East Kent Hospitals University NHS
NHS Foundation Trust

East Kent Hospitals University NHS Foundation Trust

Research & Innovation (R&I) Policy for approval of Grey Area Projects (GAPs)

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Name of originator/author:	Dr Art Ationu & Dr Tim Doulton
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1	04/05/2015	Dr Art Ationu	Draft	
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1.4	14/07/2015	Dr Art Ationu	Draft	Dr Ed Lamb reviewed and commented
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Consultation and Ratification Schedule

Name and Title of Individual	Date Consulted

Name of Committee	Date Reviewed

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1. Policy Summary

This policy 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.

2. Introduction

2.1 Background

The majority of **research projects** undertaken in EKHUFT require Health Research Authority (HRA) approval. Exceptions to this requirement are:

a) Educational projects, defined as any research project/study undertaken for the purposes of an academic award, will fall within the scope of this policy provided the project does not require (i) Research Ethics Committee (REC) review and (ii) support from the Clinical Research Network (CRN).

b) Other 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 and, in addition, staff may be unclear about whether Trust Approval should be sought. Examples include, but are not limited to, social care research methodologies, quality and service improvement, and practice development projects.

For the purpose of this policy, a **project** is defined as any piece of work involving the use of staff or patient data, their bodily tissues, organs 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.

2.2 Defining 'research' and determining requirement for REC review

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 policy are required to undertake a two-step process using these decision tools, as outlined in section 4 of this policy.

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.

2.3 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. See Appendix 2 for examples of relevant projects.

In addition, the GAP process provides the following assurances & benefits to the Trust and individual applicants:

- 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
- Compliance by Trust and individual researchers/research teams with DH Research Governance Framework
- Systematic dissemination of project outputs, outcome and impact
- Evidence of institutional review as may be requested during submission for publication in peer-reviewed publications

3. Purpose and scope

Purpose

The aim of this policy 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

Scope

This policy applies to all projects classified as GAPs submitted to the R&I office for review and Trust approval.

4. Process for obtaining R&I Approval for GAPs

Step 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 an **educational project** is confirmed to be research, applicants should then confirm that REC approval is not required using http://www.hra-decisiontools.org.uk/ethics/. Educational projects not requiring REC approval and CRN support can be processed through the GAP process.

Where the decision tool(s) indicates HRA and/or REC approval is required, applicants should apply for approval via the HRA process.

Step 2: Applicants undertaking GAPs should contact the Trust R&I office to request a GAP Approval Form (GAF). The documents that will need to be submitted are:

- **EKHUFT GAP Approval Form (GAF)**. **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).
- ~~**IRAS R&D Form**. This is available at www.myresearchproject.org. If you complete the filter questions as normal and only tick NHS/HSC Research and Development offices at Q4, this will create a simplified version of the application form~~
- **Protocol**. See relevant EKHUFT R&I SOP for guidance on how to write a research protocol.
- **Lead applicant CV**. Please use the NIHR CV template, which can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/applying-for-approvals-template-documents/.
- **Output from HRA decision tool(s)**.
- **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 office.
- **Opinion from University Ethics Committee**. Applies only to student/educational projects.
- **Other supporting documentation** e.g. Participant Information Sheet.

Step 3: The R&I office will validate your application (i.e. verify that a complete document set has been received) and register your project on its database.

Step 4: Your project will be reviewed by the R&I office and may request that the applicant arranges further peer review. Concurrently to this, the R&I office will notify the

Caldicott Guardian (CG) & Service Support Departments (SSDs) of requirement for their review, where relevant.

Step 5: Subject to no issues being raised by CG or SSDs, the R&I 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 office that your project has been approved.

Step 6: On completion of project, the results/findings/outcomes and conclusion will be added to the project template For projects that are published or presented at meetings, the relevant abstract will suffice and/or can be appended.

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

- Laboratory medicine method comparisons
- 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
- 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.

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

5. Responsibilities

Responsibilities of the applicant

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

Responsibilities of the R&I office

- To advise applicants on whether their proposed project falls within the scope of the GAP approval process. Where the R&I department considers that the proposed projects raises significant ethical issues, they may request that the applicant seek an opinion from the REC Chair
- Ensuring that the PI is provided with a reference number and access to the R&I database
- To support peer review of the application
- Circulation of application to the CG and Support SSDs and seek necessary authorisations
- Relaying of issues raised by the CG and SSDs to the applicant so that these can be addressed
- 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

Responsibility of Support Services Departments and Caldicott Guardian

- Study related documentation will be uploaded to the R&I database. SSDs and CG will access the database to review paperwork and give their approval within 10 working days unless issues requiring clarification are raised.

