STANDARD OPERATING PROCEDURE FOR ASSESSMENT OF RISK ASSOCIATED WITH RESEARCH STUDIES SPONSORED BY NHS FIFE

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1.0	Julie Aitken	N/A	New

1. PURPOSE

This document describes the process followed by the NHS Fife Research & Development (R&D) Department when completing a Sponsor review and, where required, a Sponsor Risk Assessment and corresponding Mitigation Plan.

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 Sponsorship by NHS Fife.

3. POLICY

3.1 The Risk Assessment process for research studies applying for Sponsorship by NHS Fife ensures that the R&D Department has completed a comprehensive review of the research application and has identified appropriate actions to mitigate any identified risks, prior to providing an “in principle” decision to Sponsor the Study.

3.2 The Risk Assessment is dependent on the study team’s level of experience and the capabilities of NHS Fife e.g. a high risk study by an experienced research team may be addressed by routine management processes, whereas a low risk study by an inexperienced research team may require additional management actions to mitigate potential risk.

3.3 The Risk Assessment is also dependent on the current circumstances in NHS Fife at that particular time, e.g. whether key resources or staff are available or unavailable when the study is expected to be delivered.

4. Sponsor Review and Risk Assessment

3.1 The R&D Research Coordinator must consult the Risk Assessment Decision Flow Chart (Appendix 1) to identify if a risk assessment is required as part of the Sponsor Review Process (See SOP06(Fife) - Sponsor Agreement For Research Projects Involving Humans, Their Tissue and/or Data), and document the decision(Doc Ref 07-01).

3.2 In cases of research requiring a Risk Assessment, the process will be started by the R&D Research Coordinator who will liaise with the Chief Investigtor (CI), research team members and service managers as appropriate to complete the Risk Assessment Form (Doc Ref 07-02) to assess the potential risks associated with the specific research application.

3.3 The Risk Assessment Form considers the following areas of risk for NHS Fife from the perspective of a research Sponsor:

- Clinical Trial of Investigational Medicinal Product
- Device study
- Participants rights and safety
- Facilities, Equipment and Resources
- Study Design and Reliability of Results
- Documentation, Governance and Compliance

Each area has a set of specific questions. The answers will be subject to a likelihood (Low, Medium and High) score. Mitigation strategies should be documented to address all concerns identified.

3.4 A meeting between the CI, members of the study team, and service managers as appropriate is a mandatory requirement. The purpose of this face to face meeting is to discuss the Risk Assessment in detail, and to talk through any mitigation plans. This will be followed up by email summarising the outcome of the meeting, and further discussions may be conducted via email or telephone.

3.5 The Risk Assessment Form will be updated as risk mitigation is completed, and will be revisited during the life cycle of the study if any material changes are made to the study documentation, staffing or operational circumstances.

3.6 The completed Risk Assessment Form will be reviewed by the Assistant R&D Director and Medical Director to assess the mitigation decisions for any study that has high likelihood risk scores or any issues identified during the initial risk assessment. In some cases, the Assistant R&D Director and Medical Director may decide that the risk to NHS Fife as Sponsor is too high and in these cases, Sponsorship will be refused.

