East Kent Hospitals University NHS Foundation Trust

East Kent Hospitals University NHS Foundation Trust

Research and Innovation (R&I)

Standard Operating Procedure (SOP) 13

Registration, Application and Approval of Grey Area Projects (GAPs)

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2.1	25/1/2017	Dr Art Ationu Dr Tim Doulton	Final	Revisions following review by R&I office staff
2.2	24/06/2021	Dr Jane Povey	Final	Revisions following review by R&I Central Office

Consultation and Ratification Schedule

Name and Title of Individual	**Date Consulted**
Caroline Cowley, Interim R&I Manager	May/June 2021
David Stephensen, Deputy Director R&I	June 2021
Ms Jessica Evans, Director R&I	
Ruth Hulbert, Lead Nurse	

Name of Committee	**Date Reviewed**
R&I Business Meeting	21st June 2021

Contents

1. Introduction, Background and Purpose

This SOP defines the process for seeking Trust approval for projects that are classified as Grey Area Projects (GAPs) and to ensure appropriate support is available to implement outcomes from such projects.

The majority of research projects undertaken in EKHUFT require Health Research Authority (HRA) approval. Exceptions to this requirement are: Projects which neither fit definitions of clinical audit nor the definition of research employed by the HRA (see below) and therefore sit within a “grey area” where HRA approval is not required. Examples include, but are not limited to, social care research methodologies, quality and service improvement, and practice development projects and service evaluations.

2. Definitions

2.1. GAP- Grey Area Project

2.2. HRA- Health research Authority

2.3. REC- Research Ethics Committee

2.4. Project- is defined as any piece of work involving the use of staff or patient data, or any NHS resources apart from routine management, and whose outcomes may contribute to the body of knowledge, can be disseminated and can change practice or service delivery

2.5. CG -Caldicott Guardian

3. Scope

3.1 This SOP applies to all projects classified as GAPs submitted to the R&I Central Office for review and Trust approval. The aim of this SOP is:

To describe the rationale for having a GAP approval process
To define how Trust approval for GAPs should be sought
To describe the process by which GAPs will be reviewed, approved, and for reporting of the outcomes of GAPs

3.2 The Health Research Authority (HRA) uses two self-assessment decision tools to enable researchers to judge **firstly** whether their project fulfils their definition of research, and **secondly**, whether the project requires REC review. All staff planning to undertake a project that falls under the scope of this SOP are required to undertake a two-step process using these decision tools, as outlined in section 4 of this SOP. This SOP is only applicable to projects that are NOT classified as research and do not need HRA and /or REC review.

3.3 Importance of GAP processes for capturing breadth of R&I activity & providing relevant assurances

Importantly, there is an opportunity for all projects and studies undertaken across EKHUFT to contribute to growing our research capacity and capability - one of the Trust's strategic objectives for R&I - even though HRA and/or REC approval may not be required. An additional purpose of this policy is therefore to (i) quality assure these projects and ensure these are effectively contributing to growing capacity and capability through a stepped approach (ii) comprehensively catalogue all projects across the organisation in a way that staff can access what is happening, what opportunities there are to participate and build on rather than duplicate.

3.4 The GAP process provides the following assurances & benefits to the Trust and individual applicants:

3.4.1 Peer review of project question(s), aim(s) & objectives, hypothesis, methods, design, data analysis plan, e.g. statistical input, thematic analysis etc., thereby providing quality assurance that is independent of the researcher/research team, mitigating risks of poor quality research outputs, duplication of work and/or inappropriate use of NHS resources
3.4.2 Compliance by Trust and individual researchers/research teams with DHSCUK Policy Framework for Health and Social Care Research
3.4.3 Systematic dissemination of project outputs, outcome and impact
3.4.4 Evidence of institutional review as may be requested during submission for publication in peer-reviewed publications

4. Procedure

4.1 Before submitting a proposal via the GAP process, the applicant should use the on-line Health Research Authority (HRA) decision tool http://www.hra-decisiontools.org.uk/research/ to determine whether their project is research.

