

## STANDARD OPERATING PROCEDURE FOR DISTINGUISHING 'RESEARCH' FROM AUDIT, SERVICE EVALUATION AND NEEDS ASSESSMENT

<b>SOP NUMBER:</b>	<b>Fife R&amp;D SOP02</b>
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### 1. PURPOSE

This document describes the procedure for distinguishing 'research' from audit, service evaluation and needs assessment.

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 StaffLink, the R&D section of the NHS Fife website ([www.nhsfife.org/research](http://www.nhsfife.org/research)) and EDGE (<https://www.edge.nhs.uk>). For guidance, contact the R&D Department via [fife.randd@nhs.scot](mailto:fife.randd@nhs.scot)

### 2. APPLICABILITY

This SOP applies to all staff applying to conduct clinical research in NHS Fife and all NHS Fife R&D Department staff involved in providing guidance to applicants and/or reviewing applications for NHS Fife Sponsorship or Local Management Approval.

### 3. POLICY

3.1 Research activity is subject to the requirements of the UK Policy Framework for Health and Social Care (2017). Audit, Service Evaluation and Needs Assessment are not covered under this framework but are elements of clinical effectiveness more appropriately managed through Quality Improvement (QI) systems. 'Grey areas' exist so the distinction between these activities can be blurred.

#### 3.2 Guidance

##### 3.2.1 Definitions from Health Research Authority (HRA):

- Research is "the attempt to derive generalisable or transferable new knowledge, to answer questions with scientifically sound methods"
- Audit is "designed and conducted to produce information to inform delivery of best care"
- Service Evaluation is "designed and conducted solely to define or judge current care"
- Needs Assessment (Usual Practice) is "designed to investigate the health issues in a population in order to improve population health"

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Please visit [www.nhsfife.org/research](http://www.nhsfife.org/research) to guarantee adherence to the latest version of this SOP.

- 3.2.2 A decision tool to help decide whether or not a study is research is available via the HRA website at: <http://www.hra-decisiontools.org.uk/research/>.
- 3.2.3 NHS Fife R&D Approvals Team, in conjunction with the NHS Fife Clinical Effectiveness Team ([Fife.clinicaleffectivenesssteam@nhs.scot](mailto:Fife.clinicaleffectivenesssteam@nhs.scot)) will make the final decision about how projects are defined and advise accordingly.

## 4. PROCEDURE

### 4.1 Research

- 4.1.1 Research projects must be registered with the NHS Fife R&D Approvals Team. The R&D Approvals Team ([fife.fiferesearchapprovals@nhs.scot](mailto:fife.fiferesearchapprovals@nhs.scot)) can provide guidance on the application process for Sponsorship and Local R&D Management Review and Approval.
- 4.1.2 If a project is considered to be research and involves NHS patients, their data or tissue it will normally require review by an NHS Research Ethics Committee (REC).

Research projects involving NHS staff recruited as research participants by virtue of their professional role do not usually require review by an NHS REC unless there are specific ethical concerns but do still require Local Management Approval.

A decision tool to help decide if REC Approval is required is available via the HRA website at: <http://www.hra-decisiontools.org.uk/ethics/>

- 4.1.3 If in doubt, further advice can be obtained via the East of Scotland Research Ethics Service (EoSRES) at: <https://www.nhstayside.scot.nhs.uk/OurServicesA-Z/EastofScotlandResearchEthicsService/index.htm> or by emailing the Ethics Service: [tay.ethicshelpline@nhs.scot](mailto:tay.ethicshelpline@nhs.scot)

### 4.2 Audit, Service Evaluation and Needs Assessment

- 4.2.1 If the project is considered to be either Audit, Service Evaluation or Needs Assessment then this must be registered as a Quality Improvement Initiative on the NHS Fife Quality Improvement Register.
- 4.2.2 Further information and guidance on registering these projects is available from the NHS Fife Clinical Effectiveness Team ([Fife.clinicaleffectivenesssteam@nhs.scot](mailto:Fife.clinicaleffectivenesssteam@nhs.scot)).
- 4.2.3 Audit, Service Evaluation and Needs Assessment do not require review by an NHS Ethics Committee, however, any of these activities may raise ethical issues and, if in doubt, advice must be sought from the East of Scotland Research Ethics Service: [tay.ethicshelpline@nhs.scot](mailto:tay.ethicshelpline@nhs.scot)

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## 5. REFERENCES

UK Policy Framework for Health and Social Care Research (2017)

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

HRA Decision Tool

<http://www.hra-decisiontools.org.uk/research/>.

## 6. ABBREVIATIONS

EoSRES	East of Scotland Research Ethics Service
HRA	Health Research Authority
QI	Quality Improvement
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure

## 7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of editions made:
1	Dr David Chinn Senior R&D Research Advisor	01/10/2012	New
2	Julie Aitken, R&D Trials Facilitator  Dr Allyson Bailey, Commercial Research Manager	31/10/2014	Title amended Footer amended to remove reference to TASC Doc Ref 001.  Minor editing for clarity
3	Aileen Yell R&D Approvals Coordinator	16/04/2021	Fife R&D SOP02 was withdrawn after Version 2 and re-issued as WI34. WI34 version 1 has now been updated and re-issued SOP02 Version 3.  Definitions updated to correspond with HRA Decision Tool.  Email addresses updated throughout.

## 8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife  Signature: 	15 April 2021

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