect changes in HRA approvals process and HR Good Practice Resource Pack, and the introduction of the EthOS online approvals system |

This is a controlled document. The master document is posted on the RKE website:

http://www2.mmu.ac.uk/research/research-governance/

Any print-off of this document will be classed as uncontrolled. Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking the RKE website for more recent versions.

1. **Background**

Prior to the commencement of any research organised by Manchester Metropolitan University (MMU), all projects must have the following in place:

* Ethical approval
* Confirmation of insurance cover (where insurance notification is required)
* Approval to access research sites/participants. This could include:
	+ Honorary Contracts/Letters of Access via the research passport process - for staff working on NHS sites,
	+ DBS checks - for research involving regulated activities with vulnerable adults or children

Other specialised approvals may be required depending upon the setting in which the research takes place:

* NHS REC and/or HRA approval, for projects working with the NHS [Section 3.9 and 3.11]
* Confidentiality Advisory Group (CAG), for research using identifiable NHS data without consent [Section 3.10 and 3.11]
* Social Care Research Ethics Committee (SCREC), for research in social care settings [Section 3.12]
* National Offender Management Service (NOMS), for research in prison and probation services [Section 3.13]
* Ministry of Defence Research Ethics Committee (MoDREC), for research in MoD settings [Section 3.14]
1. **Purpose**

This SOP describes the processes for gaining the necessary approvals for all research projects undertaken at MMU. This includes student and staff research.

1. **Procedure**
	1. **Ethical Approval**

All research projects undertaken at MMU must submit their proposal for internal ethics review using the appropriate process. This includes all student and staff research, as well as student coursework using research methods. Ethical approval must be gained before any research activity takes place.

**3.1.2 Internal Ethics Review**

All applications are completed and managed through [Ethos](https://mmuintranet.mmu.ac.uk/Interact/Pages/Content/Document.aspx?id=2300&SearchId=), the online system which enables the ethical review form to be electronically approved by the appropriate reviewer. The system is accessed using the applicant’s University log-in credentials; full [guidance](https://www.mmu.ac.uk/research/staff/systems-and-resources/ethos-guidance/) on how to use the system is available online.

* 1. **Amendments**

Any amendments to ethically approved documentation (e.g. Protocol, PIS, Consent Form, Invitation Letters/Advertisements) must be re-submitted for further ethical scrutiny. For projects that only received MMU ethics approval, an amendment should be created in EthOS. The amendment must include a description of the changes alongside copies of all amended documentation. Projects which received NHS REC approval should follow the guidance on the HRA website for submitting [substantial and non-substantial amendments](http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/).

* 1. **Security sensitive information**

Any research that may involve the download and storage of sensitive information terrorist-related activity must be registered under the Prevent Duty.

Researchers are asked to read [SOP16 ‘Prevent Duty in Research’](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP16-Prevent-Duty-in-Research-Feb-2018---SOP---Form--final-approved-uploaded-1.docx) to learn more about this. To register under the Prevent Duty, the researcher must declare their terrorism related interest in EthOS section A13 and answer the specific questions that the form will asking in relation to this. Project that are Prevent relevant but are not associated with an EthOS application should follow instructions given in SOP16 for registry.

* 1. **Risk Assessments**

Risks assessments must be performed for all research. Applicants may use a faculty specific risk assessment template or use the general guidance and forms provided by the [MMU Health and Safety](https://mmuintranet.mmu.ac.uk/Interact/Pages/Section/Default.aspx?section=4637) team. Faculties/departments may also maintain risk logs containing risk assessments for common research activities which may assist with completing the risk assessment.

* 1. **Indemnity**

MMUs insurers require notification of all research in the following categories:

* Non-UK research or involving non-UK contacts/collaborations
* Involve people who lack the capacity to consent (for example, people with learning difficulties)
* Anything that assists with and/or alters the process of contraception, or investigating or participating in methods of contraception
* Anything involving genetic engineering other than research in which the medical purpose is treating or diagnosing disease
* Where the substance under investigation has been designed and /or manufactured by MMU
* Anything involving pregnant women
* Drug trials
* Research involving children under sixteen years of age
* Professional sports persons and/or elite athletes

Insurance approval is managed through the University’s Research Ethics process, and all researchers must accurately describe their proposed activities in their EthOS application. The CI must ensure that adequate insurance is in place before the research project begins. Insurance arrangements should be clearly detailed in the protocol and the participant information sheet (where applicable). Amendments to research projects are also subject to the University’s research ethics process, where the CI must highlight anything compromising the validity of the insurance.

If equipment is to be provided to site(s) for the purposes of the study, the CI should ensure that adequate arrangements are in place to meet the potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment).