Where the decision tool(s) indicates HRA and/or REC approval is required, applicants should apply for approval via the HRA process via the IRAS website Integrated Research Application System (myresearchproject.org.uk).

4.2 Applicants undertaking GAPs should contact the Trust R&I Central Office to request a GAP Application Form. The documents that will need to be submitted are:

4.2.1 EKHUFT GAP Application Form. Peer review sections should be completed by a colleague with appropriate knowledge and expertise in the area under study OR by an appropriate supervisor (e.g. university).
4.2.2 Protocol. See relevant EKHUFT R&I SOP for guidance on how to write a research protocol.
4.2.3 Lead applicant CV. Please use the NIHR CV template, which can be obtained from R&I Central Office or found at http://www.hra.nhs.uk/resources/applying-for-reviews/applying-for-approvals-template-documents/.
4.2.4 Output from HRA decision tool(s).

4.2.5 Project Dissemination Template. This will be used to facilitate the cataloguing process described above. The first four sections of the template should be completed alongside your GAP application. Remaining sections should be completed at the conclusion of the project. The completed template should be resubmitted to the R&I Central Office.

4.2.6 Opinion from University Ethics Committee. Applies only to student/educational projects.

4.2.7 Other supporting documentation e.g. Participant Information Sheet.

4.3 The R&I Central Office will validate your application (i.e. verify that a complete document set has been received) and register your project on its database.

4.4 Your project will be reviewed by the R&I Central Office and may request that the applicant arranges further peer review. Concurrently to this, the R&I Central Office may notify the Caldicott Guardian (CG) of requirement for their review, where relevant.

4.5 Subject to no issues being raised by CG, the R&I Central Office will issue a **Trust Approval Letter** within 14 days of a valid application. Please do not start your project until you have confirmation from the Trust R&I Central Office that your project has been approved.

4.6 On completion of project, the results/findings/outcomes and conclusion will be added to the project dissemination template. For projects that are published or presented at meetings, the relevant abstract will suffice and/or can be appended.

4.7 Exemptions: The following are exempt from Trust R&I Approval of GAPs

4.7.1 Laboratory medicine method comparisons

4.7.2 Performance assessments –this term is intended to encompass use of material in the evaluation and assessment of in-vitro diagnostic kits. This is to make it quite clear, for example, that surplus diagnostic tissue can continue to be used to calibrate and assess the comparative performance of medical devices without specific consent- See -Use of patient samples for method validation and verification within pathology: ethical considerations- Pathology Document -DIR-MP-Q213 for details.

4.7.3 Quality assurance - A programme for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met. This includes separate examination or testing of tissue in order to ensure a high quality service and effective clinical procedures and diagnostic tests. In practice, this term could cover a review of the whole diagnostic process, including checking how information relating to tissue is recorded. The review is not, for example, limited to checking the accuracy of apparatus. If your project is QA contact Clinical Audit- Clinical Audit - East Kent Hospitals University NHS Foundation Trust (ekhuft.nhs.uk)

These activities are governed by applicable laws and regulations and undertaken within clear guidelines

4.8 Responsibilities of the applicant

4.8.1 To provide complete and accurate answers to questions relating to the nature of the project (e.g. to HRA decision tools), to R&I Central Office to enable correct classification as a GAP
4.8.2 To obtain Trust approval through the R&I Central Office prior to the commencement of the project
4.8.3 To ensure compliance with Information Governance requirements and to maintain duty of confidentiality
4.8.4 To ensure that all the costs associated with the GAP are identified and adequate support or resources are available to undertake the project
4.8.5 To seek appropriate peer review of the proposed project
4.8.6 To respond to all questions raised by the Caldicott Guardian (CG)
4.8.7 For non-EKHUFT staff) To obtain a Letter of Access (LoA) if study activities will take place on EKHUFT premises

