STANDARD OPERATING PROCEDURE FOR THE PROCESS OF LOCAL MANAGEMENT REVIEW AND APPROVAL OF ALL RESEARCH UNDERTAKEN IN NHS FIFE

SOP NUMBER:	**Fife R&D SOP 11**
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1. PURPOSE

This document describes the process of local management review and approval for all research conducted in NHS Fife and complies with the principles of Good Clinical Practice (GCP).

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Department via fife-uhb.randd@nhs.net

2. APPLICABILITY

This SOP applies to all staff involved in reviewing applications for proposed research seeking Local Management Approval.

3. POLICY

3.1 Researchers wishing to conduct research in the NHS Fife must obtain Local Management Approval (LMA). The Local Management Review must be completed and the appropriate approval letters/contracts signed before any data collection/research activity can take place within NHS Fife.

3.2 Please note that this Local Management Approval relates to the role of NHS Fife in hosting research, i.e. recruiting participants or conducting interventions. NHS Fife may also Sponsor research, for example where NHS Fife is the employer of the Chief Investigator (see R&D SOP06 - Sponsor Agreement for Research Projects Involving Humans, their Tissue and/or Data).

4. PROCEDURE

4.1 The NHS Fife R&D office will normally be informed of a proposed study by the Chief Investigator (CI), local Principal Investigator (PI) being invited to join the study, R&D Research nurse, commercial company carrying out the study, study co-ordinator/Sponsor or by NHS Research Scotland Permissions Coordinating Centre (NRSPCC) making the study documentation available via the Scottish Research Database Application (SReDA).

4.2 For multi-centre studies, although discussions about the study may start earlier, the formal review process can only commence in NHS Fife once the appropriate documentation has been accepted on SReDA by the NHS Fife R&D Approvals Team.

4.3 Where a project is single centre the study record will normally not be initiated on SReDA by NRSPCC and instead must be added by the R&D Approvals Team.

4.4 The R&D Approvals Team must record details of the project on the Study Approvals Tracker (S:\Research\PROJECTS\STUDY TRACKING) and allocate a local Project ID (next sequential local R&D approval number).

4.5 On receipt of the localised Organisation Information Document (OID) and Schedule of Events (SoE)/ Schedule of Events Cost Attribution Template (SoECAT), and following completion of Generic Review (for multi-centre studies), the R&D Approvals Team must collate, review and check all the documentation to identify any site specific issues prior to issue of Local Management Approval of the study. Although a complete document set does not have to be provided immediately, **approval cannot be granted** until all appropriate documents are in place.

4.6 In most cases the Sponsor and Generic Reviewer will have confirmed whether the study is a Clinical Trial of Investigational Medicinal Product (CTIMP). In the case of any uncertainty the MHRA algorithm should be used to determine the study type (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf).

4.7 The R&D Approvals Team must send a Principal Investigator Responsibilities Form (Doc Ref 11-02) or Chief Investigator Responsibilities Form (Doc Ref 11-03) electronically to the PI or CI with instructions to read, and if in agreement, to sign two copies, returning one copy to the R&D Approvals Team. The returned form must be retained within the R&D study file. The second copy must be retained by the PI or CI and filed in the Investigator Site File/Study Master File.

4.8 The Approvals Team must conduct a Risk Assessment of the study and complete Risk Assessment Form (Doc Ref 11-04).

For NHS Fife sponsored studies a more detailed Risk Assessment may be required (see R&D SOP07 - Assessment of Risk Associated with Research Studies Sponsored by NHS Fife).

4.9 The R&D Approvals Team must carry out the required checks on the supplied documents, complete Doc Ref 11-05 - Checklist for Local Management Approval of New Studies and complete the appropriate Project Workflows in EDGE.

4.10 For multi-centre studies, any questions relating to the study documentation must be referred to the NRSPCC office (Nhsg.nrspcc@nhs.net or the Generic Reviewer rather than directly to the CI/study centre.

4.11 The R&D Approvals Team must be satisfied that all paperwork is in place, up to date and complete; that all questions concerning the conduct, cost and other implications of

the study have been answered; that any contracts contain appropriate provisions and that overall there are sufficient safeguards to protect NHS Fife, its patients and staff.

4.12 Once all required checks have been completed, the R&D Approvals Team, must forward copies of the OID and SoE/SoECAT, Patient Information Sheet and Informed Consent Form and completed Risk Assessment Form to the Assistant R&D Director for review.

4.13 If the Assistant R&D Director confirms that the Risk Assessment score is low (and there are no other concerns) then the Risk Assessment Form must be signed off by the Assistant R&D Director and no further review will be required.

4.14 If the Assistant R&D Director confirms that the Risk Assessment score is medium (and there are no other concerns) then the Risk Assessment Form must be signed off by the Assistant R&D Director and forwarded by the R&D Approvals Team to the R&D Quality & Performance Lead and R&D Lead Research Nurse for assessment of the QCC requirements.

4.15 Where the Risk Assessment score is high, the Risk Assessment must be reviewed jointly by the Assistant R&D Director, R&D Lead Nurse, R&D Quality & Performance Lead and R&D Research Coordinator to review the risk mitigation and determine whether the study can safely be approved to run in NHS Fife. Any outstanding concerns which cannot be dealt with by this group must be referred to the Medical Director, appropriate Support Department or the CLO.

If it is agreed that the study can be approved then the Risk Assessment Form must be finalised and signed off by the Assistant R&D Director and forwarded by the R&D Approvals Team to the R&D Quality & Performance Lead and R&D Lead Research Nurse for assessment of the QCC requirements.