6. Escalation & Monitoring

a) Escalation

The decision that a project be assigned GAP status is made using all the available evidence by the R&I team, with escalation to the R&I Manager where necessary.

If the R&I team and/or Manager considers that a project should not be assigned GAP status, the applicant will be provided a full written explanation why that decision was reached along with necessary supporting evidence.

Where the applicant disagrees with the decision reached by the R&I team/Manager, the applicant will then be directed to seek advice from the HRA as to whether a given project should be classified as research and/or REC approval be sought. The process for doing this is as described in the HRA decision tool, and should be by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net. If in doubt, we suggest also including a copy of the project protocol.

The applicant has the final right of appeal to the Director of R&I. The process to be followed in the event of an appeal is:

- R&I will provide all relevant documentation including how the decision was reached and advice provided by the HRA
- The Director of R&I will review the decision and, if unable to resolve the matter him/herself, will present to the R&I Committee for discussion and decision by majority vote of a quorate committee if necessary.

b) Monitoring

It is mandatory for applicants to provide progress reports and end-of-study reports when requested by R&I. Failure to provide reports will constitute non-compliance with Research Governance Framework and this Trust policy and will be escalated to the Director of R&I.

c) Breaches of policy

Breaches of this policy or 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.

7. Consultation, Approval, Ratification, Review and Revision Arrangements

This policy will be overseen and ratified by the R&I Committee. SOP/policy revisions and amendments will also be ratified by the R&I Committee in accordance R&I SOP No 1 - Production, Review and Approval of Research & Innovation Standard Operating Procedures (SOPs).

8. Dissemination and implementation

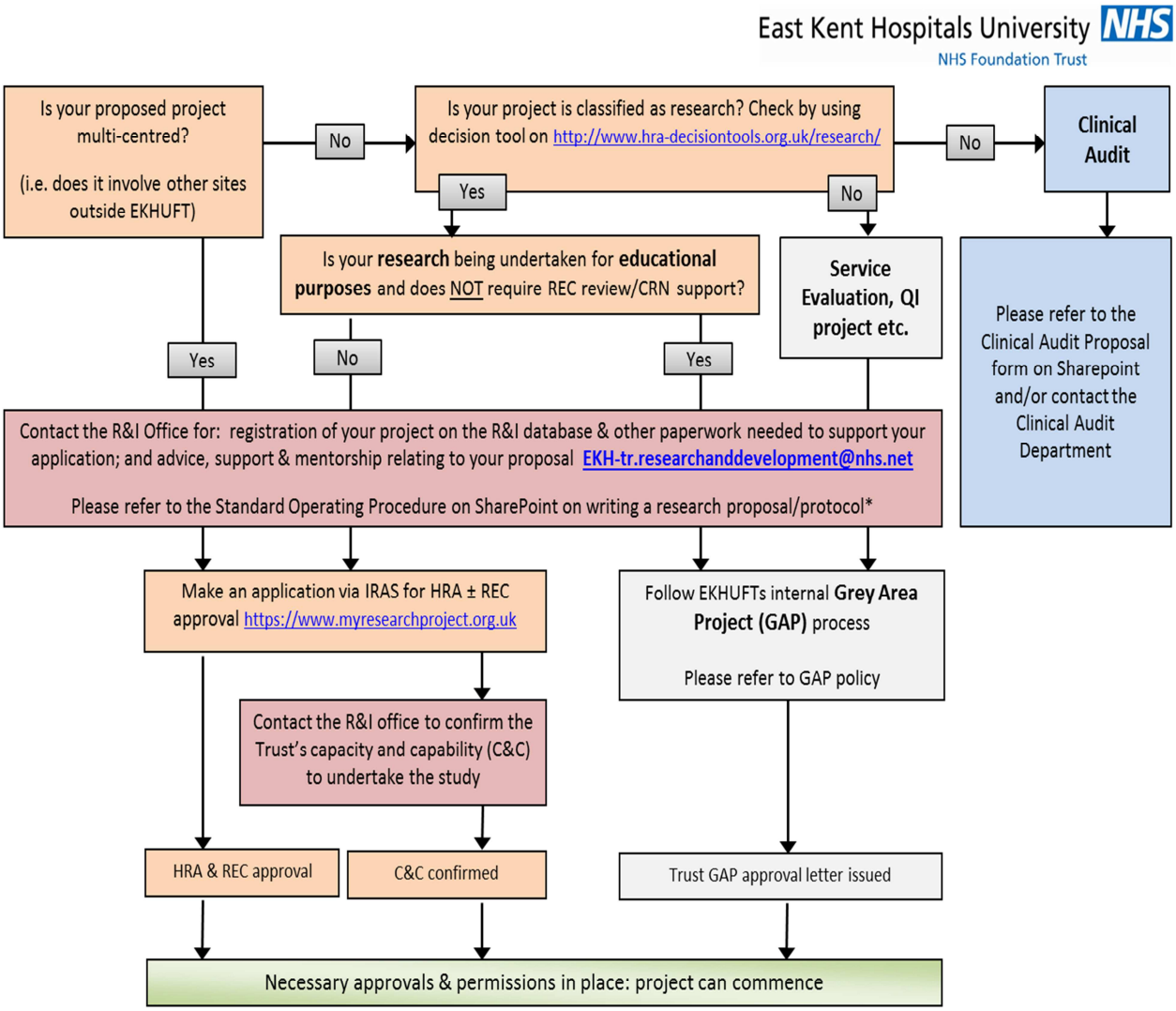
Once authorised this policy will be distributed in accordance with Dissemination Plan (Appendix C). All trust wide R&I SOPs/policies will be available in SharePoint on the Trust website for access by all relevant personnel. It is the responsibility of all research staff undertaking research at EKHUFT (including external researchers) to check SharePoint for current SOPs/policies.