3.7 The Risk Assessment process will be used to inform the Monitoring Plan (See SOP 30(Fife) – Monitoring Research.

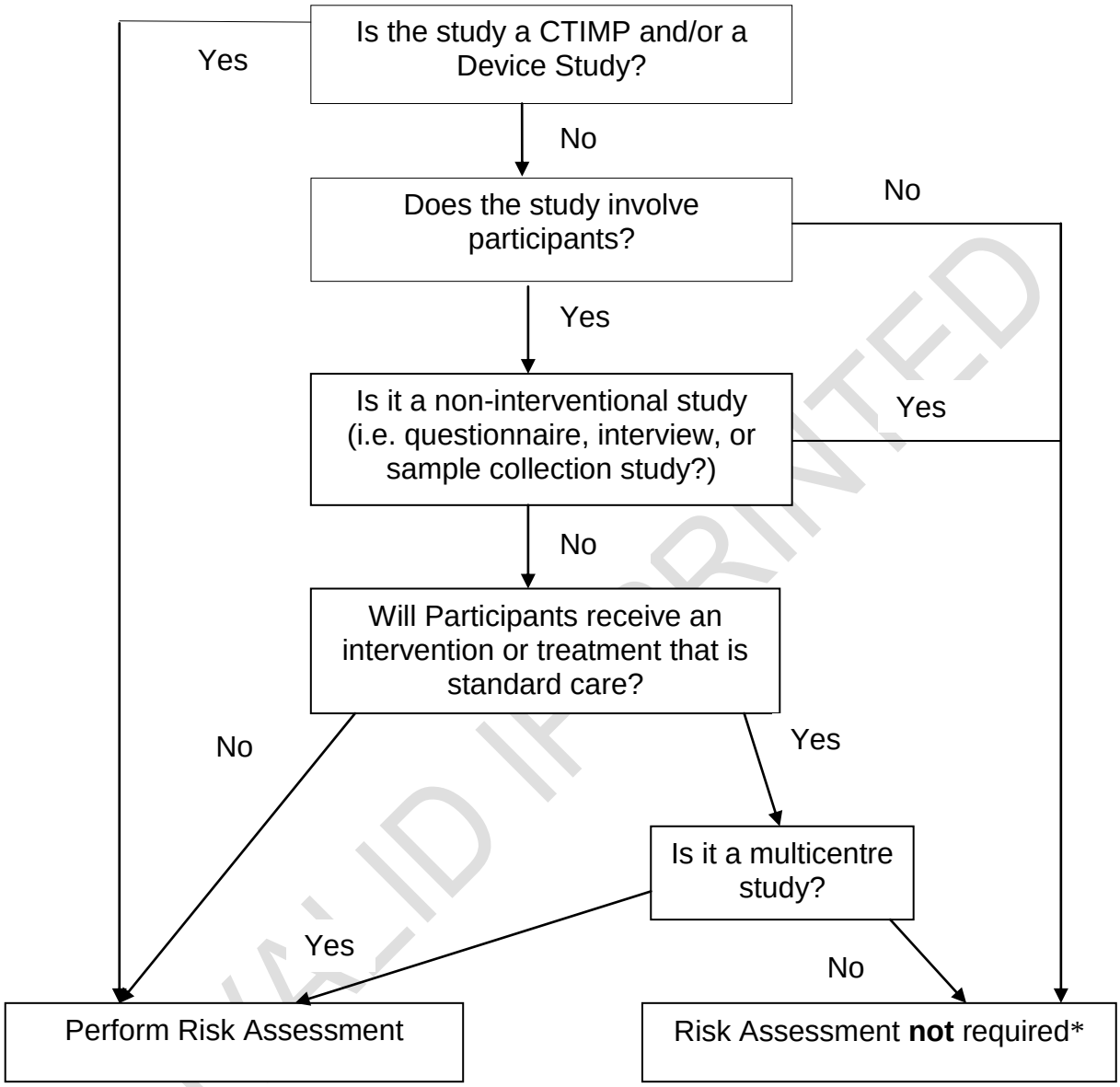
4. ASSOCIATED DOCUMENTS

Doc Ref 07-01 - Risk Assessment Decision Flow Chart
Doc Ref 07-02 - Risk Assessment Form
See SOP06(Fife) - Sponsor Agreement For Research Projects Involving Humans, Their Tissue and/or Data.
See SOP 30(Fife) - Monitoring Research

5. ABBREVIATIONS

CI	Chief Investigator
R&D	Research and Development

Appendix 1
Risk Assessment Decision Flow Chart



**In cases where for organisational reasons it is appropriate to risk assess a study (e.g. new research teams, facilities etc.), the Sponsor may decide to to undertake a Risk Assessment.*