* 1. **Green Light for Project Start**

Prior to any research activity, the researcher (or supervisor for UG/PGT students), must:

* Have received written confirmation of ethical approval, which should contain:
	+ Project title
	+ Chief Investigator
	+ Date of approval
	+ A list of approved documents including document title, version and date
	+ Details of the requirement for and process of submitting amendments
* Have received written confirmation that insurance is in place
* Have created a suitable research file
	1. **Research where MMU is not the lead organisation**

For projects where MMU staff are acting as co-investigators on a research project hosted by another organisation, the researcher should obtain evidence that the project has undergone ethical review. An agreement should be in place between organisations to clarify arrangements for the management and insurance of the research. Where the lead organisation is outside of the UK a check should be made to ensure that the regulatory arrangements (including ethical approval) in the host country are equivalent to those in the UK.

Where Non-UK led research will take place in the NHS the researcher must apply for HRA approval with MMU acting as the sponsor. A record of all ethical and regulatory approvals and collaboration agreements should be stored in the Study Master File.

* 1. **Visiting PhD Student Research**

All visiting PhD students should complete an EthOS application. Evidence of ethical approval gained from their home organisation should be provided where available. This may be accepted if the regulatory arrangements in the student’s home country are equivalent to those in the UK.

All research in the NHS is governed by the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/), and as such requires a research sponsor. Researchers should follow [SOP8 Sponsorship](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP8-Sponsorship.docx) in order to obtain sponsorship for the project. For student research projects, the Chief Investigator should be the academic supervisor of the research.

A quality assurance check should be performed by the study team (including research supervisors, administrative staff, statisticians where appropriate) on study related documentation prior to submission to the IRAS system. This is to ensure that the application is consistent with all study documentation, the research protocol, and departmental working practices. This should include:

* Protocol
* IRAS Application
* CRFs
* Patient Information Sheets
* Consent Forms

* + 1. **NHS REC and HRA Approval**

Research projects that use NHS patients or staff, NHS patient data or NHS premises must apply for HRA and/or NHS REC approval. Guidance on the approvals required in each circumstance can be found on the [HRA website](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/). Applications for REC and HRA approval are made using the [Integrated Research Application System](https://www.myresearchproject.org.uk/) (IRAS).

* + 1. **Certification of external approval**

Where approval is obtained from an external body such as NHS REC, an application should be created in EthOS via the ‘full application’ route. All approved documents should be uploaded together with the relevant approval letters.

This will be routed to the Ethics and Governance team, who will produce a letter of certification from MMU.

**3.9.3 NHS confirmation of capacity and capability**

For projects involving NHS sites, discussions should commence during the planning of the project, to ensure that the sites have the potential to participate. NHS organisations are then able to determine whether they will have the capacity and capability to host the research. Once REC and/or HRA approvals are in place, the local information pack is sent to the NHS site who will formally confirm capacity and capability. After this, the Research Ethics and Governance Office can provide ‘green light’ approval to commence the research.

* + 1. **Research Passports**

In addition to NHS R&D or HRA permission for a research project, all researchers who will perform research activities at NHS sites must have appropriate permission to be on the site. Additional permission is not required for researchers who:

* are employed by an NHS organisation
* are an independent contractor (e.g. GP) or employed by an independent contractor
* have an honorary clinical contract with the NHS (e.g. clinical academics)
* are a student undertaking an education course for which there is a healthcare placement agreement already in place with the NHS organisation which is also hosting the student’s research activity
* are a student who will be supervised within clinical settings by an NHS employee or HE staff member with an honorary clinical or research contract

Researchers who are not in any of the above categories and who have no contractual relationship with the NHS will need a Research Passport. The [algorithm of research activity and pre-engagement checks](https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Research-Passport) provides guidance on the pre-engagement checks that should be carried out in particular research situations, and whether or not an honorary research contract is required. Please note that not all researchers involved in a particular project will be conducting the same research activities and so there may be different requirements for different members of a research team.

To apply for a Research Passport:

* The researcher completes sections 1-3 of the [Research Passport Form](https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Research-Passport)
* The researcher's line manager (or academic supervisor) completes section 4
* Students should take the form to their Graduate School who will complete section 5
* Staff should take the form to the Business Solutions team in HR, who will complete section 5

Depending upon the type of research activity, the researcher may need to complete occupational health assessments and/or DBS/ISA checks. For occupational health assessment, student researchers should contact occupationalhealthenquiries@mmu.ac.uk .*Please note that a DBS check may take up to 6 weeks to obtain, and if vaccinations are required for the research activity this could take considerably longer.*

* Once sections 4 and 5 have been countersigned, the researcher should complete section 6 and then take the completed Research Passport form with required attachments (e.g. CV, evidence of occupational health clearance, researcher’s own copy of the criminal record disclosure) to the lead NHS organisation.

Once the form has been authorised by one NHS organisation it becomes a valid Research Passport that can be provided to other NHS organisations.

* 1. **CAG**

Researchers who wish to use identifiable patient information relating to people living in, or receiving healthcare in, England and Wales without explicit consent must apply to the CAG. Applications are made through the IRAS system.

