East Kent Hospitals University NHS
Foundation Trust

Standard Operating Procedure (SOP) – Developing a research protocol or proposal

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Ratified by:	Research & Innovation Committee
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Name of originator/author:	Dr Art Ationu, R&I Manager
Director responsible for implementation:	Dr Tim Doulton, R&I Director
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Review	*This document will be reviewed prior to review date if a legislative change or other event otherwise dictates.*

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Version Control Schedule

Version	Date	Author	Status	Comment
1	30.09.2012	Dr Art Ationu	Draft	
	10.04.2013	Dr Art Ationu	Draft	Incorporated comments from Dr Tim Doulton
	16.05.2013	Dr Art Ationu	Draft	Incorporated comments from Dr Tim Doulton
2	07.06.2016	Dr Art Ationu	Draft	Updated and revised
3	21.11.2016	Dr Art Ationu	Updated	
4	23.08.2018	Dr Art Ationu	Updated	

Contents

1. SOP Summary

All research studies undertaken within East Kent Hospitals University NHS Foundation Trust (EKHUFT) .comply with all relevant and applicable laws, such as the General Data Protection Regulation (GDPR) May 2018, the Human Tissue Act (2004), the mental capacity Act (2005) and adheres to the UK Policy framework for Health and Social Care Research (2018), and the Principles of (ICH) Good Clinical Practice (GCP). This includes having a clear protocol, which is a 'plan for engaging in systematic inquiry'.

2. Purpose and Scope

The purpose of this SOP is to provide guidelines for writing a research protocol for studies sponsored by EKHUFT. This SOP will not apply to Clinical Trials of Investigational Medicinal Products (CTIMPs) and multi-centre studies for which EKHUFT is not the sponsor as it is assumed protocols adhering to sponsor's requirements already exist. . The general principles set out here in this SOP m*ay be adapted* to suit any type of research study, including studies that require Health Research Authority (HRA) review.

3. Responsibilities

- The writing of a research protocol is the responsibility of the Chief Investigator (CI) or Principal Investigator (PI).
- It is recommended that the Investigator contacts the R&I Department at an early stage if planning to undertake a research study.
- The Investigator is advised to use a self-assessment decision tool http://www.hra-decisiontools.org.uk/research/ to ascertain whether their proposed study would need to be registered with the HRA.
- It is the responsibility of the CI or PI to ensure that the protocol will comply with all relevant applicable laws.

4. Recommended structure for research protocols

A research proposal or protocol will vary in format, but typically or most commonly cover:

- A title
- An introduction
- An overview of the relevant literature
- Aims & objectives or hypothesis
- An overview of the study design and methods
- Details of data collection and data analysis

The following is a suggested format for a protocol:

4.1 Title

The title should be short and uniquely identifies the study.

4.2 Principle Investigator and significant co-investigators

Should be listed. Contact details (minimum: e-mail and internal phone number) should be provided for PI.

4.3 Abstract/Summary

Summarise the aims or objectives of the study and give a brief outline of the design and methods. If the proposal is to be circulated to patients or public for comment, a lay summary should also be included.

4.4 Background/Introduction

This section should provide an overview of the background to the research, including a critical review of the current knowledge or literature. Any gaps in the evidence should be identified as should the potential value of furthering knowledge in this field, such as theoretical or practice based applications of the potential research outcomes. An explanation of the reasons for undertaking the work could also be included in this section, ideally incorporating a reflective stance whereby the researcher(s) reflect upon their own reasons for undertaking the research and interest in the field.

4.5 Aims & Objectives

Outline broad objectives that should follow on from the identified gaps in the literature and rationale for the study. Where relevant, explicit hypotheses for investigation in the study should be stated.

4.6 Study Design & Methods

• Study Design. Consider what study design is most appropriate to answer your particular research question.
• Setting. Where will the research take place? Your study may take place in a number of different sites (multi-centred), or you may be visiting participants in their homes. You need to address any practical issues involved.
• Participants. Some information regarding your participants should be given, if possible. For example:
- describe the expected study population, including a rationale of why they are to be approached.
- describe the methods by which participants will be identified and recruited and what criteria will be used for deciding whether or not individuals are eligible to participate (i.e. inclusion & exclusion criteria).
- you should state your expected sample size, and provide some justification. Advice from the Trust's statistician may be required.
- issues such as the potential transferability of results to alternative populations should be considered

• Sampling methods. You will need to explain and justify what sampling methods you plan to use. Justifications may be framed in terms of gaining access to particular populations, or in terms of fit with the research design.
• Methods of data collection. What data will be collected, why and how it will

be collected. For example: if you are undertaking semi-structured interviews about a particular topic, the interview guide should be discussed, with information about how participants may be given freedom to discuss unforeseen issues of importance to them. If you are using any equipment, e.g. tape or video recorders, it should be clearly described.