4.16 Following a review of the completed Risk Assessment Form by the R&D Quality & Performance Lead and the R&D Lead Research Nurse, the R&D Quality & Performance Lead must update the form with the agreed QCC requirements and add the details of the QCC requirements to the QCC Log held in S:\Research\QUALITY ASSURANCE\QA LOGS (See R&D SOP48).

4.17 Once all the study documentation is in place and all queries have been resolved, the finalised Risk Assessment Form (with the agreed QCC requirements included), an approval memo and relevant study documentation submission checklist must be reviewed and signed off by the Assistant R&D Director (or the R&D Research Coordinator in their absence).

4.18 An approval letter, addressed to the PI (cc'd to the CI, Study Co-ordinator, Research Nurse, Pharmacy, Student Supervisor and others as appropriate) must then be prepared by the R&D Approvals Team.

4.19 For Non-CTIMP studies with no associated contract/agreement, the Local Management Approval Letter can be signed by the Assistant R&D Director. For all other studies the Local Management Approval letter and, where required, contracts/ agreements studies must be signed by the Medical Director/delegate.

4.20 Letters of Access must be issued by the R&D Approvals Team, if required, once Local Management Approval has been granted. Honorary Research Contracts must be issued from Human Resources via R&D.

4.21 Signed hard copy documents must be scanned, the file allocated the appropriate study number and document title and stored in the electronic file for the study (S:\Research\PROJECTS\PROJECT DOCUMENTATION\SReDA STUDY FOLDERS) prior to emailing (or posting if required).

4.22 The R&D Approvals Team must track the progress of the Local Management Approval Process using Doc ref 11-05 – Checklist for Local Management Approval of New Studies and via the Approvals Workflow in EDGE. The completed checklist will be saved in the study specific folder in S:\Research\PROJECTS\2 PROJECT DOCUMENTATION\SReDA STUDY FOLDERS.

4.23 The local review clock on SReDA must be started and stopped as per NRS-GUI-001 - Guidance for NRS Clocks (available from the Document Store on SReDA).

4.24 Except where there are unusual issues or problems with the set up of a study, Local Management Approval will be given within 15 calendar days of the receipt of a complete and valid document set. The local review clock can be temporarily stopped only in particular circumstances (see NRS-GUI-001 - Guidance for NRS Clocks).

4.25 The SReDA record for the study must be checked to ensure that the minimum dataset has been recorded (see NRS-GUI-003-SReDA Minimum dataset, available from the Document Store on SReDA). Reminders will be set up for the collection of updates on time limited documents such as GCP training by the R&D Support Officer.

4.26 Where NHS Fife is the lead for an 'eligibly' funded study, the R&D Research Coordinator will liaise with the CI and, where required, the R&D Approvals Assistant will arrange for the study to be initialised on the Central Portfolio Management System (https://cpms.nihr.ac.uk/). The CI will also be made aware of the requirement for uploading of monthly recruitment data.

4.27 When a study is subject to an amendment (either substantial or non-substantial), this may require further Local Management Approval (See R&D SOP40 – Local Management Review of Amendments to Studies).

4.28 The SReDA record for the study is considered to be the R&D file for that project, although there will be an electronic record in S:\Research\PROJECTS\2 PROJECT DOCUMENTATION and potentially also a hard copy folder with some study documents. Both the electronic and hard copy folders should reflect the organisation of documents in SReDA.

4.29 At the end of the study, all hard copy documents can be scanned and discarded (with the exception of wet ink signed contracts/agreements). All scanned and electronic documents can then be uploaded to SReDA and any duplicate documents in the study folder in the shared 'Research' drive can be deleted.

5. ASSOCIATED DOCUMENTS

Doc Ref 11-02 - Principal Investigator Responsibilities Form
Doc Ref 11-03 - Chief Investigator Responsibilities Form
Doc Ref 11-04 - Hosted Study Risk Assessment Form
Doc Ref 11-05 - Checklist for Local Management Approval of New Studies
R&D SOP06 - Sponsor Agreement for Research Projects Involving Humans, their Tissue and/or Data
R&D SOP07 - Assessment of Risk Associated With Research Studies Sponsored By NHS Fife
R&D SOP40 - Local Management Review of Amendments to Studies
R&D SOP48 - Quality Control Checking of NHS Fife Hosted Studies
NRS-GUI-001 - Guidance for NRS Clocks
NRS-GUI-003 - SReDA Minimum dataset

6. ABBREVIATIONS

CI - Chief Investigator
CLO - Central Legal Office
CTIMP - Clinical Trial of Investigational Medicinal Product
GCP - Good Clinical Practice
IRAS - Integrated Research Application System
mCTA - Model Clinical Trial Agreement
MHRA - Medicines and Healthcare products Regulatory Agency
NRSPCC - NHS Research Scotland Permissions Coordinating Centre
OID - Organisation Information Document
PBPP - Patient Public Benefit And Privacy Panel For Health & Social Care
PI - Principal Investigator
REC - Research Ethics Committee
SoE - Schedule of Events
SoECAT - Schedule of Events Cost Attribution Template
SOP - Standard Operating Procedure
SReDA - Scottish Research Database Application (https://www.reda.org.uk/.)

7. REFERENCES

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/.

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	31/10/2014	N/A – new SOP
2	Julie Aitken R&D Trials Facilitator	09/11/2017	Amended for consistency with NHS Fife SOP template. Amended to reflect current practice.

3	Aileen Yell R&D Research Coordinator	04/08/2020	Amended for consistency with R&D SOP template. Amended to reflect current practice - SSI replaced by OID and requirement for SoE and SoECAT added. Details regarding the process of Risk Assessment for hosted studies have been added. Doc Ref 11-01 has been withdrawn and new associated documents Doc Ref 11-04 and Doc Ref 11-05 have been added. Text refreshed throughout for clarity.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	23 July 2020