* 1. **Reports to NHS REC / CAG**

Following NHS REC approval, research projects must submit an annual progress report via email to the approving REC. Template reports are provided on the HRA website, and should be completed by the Chief Investigator or their delegate. The Ethics and Research Governance Manager will keep a record of the due date for annual reports and will send out a reminder to the Chief Investigator. A copy of submitted reports must be sent to the Ethics and Research Governance Manager.

An end of study declaration must be sent to the approving NHS REC within 90 days of the end of the study. The end of study is normally considered to be following lock of the study database, and prior to final analysis and report writing. The appropriate form, found on the HRA website, should be completed and emailed to the approving REC. A copy should be sent to the Ethics and Research Governance Manager.

A final report should be emailed to the REC within 12 months of the declaration of the end of study. There is no standard format for final reports. As a minimum, it should include whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

For studies that were approved by the Confidentiality Advisory Group, the CI should notify the Confidentiality Advice Team as soon as possible in writing when the study is completed. Once received the Confidentiality Advice Team will review the information provided, update the approval register and write to confirm receipt of the application closure notice. The application will remain on the approval register on the HRA website for at least 12 months following notification of application closure.

* 1. **SCREC**

Social care research in the categories below must apply for SCREC approval using the IRAS sytem:

* Studies funded by Department of Health:
	+ Research commissioned directly through the Policy Research Programme
	+ Health and Social Care Information Centre (HSCIC) studies
	+ Studies commissioned by or through National Institute for Health Research (NIHR) School for Social Care Research
	+ Social care studies funded (in rare cases) through NIHR
* Research that involves people lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005.
* Research involving sites in England and another United Kingdom country
* “Own account” research undertaken by Councils with social services responsibilities, where the Chief Investigator and/or sponsor feels there are substantial ethical issues
* Studies of integrated services (health and social care), provided that there is no clinical intervention involved (Research involving clinical interventions should be reviewed by NHS REC)
* Studies taking place in NHS settings with patients or staff where the approach to data collection uses social science methods, provided that the research involves no change in treatment or clinical practice
* Other social care studies not suitable for review by other NHS RECs, subject to the capacity of the Social Care REC. This could include service user-led research
* Intergenerational studies in social care where both adults and children, or families, are research participants.
* Research which involves changes in participants’ care or even the withdrawal of some aspect of their care.

Other social care research does not require review by the Social Care REC if it is has undergone review through the MMU Research Ethics process.

* 1. **NOMS**

National Offender Management Service (NOMS) permission is required for social research (including health research) and science/technology research across the prison service and probation providers. This includes research in Young Offenders’ Institutions (YOIs), but excludes research in Secure Training Centres, Secure Children’s Homes or with Youth Offending Teams – applications to conduct research in these excluded areas should be directed to the Youth Justice Board (research@yjb.gov.uk). Research commissioned by the Ministry of Justice is also excluded – this research will go through separate MoJ quality assurance processes (research@justice.gsi.gov.uk). Depending on the subject area of the research, contact may also need to be made with other Government Departments, e.g. the Home Office.

Applications to NOMS should be prepared in IRAS and submitted by email to the NOMS National Research mailbox. The submission should include:

* The completed IRAS application form in XML and PDF format
* CV for Researcher and all other Researchers Questionnaire for participants (if applicable)
* Information/Consent form for participants
* Ethics approval form/an ethics assessment from an appropriate body/covering letter from sponsor if appropriate

Further guidance on the research application process can be found [here](http://www.justice.gov.uk/downloads/offenders/psipso/psi-2012/psi-13-2012-research-application.doc).

* 1. **MoDREC**

Research involving MOD personnel may require the approval of MoDREC. Further guidance on the types of research requiring approval and the approval process can be found [here](https://www.gov.uk/guidance/apply-for-ethical-approval-for-mod-research-involving-humans).

1. **Related Documents**

[SOP8 Sponsorship](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP8-Sponsorship.docx)

[SOP16 Prevent Duty in Research](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP16-Prevent-Duty-in-Research-Feb-2018---SOP---Form--final-approved-uploaded-1.docx)

[Insurance Checklist Form](https://www.mmu.ac.uk/research/staff/ethics-and-governance/ethics/)

[Security Sensitive Information Form](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/Security-Sensitive-Information-Form.docx)

[Research Passport Form](https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx%22%20%5Cl%20%22Research-Passport)

1. **References**

[HRA Amendments](http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/)

[MMU Health and Safety](https://mmuintranet.mmu.ac.uk/Interact/Pages/Section/Default.aspx?section=4637)

[Integrated Research Application System](https://www.myresearchproject.org.uk/)

[Research Passport: Algorithm of research activity and pre-engagement checks](https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx%22%20%5Cl%20%22Research-Passport)

[NOMS](http://www.justice.gov.uk/downloads/offenders/psipso/psi-2012/psi-13-2012-research-application.doc)

[MoDREC](https://www.gov.uk/guidance/apply-for-ethical-approval-for-mod-research-involving-humans)