9. Document control and archiving

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

Appendix 1

a) Flowchart describing process for obtaining permission



*http://sharepoint.ekhuft.nhs.uk/ekhuft/documents/policies/Master%20Documents/Clinical%20Quality/Research%20and%20Development/SOP%2010%20-%20Developing%20a%20research%20protocol%20or%20proposal.doc

Appendix 2: Levels of study or project

The table below provides a guide for the nature of Quality and/or Service Improvement or Practice Development projects at three different levels and identifies the criteria expected of each.

Level	Purpose	Example	Criteria to be met	Increases research capacity and capability through:
Level 1	Individual/Team that ONLY intend to improve own context	• TIPS Programme projects; • QI/SI projects • Implementation of best practice projects • Trying out new ideas/innovations • MSc module workplace projects	• Does not require REC approval (per 2nd HRA decision tool) • Has a specific question or aim as an individual practitioner or team • Has a systematic and rigorous approach to addressing the aim/question • Includes at least one evaluation element in the project • Ethical principles of consent and beneficence • Information governance	• Growing and supporting staff to be curious and systematic • Identifying potential research gaps and ideas for taking forward • Encourages individuals to obtain academic accreditation and an interest in pursuing their interests formally
Level 2	Individual/Team Quality Improvement/service improvement /practice development projects/qualitative research that **intend to contribute to the body of knowledge**	• Projects that undertake detailed analysis of contexts (including evaluation, culture , leadership), ways of working, staff and /or service user experiences • MSc theses	**In addition to above:** • University ethical governance approval if university related • Identifies gap in the literature/understanding • Describes detail of context	• Growing and supporting staff with research related skills • Growing a range of methodological expertise across the trust • Identifying the potential for bigger funded studies of

	and transferability to other settings	/MPhil/doctoral studies that answer NO to all HRA questions • Data mining projects aimed at identifying patterns and correlations	• Identifies: ○ specific methodology, methods and analysis ○ Assumptions/biases ○ Approaches to quality assure findings ○ Limitations ○ How contributes to body of knowledge ○ Makes recommendations/rolls out strategies that are transferable	significance to the trust • Exposes other staff to the potential for taking forward research related studies and topics • Integrates research and research impact as well as cataloguing what is happening
Level 3	Identified to require approval by REC: Proceed through the HRA Registration Process			