4.9 Responsibilities of the R&I Central Office

4.9.1 To advise applicants on whether their proposed project falls within the scope of the GAP approval process.
4.9.2 Ensuring that the PI is provided with a reference number
4.9.3 If required, circulation of application to the CG to seek necessary authorisations, and relaying of any issues raised by the CG to the applicant so that these can be addressed
4.9.4 Provision of Trust approval for GAPs within 14 days of a valid initial application if all authorisations are in place and all outstanding queries are addressed

4.10 Responsibility of the Caldicott Guardian
If necessary, the CG will review paperwork and give their approval within 10 working days unless issues requiring clarification are raised.

5. Consultation and Approval

5.1. R&I SOPs will be overseen and ratified by the SMT. SOP revisions and amendments will also be ratified by the SMT.

5.2. Key Stakeholders – Trust Research Delivery Teams and Investigators, Clinical Research Networks, local Higher Education Institutions, Medical Research Charities, National Institute for Health Research, Industry and Health Research Authority.

6. Review and Revision Arrangements

6.1. All SOPs will have an effective date issued and a review date which should not be more than two years from effective date issued.

6.2. SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process, or organisational change.

6.3. Any personal using specific SOPs will notify the RICO team if any changes/amendments they consider necessary due to changes in process.

7. Training

The staff in the R&I Central Office and the Research Facilitator will be trained in this process. They can explain the process to researchers when they need to use it.

8. Document Control including Archiving Arrangements

This SOP will be stored and accessible and superseded SOPs/policies archived for at least fifteen years.

9. Decisions & Monitoring

9.1 Decisions

The decision that a project be assigned GAP status is made using all the available evidence by the R&I team.
If R&I feel that the application does not meet the GAP criteria and requires HRA and/or REC approval and the applicant disagrees, further discussions will take place and the HRA contacted if deemed necessary (HRA.Queries@nhs.net.). If the decision is that the project needs HRA and/or REC approval it is the responsibility of the Chief Investigator to follow this process with the support of R&I. Not following this process could be deemed contrary to UK law.

See Appendix 2 for the HRA Defining Research Table.

9.2 Monitoring

Applicants must provide progress reports and end-of-study reports when requested by R&I.
Failure to obtain Trust R&I approval for GAPs will be brought to the attention of the Director of R&I and appropriate further escalation and/or action.

