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Signature of Authorisor			

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Standard Operating Procedure (SOP)
Applying to the NIHR Portfolio

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Lisa Clutterbuck
V2.0	New logo, new trust name, change of title from CRGM to HRG	Deborah McCartney
V3.0	Updated to incorporate new HRA process in England	Deborah McCartney

1. Background

The National Institute for Health Research (NIHR) commissions and funds NHS, social care and public health research that is essential for developing research evidence to support decision making by professionals, policy makers and patients, making this evidence available, and encouraging its uptake and use which provides clinical and non-clinical evidence and best practice, to make informed decisions. The NIHR's key objective is to improve the quality, relevance, and focus of research in the NHS and social care by distributing funds in a transparent way after open competition and peer review.

The National Institute for Health Research Clinical Research Network (NIHR CRN) Portfolio is a database of high-quality clinical research studies that are eligible for support from the NIHR Clinical Research Network in England. In order to be considered for NIHR Clinical Research Network (CRN) support a research study must be identified as being 'Eligible'. In England, the Department of Health has established the eligibility criteria for CRN support. The CRN Portfolio team assesses eligibility for CRN support on behalf of the Department of Health (in England).

Studies that are eligible for consideration for CRN support are included in the NIHR CRN Portfolio. Applications to be considered for CRN support are made through the NIHR Coordinated System for gaining NHS Permission via the Integrated Research Application System (IRAS).

Studies that are eligible must be fully funded through a grant that was awarded in open competition. For further information on eligibility, please see www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support/ although as the eligibility criteria may be amended from time to time **and** the Portfolio Adoption Form (PAF) must now be submitted **prior to HRA/REC submission**, Investigators are encouraged to apply for adoption. NB. You cannot apply for adoption after you have received your HRA initial assessment.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP outlines the role of the JREO in the review process for all St George's sponsored non-CTIMP and CTIMP research that is to be considered for adoption onto the NIHR CRN Portfolio. The SOP will also outline the submission procedure for the Investigator when a research project is potentially eligible for adoption onto the Portfolio.

4. Definitions

4.1 Research

This is the attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.

4.2 Sponsored Non-CTIMP

Trials sponsored by St George's that do not involve an Investigational Medicinal Product (IMP) as defined by the MHRA, and therefore do not fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.

4.3 Sponsored CTIMP (Clinical Trial of an Investigation Medicinal Product)

Trials sponsored by St George's that do involve an Investigational Medicinal Product (IMP) as defined by the MHRA, and therefore do fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.

4.4 Clinical Research Network (CRN)

There are 15 Local Clinical Research Networks (CRN) that cover the whole of England. Each local CRN delivers research across 30 clinical specialties including cancer, cardiovascular

disease and children, for example. Typically, Local Research Network teams comprise a clinical director and senior manager who oversee a range of research support staff including nursing and other health professions, life-sciences backgrounds, RM&G, data managers and administrative staff. The Local CRN for St George's is South London.

4.5 CRN Portfolio

This is a database of clinical research studies taking place in the NHS that are funded by the life sciences industry, charities, central and overseas governments, and commercial collaborating bodies. All studies funded by the NIHR, and some studies that meet certain criteria, will be eligible for adoption onto the Portfolio, and thus eligible for free support from the CRN. 'Support' may be in the form of network funded staff to facilitate identification and consenting of participants. Should a study potentially fulfil portfolio adoption, the Network Study support service may assist in completion of the HRA Schedule of Events by attribution of costs to study activities in line with AcoRD guidelines.

4.6 UK Central Portfolio Management System (CPMS)

This database has replaced the UKCRN Portfolio database, which used to comprise the four CRN portfolios form England, Northern Ireland, Scotland and Wales. It is open to public search on the Clinical Trials Gateway website on www.ukctg.nihr.ac.uk

4.7 Regulatory Checks

The Health Research Authority (HRA) was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research.

HRA Approval is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. The HRA has taken over the responsibility for ensuring that each new study complies with all applicable regulatory requirements in England. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study (www.hra.nhs.uk).

In question A68 on the Integrated Research Application System (IRAS) form, the Investigator states which will be the lead NHS Trust site for the study. This question obviously determines which R&D office will lead the study and which Local CRN will be involved if the study is eligible or applying for Network Support, whether commercially sponsored or not. That CRN will offer support services to help study feasibility, set up and delivery to time and target (www.crn.nihr.ac.uk/can-help) e.g. completion of the Schedule of Events –attribution of associated costs in accordance with the ACoRD guidelines.