4.7 Data Collection, Management & Analysis

Explain how the data will be collected and managed and who will have access to it. The method and approach to data analysis should also be discussed and may include the following points:
• Method of data recording (e.g. paper 'case report forms (CRF), electronic CRFs, direct entry into a database etc.
• Plan of analysis, including statistical methods to be used where appropriate
• Data analysis package (e.g. SPSS, Stata etc.)
• Planned presentation of the data, i.e. written reports, vignettes, etc

4.8 Study Plan

You may wish to include a study plan, showing a brief summary or flow chart of the order, site and timing of all study procedures. It may also be useful to include consent forms & participant information in appendices.

4.9 HRA Issues

It is your responsibility to ensure that you seek HRA approval for your proposal. If you are uncertain as to whether HRA review of your proposal is required, advice should be sought from EKHUFT R&I department in the first instance. You may be subsequently advised to approach the HRA for guidance using the weblink below http://www.hra.nhs.uk/research-community/applying-for-approvals/research-ethics-committee/

It is important to outline the methods by which the participant's interests will be safeguarded, for example how you will maintain confidentiality, take steps to anonymise participant data, minimize risk of harm to participants as a consequence of being involved in this study etc.

4.10 Resource Requirements

The resource implications to the host organisation and any other involved departments should be defined in this section. Costings (e.g. for research staff time, investigations, equipment, IT, stationary etc,) should be included in this section, along with detailed justifications of costings that refer back to the study design, plan etc.

4.11 Milestones

For a complex project, it may be helpful to include a timeline with significant milestones to be achieved along the way. For example: HRA approvals; recruitment

of first patient; mid-point of recruitment; recruitment of last patient; data analysis; dissemination of results etc.

4.12 Supervision

Where applicable (e.g. educational studies), the protocol should name the individual(s) who will supervise the research project and the intended arrangements for the supervision.

4.13 Dissemination & Outcome

How will the study's findings be made available? State how ard in what formatyou intend to publish or present the findings. Any implications for future practice and theoretical knowledge advancement should also be suggested.

4.14 Other

State whether there has been user involvement in design of the study, and whether user involvement will be incorporated as an ongoing aspect of the research.

If applicable, the proposal should clearly state who is sponsoring the research study and what interest they have in its outcome.

5. Key Stakeholders, Consultation, Approval and Ratification, Review and Revision Process

R&I SOPs will be overseen and ratified by the R&I Committee. SOP 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).

Key Stakeholders – Trust researchers and research teams, R&I staff, Service Support Department staff, and key stakeholders.

6. Dissemination and implementation

Once authorised the SOP will be distributed in accordance with Dissemination Plan (Appendix).

7. Document control and archiving

SOP will be stored and accessible in SharePoint and superseded SOPs archived for at least fifteen years.

8. Monitoring SOP Compliance

Internal review and audit by R&I staff.

9. Abbreviations

CRF	Case report form
CTIMP	Clinical Trial of Investigational Medicinal Product
EKHUFT	East Kent Hospitals University NHS Foundation Trust
GAP	Grey Area Project
GDPR	General Data Protection Regulation
HRA	Health Research Authority
REC	Research Ethics Committee
SOP	Standard Operating Procedure

10. Appendices

Appendix A: Equality Impact Assessment
Appendix C: Author's Checklist of Content
Appendix D: Plan for Dissemination of Policies

Appendix A - 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 – Developing a research protocol or proposal
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 developing a research proposal or protocol and applies to all staff
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 B – Author's Checklist of compliance with the Policy for the Innovation and Management of Organisation Wide Policies and Other Procedural Documents

POLICY: Research & Innovation (R&I) Standard Operating Procedure (SOP) Archiving for Research Study documents post Trial

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

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Appendix C – Plan for Dissemination of Policies

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

Acknowledgement: University Hospitals of Leicester NHS Trust (Amended)

Title of document:	R&I Standard Operating Procedure (SOP) – Developing a research protocol or proposal		
Version Number:			
Approval Date:		**Dissemination lead:**	
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:		**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:**