STANDARD OPERATING PROCEDURE FOR WRITING A RESEARCH PROTOCOL

SOP NUMBER:	**Fife R&D SOP 05**
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1. PURPOSE

This document describes the procedure for writing a research protocol to the standards of Good Clinical Practice (GCP).

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

2. APPLICABILITY

This SOP applies to all staff involved in writing a research protocol where NHS Fife is the study sponsor.

3. POLICY

3.1 A research protocol is the document that outlines the plan for a study and must be designed to safeguard the health and safety of research participants, as well as detailing the research methods being used to answer specific research question(s).

3.2 All research studies sponsored by NHS Fife require a study protocol and this must incorporate the principles of GCP.

3.3 The content and detail of the protocol will vary depending on the type of study to be undertaken, as will the supporting documentation.

3.4 All protocols must be submitted for Sponsor approval (see Fife R&D SOP06) via the NHS Fife R&D Research Approvals Team (fife.fiferesearchapprovals@nhs.scot) and thereafter for Research Ethics Committee (REC) review and NHS Fife Local Management Approval (See Fife R&D SOP11 and Fife SOP28).

3.5 For multi-site studies, REC and Local Management Approval must also be obtained for external NHS sites. All other necessary approvals must also be sought as appropriate.

4. PROCEDURE

4.1 General advice on writing a protocol and protocol templates can be found on the Heath Research Authority (HRA) website: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/.

4.2 Researchers undertaking a qualitative study are advised to use the HRA protocol template for qualitative studies available from the HRA

4.3 Researchers undertaking other studies are advised to adapt the HRA protocol template for Clinical Trials of an Investigational Medicinal Product (CTIMP) as the template is designed to be applicable to all studies. The template and notes are comprehensive, running to 71 pages at the time of writing. However, NHS Fife does not currently sponsor CTIMPs so many sections of the template are irrelevant and can be omitted. If using the template, the word 'trial' should first be replaced with 'study' and any numbers for trial registries, EudaCT or ISRCTN ignored. The following sections should be either omitted or carefully revised:

- Section 8 on drugs
- Section 9 on Pharmacovigilance
- Some appendices

Where appropriate, some information may be listed in other documents and then referenced in the protocol e.g. Data Management Plan or appendices describing Study Steering or Data Monitoring Committee remit and membership, if relevant.

4.4 The NHS Fife R&D Senior Research Advisers can offer advice and guidance about what will be required to be included or excluded in the protocol for a specific study. They can be contacted via: fife.randd@nhs.scot.

4.5 An introductory Study Guide (NHS Fife R&D Study Guide 02 - Writing a Research Protocol) is available with examples of some of the various protocol sections, including:

- Project title
- Abstract
- Background
- Aims and objectives
- Research questions
- Methods
- Analysis, data storage and security
- Ethical considerations
- Research governance
- Timetable
- Dissemination plan
- Costs
- Data Management Plan
- Appendices describing study Steering or Data Monitoring Committee remit and membership.
- References
- Summary
- Glossary

The Study Guide can be accessed via the R&D page on NHS Fife Stafflink.

4.6 All protocols must be version controlled and the study title, version number, date included on all pages (see Fife R&D WI37).

4.7 The Protocol Signature page must be signed by the Chief Investigator (CI), the Sponsor representative and any other appropriate study staff e.g. Statistician, prior to distribution.

4.8 Any planned amendments to the study protocol must be submitted, in the first instance, to the Sponsor for review (See Fife R&D SOP20), via the R&D Approvals Team (fife.fiferesearchapprovals@nhs.scot).

5. ASSOCIATED DOCUMENTS

Fife R&D SOP06 - Sponsor Agreement for Research Projects Involving Humans, Their Tissue and/or Data

Fife R&D SOP11 - Local Management Review and Approval of all Research Undertaken in NHS Fife

Fife R&D SOP20 – Management of Amendments to Studies Sponsored by NHS Fife

Fife R&D SOP28 - Setting up Studies Sponsored by NHS Fife

Fife R&D WI37 - Version Control of Clinical Research Study Documentation

R&D Study Guide 02 - Writing a Research Protocol.

6. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure (SOP)

7. REFERENCES

Heath Research Authority website
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

https://www.who.int/ethics/review-committee/format-research-protocol/en/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6172884/

https://www.research.yorkhospitals.nhs.uk/for-researchers/planning-your-own-research-project/.

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	31 Oct 2014	New - adapted from TASC SOP 14, Version 4.0
2	David Chinn R&D Senior Research Advisor	26 Oct 2020	Between versions 1 and 2 this SOP was withdrawn and re-issued as WI36. WI36 has now been withdrawn. Format updated for consistency with R&D SOP template. Contact details for R&D Research Approvals Team and R&D Senior Research Advisors updated throughout. Information relating to the writing of a protocol for CTIMPs deleted. Associated protocol templates removed and reference to HRA templates added. Details of associated NHS Fife R&D SOPs and WI updated.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	26 Oct 2020