5. Responsibilities

This SOP is to be followed by the JREO Governance team: Head of Research Governance (HRG), Research Governance Officers (RGOs) and, if applicable, Regulatory Assurance Manager (RAM), and Clinical Trial Monitors (CTMs).

It is the responsibility of the HRG to ensure that the SOP is updated and audited where necessary.

It is the responsibility of the Chief Investigator (CI) or local Principal Investigator (PI) to ensure that the completed documentation is submitted through the Integrated Research Application System and to respond to subsequent requests from the CRN, HRA, REC, and/or the JREO.

It is the responsibility of the assigned member of the Research Governance Team (RGT) to ensure review of all relevant documents in accordance with this SOP prior to sponsorship being issued.

6. Procedure

6.1 Investigator Procedure

a) If it is ascertained (either from consultation with personnel from the NIHR, the IRAS website, the HRA website, the local CRN or the JREO) that a study may be potentially eligible for NIHR adoption, the CI or delegated research team member, should answer yes to the following question in the IRAS Project Filter questions:

b) *5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio?* The CI and/or delegated research team member will need to complete

the NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) and submit the form through IRAS before the IRAS form is submitted.

c) The CI and/or delegated research team member will then need to follow the Sponsorship process (Applying for Sponsorship for Non CTIMPs JREOSOP0028 and JREOSOP0003 and JREOSOP0004 for Sponsorship in Principle and Sponsorship in Full for CTIMP studies) and the HRA/ REC application process (if required- JREOSOP0040)

d) The CI and/or delegated research team member should respond to requests from the NIHR Portfolio team if further information regarding the funding for the study is required. This normally entails providing the grant award letter to the CRN.

6.2 JREO Procedure

a) On receipt of a new study application for Sponsorship (whether a non-CTIMP or CTIMP), it is the lead RGO, RAM and/or CTM's responsibility to review the application in order to ascertain whether the study may be eligible for NIHR CRN Portfolio adoption.

b) The lead RGO or RAM and/or CTM reviewing the application will review the financial section of the IRAS form. Eligibility criteria for the NIHR CRN Portfolio can be found on the NIHR website : www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support

c) Studies fall into three categories: automatically eligible, potentially eligible and not eligible. If it is deemed by the lead RGO, RAM and/or CTM that the study is eligible or potentially eligible for NIHR CRN Portfolio Adoption, they will advise the CI or delegated research team member to submit the NIHR CRN Portfolio Application Form through IRAS.

d) The RGO or RAM and/or CTM will then advise the CI and/or delegated research team member to complete the Sponsorship process (Applying for Sponsorship for Non CTIMPs JREOSOP0028) (JREOSOP0003 and JREOSOP0004 for Sponsorship in Principle and Sponsorship in Full respectively for CTIMP studies) and the HRA/REC application process (JREOSOP0040), if applicable.

e) The CI, as stated in the IRAS form and as agreed with St George's, and the Sponsor's representative will receive notification from the NIHR Portfolio team regarding the eligibility of the study. On receipt of notification from the NIHR portfolio team that the study is **not eligible** the CI will need to go back into IRAS and unselect yes on the project filter question 5b. The CI should discuss the financial feasibility of the study with the RGO/RAM and/or CTM.

f) On receipt of notification from the NIHR Portfolio team that a study is **potentially eligible** for NIHR Portfolio adoption, the RGO or RAM and/or CTM should advise the CI and/or delegated research team member to submit the HRA/REC submission through IRAS in accordance with JREOSOP0040.

g) The RGT must request a PDF copy of the PAF that was submitted through IRAS from the CI and retain within the study e-folder. The ReDA events tab will need to be updated with PAF submission date and decision status.

h) Upon submission of the project through IRAS, notification will be received from the NIHR Portfolio team to the CI as well as the Sponsor's representative as stated on the IRAS form. The notification will confirm NIHR Portfolio adoption for the study, which is proceeding through HRA, or will advise that the study cannot be adopted. The Portfolio Adoption team may also require further information within a given timeline and it is very important to make sure that the timeline is met. The Investigator will then need to take further steps to set up the study in accordance with JREOSOP0017.

7. References

IRAS (Integrated Research Application System) - www.myresearchproject.org.uk
National Institute for Health Research (NIHR) - www.nihr.ac.uk/

NIHR Eligibility criteria www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support

AcoRD guidance and information https://www.crn.nihr.ac.uk/acord/

8. Appendices

None associated with this SOP.