Appendix 3: Links to other resources

How to write a research protocol/proposal

\\Ekkch06\shrdata\Dover\BHD\NonClin\R&D\Old U Dive\Workarea\Workarea\Workarea\workarea\docs\SOPs\2015\SOP 10 - Writing research protocol-proposal v 1.docx

GAP approval form (GAF)

\\Ekkch06\shrdata\Dover\BHD\NonClin\R&D\Old U Dive\Workarea\Workarea\Workarea\workarea\docs\STANDARD LETTERS\TRIAL FEASIBILITY FORMS\GAP - R&D Trial Feasibility Form v 2.5 - March 2014.docx

Appendix 4 - Equality Impact Assessment

This Equality Analysis should be attached to any policy, strategy or business case for decision.	
Name of the policy, strategy or business case:	R&I SOP – Grey Area Projects
Details of person completing the Analysis	
Name	Dr Art Ationu
Job Title	R&I Manager
Division/Directorate	R&I/Corporate
Telephone Number	01843 234281
What are the main aims, purpose and outcomes of the policy, strategy or business case?	The purpose of this SOP is to describe the process of Grey Area Projects within East Kent
Does it relate to our role as a service provider and/or an employer?	Relates to both as a service provider and employer.
Is the policy, strategy or business case relevant to the aims of the equality duty? Guidance on the aims can be found in the EHRC's PSED Policy Guidance.	
Aim	**Yes/No**
Eliminate discrimination, harassment and victimisation	**Yes**
Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it	**Yes**
Foster good relations between persons who share a relevant protected characteristic and persons who do not share it	**Yes**

Assess the relevance of the policy to people with different protected characteristics and assess the impact of the policy on people with different protected characteristics. When assessing relevance and impact, make it clear who the assessment applies to within the protected characteristic category. For example, a decision may have high relevance for young people but low relevance for older people; it may have a positive impact on women but a neutral impact on men.		
Protected characteristic	**Relevance to decision** High/Medium/Low/None	**Impact of decision** Positive/Neutral/Negative
Age	**None**	**None**
Disability	**None**	**None**
Gender reassignment	**None**	**None**
Marriage and civil partnership	**None**	**None**
Pregnancy and maternity	**None**	**None**
Race	**None**	**None**
Religion or belief	**None**	**None**
Sex	**None**	**None**
Sexual orientation	**None**	**None**
Mitigating negative impact: Where any negative impact has been identified, outline the measures taken to mitigate against it.	N/A	

Information and research: • Outline the information and research that has informed the policy. • Include sources and key findings. Include information on how the policy will affect people with different protected characteristics.	1 – Department of Health Research Governance Framework 2005 2 – Health Research Authority guidance 3 - Medicines for Human Use (Clinical Trials) Regulations 2004, Medicines for Human Use (Clinical Trials)
Consultation: • Has there been specific consultation on this policy? • What were the results of the consultation? • Did the consultation analysis reveal any difference in views across the protected characteristics? Can any conclusions be drawn from the analysis on how the policy will affect people with different protected characteristics?	R&I Committee members
Conclusion: • Consider how due regard has been had to the equality duty, from start to finish. • There should be no unlawful discrimination arising from the decision (see PSED Guidance). Advise on the overall equality implications that should be taken into account in the final policy, considering relevance and impact.	No negative impact – full EHRIA not required

Appendix 5 – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY: Research & Development (R&I) Standard Operating Procedure (SOP) Grey Area Projects

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	
4.	**Ratification process**	Yes	
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Yes	
7.	**Associated documents**	Yes	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	No	Not applicable
10.	**Any other requirements of external bodies**	Yes	Subject to review by statutory regulatory authority
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	Yes	Subject to review by statutory regulatory authority

Appendix 6 – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Title of document:	R&I Standard Operating Procedure (SOP) – Grey Area Projects		
Version Number:	2.1		
Approval Date:	27.1.2017	**Dissemination lead:**	Dr Art Ationu
Previous document already being used?			
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	Electronic on Trust Website - SharePoint		
Proposed instructions regarding previous document:	To be archived		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (i.e. paper or electronic)**	**Comments:**
Trust wide	SharePoint	Electronic	

Author's Dissemination Record - to be Used Once Document is Approved – to be kept with the master document

Date document forwarded to be put on the Trust's central register / in Sharepoint:	**08.12.2016**	**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**