10. References and Associated Documentation

How to write a research protocol/proposal

R&I SOP 10 available from ekhuft.researchandinnovation@nhs.net

GAP Application Form

Available from: ekhuft.researchandinnovation@nhs.net

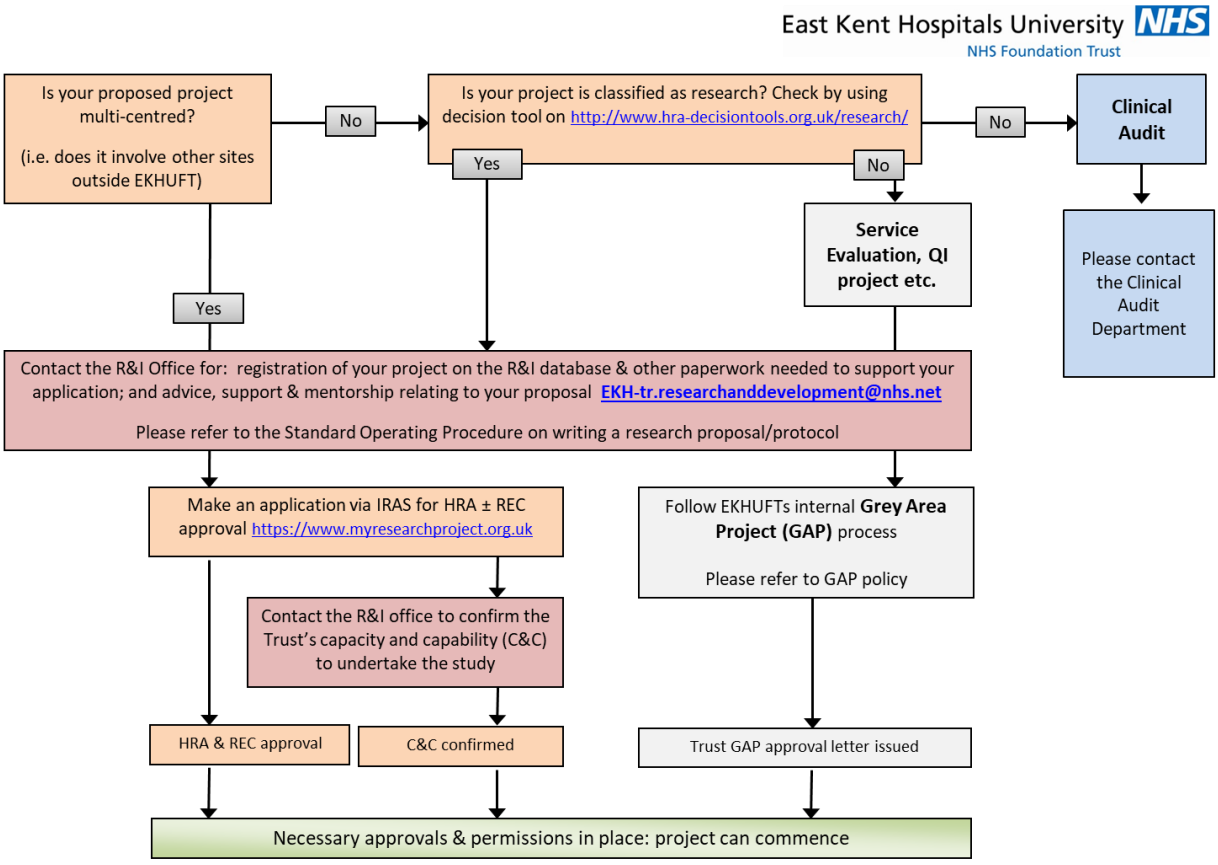
Pathology Document -DIR-MP-Q213

Clinical Audit - East Kent Hospitals University NHS Foundation Trust (ekhuft.nhs.uk)

11. Appendices

Appendix 1

Flowchart describing process for obtaining permission



The HRA decision tool for defining whether a project is research tool (http://www.hra-decisiontools.org.uk/research/) uses three questions:

1. Are the participants in your study randomised to different groups?
2. Does your study protocol demand changing treatment/patient care from accepted standards for any of the patients involved?
3. Are your findings generalizable?

The last question is narrowly defined with a focus on biomedical research. It means 'the extent to which the findings of a clinical study can be reliably extrapolated from the subjects who participated in the study to a broader patient population and a broader range of clinical settings' [HRA]. The purpose of healthcare research is to contribute to the body of knowledge and understanding. This embraces both clinical interventions and treatments, which is mainly the concern of the HRA, as well as how we provide and experience health care at every level. Research approaches that contribute to this wider understanding may use different approaches to ensuring that research quality is assured which embrace the concept of transferability, trustworthiness and credibility through a deep understanding of the relationship between the context of care and the broader

outcomes. As such, these insights may be transferrable to other settings, although the extent that findings of a particular project should be regarded as ‘generalizable’ under the HRA definition will, on occasions, require a balanced judgement by the researchers and/or EKHUFT R&I Department.

Appendix 2: HRA Defining Research Table

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health including health protection)
The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate an outbreak or incident to help in disease control and prevention
Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What are the health issues in this population and how do we address them?" Designed to answer: "What is the cause of this outbreak or incident and how do we manage it?"
Quantitative research - addresses clearly defined questions, aims and objectives. Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, quantitative or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.
Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	No allocation to intervention.
May involve randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment/ care/ intervention.
Normally requires REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.