York Foundation Trust R&D Unit Guidance Document R&D/G05



R&D Unit Research Adviser Services

IT IS THE RESPONSIBILITY OF <u>ALL</u> USERS OF THIS GUIDANCE DOCUMENT TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-quidance-/ and/or Q-Pulse

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Name/Position:

Approved by:

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Date: 24th June 2019

This document will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

1.0 2.0	Date Implemented 17 th October 2011	Details of significant changes
	5 th June 2017	Change of Author. Removal of references to
		the North and East Yorkshire R&D Alliance.
3.0	22 nd July 2019	Change to link for R&D website.
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1 Purpose of Guidance

The purpose of this guidance document is to:

- clarify the basis on the Research Adviser in the R&D Unit may have different levels of involvement in specific research projects;
- o outline the subjects on which support can be provided.

2 Levels of Involvement

2.1 Advice

The Research Adviser is available to provide advice on planned or ongoing research to all members of staff in the Trust. This may include participation in discussions between Trust staff and research collaborators in other NHS or academic organisations.

The services of the Research Adviser may also be used:

- 1. By staff in non-Trust organisations that have contracted to use the services of the R&D Unit;
- 2. By anyone needing information about research management and governance in the Trust.

Where the (proposed) research is being carried out by a Trust staff member *in connection with an educational qualification* the following points should be borne in mind:

- Educational institutions are expected to take responsibility as sponsors for all research conducted in the Trust by their registered students, including those who are members of Trust staff. This sponsorship responsibility includes assuring protocol quality, providing statistical and methodological guidance and supervising conduct of the research.
- 2. It follows that, while R&D Unit Research Adviser may provide supplementary advice, particularly on regulatory aspects, the educational institution must retain primary responsibility. Students should always check with their academic supervisors that a Research Adviser's opinion does not conflict with the requirements for their course.

2.2 Active Assistance

The Research Adviser may support Trust staff by helping to draft documents of various kinds or setting up databases. However such assistance is given on the understanding that all study related documents remain under the ownership of the Principal / Chief Investigator. S/he must have full knowledge of the content of all study documents and regulatory applications and take responsibility for them.

The Research Adviser will not normally provide this type of assistance for Trust staff undertaking research in connection with educational qualifications,

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because students must produce their own work for assessment and provision of direct assistance might cause difficulty.

2.3 Collaboration

Occasionally it may be advantageous for a Research Adviser with expertise in a particular area to act as a full collaborator / research grant applicant. If a member of Trust staff would like a Research Adviser to have significant involvement in a study - for example significant contribution to drafting the research protocol, carrying out data analysis, writing the report or article – they should come to an explicit understanding about collaboration at an early stage. The Research Adviser has full discretion about whether to become a full member of a research team in this way, and will only do this where s/he has an academic contribution to make.

These collaboration agreements should include clear discussion of all relevant matters, including (but not limited to):

- 1. conflicts of interest (see R&D/G06 Conflicts of Interest in Research);
- expectations about how the work will be shared;
- 3. expectations about authorship of reports and articles.

When collaboration is being discussed the Research Adviser will give the member of staff copies of this Guidance and of R&D/G06.

3 Subject Scope

The Research Adviser is able to provide support at all stages of the research process including:

1. Developing research ideas and formulating research questions

 Identification, review and appraisal of the literature in order to ensure there is a good justification for the project.

2. Designing and planning the study

- Choosing a suitable study design for the research question;
- Choosing appropriate standardised research instruments and obtaining any necessary copyright approvals;
- Design of questionnaires, structured interview schedules, focus group topic guides and other forms of data collection tool where standard models do not exist or are unsuitable;
- Sample size calculations (referring to a statistician where appropriate);
- Planning the study and considering the resource implications;
- Identification of possible sources of project funding and completion of grant applications;
- Referral to other available sources of support.

3. Writing the research protocol and other study documents

 The structure, format and content of the research protocol, participant information leaflets and other study documentation.

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4. Applying for study approvals

The application process and documentation for an NHS ethics committee opinion, HRA approval, clinical trial authorisations and/or other regulatory approvals.

5. Analysing data

- Setting up data management and analysis files using the Statistical Package for the Social Sciences (SPSS) or other suitable statistical software:
- an continue to the continue to o Analysis and interpretation of research data (working with / referring to a statistician where appropriate).

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