SOP27: Standard Operating Procedure for Qualitative Components of Trials & other Rigorous Studies in Health & Social Care


Approved by WWORTH Joint Management Group (Ian Russell in chair)

Signature

Date 07 May 2014

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<td>Comments by HS</td>
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<tr>
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<td>21 Oct 2009</td>
<td>Approved in principle</td>
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<tr>
<td>1.1</td>
<td>23 Oct 2009</td>
<td>Minor amendments following ACS review</td>
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<td>23 May 2010</td>
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<td>21 Apr 2011</td>
<td>Amendments following JSOPG, FR &amp; MS</td>
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2 Glossary

The full Glossary is in Swansea University H drive/Documents/526-WWORTH/Development Group/Glossary.

3 Introduction

Standard Operating Procedures (SOPs) are succinct formal documents designed to achieve consistency in specified trial functions by specifying standard practice in performing those functions (GCP 1.55 & 5.1.1). While SOPs should cite relevant legislation & regulations, and key references & evidence, they need not expound theory. This document is the SOP for qualitative components of trials & other rigorous studies in health & social care of the West Wales Organisation for Rigorous Trials in Health (WWORTH).

WWORTH SOPs should accord with all relevant regulations, including the European Union Clinical Trial Directive, ICH Good Clinical Practice (GCP) and the current NHS Research Governance Framework. They will seek to distinguish between regulations for CTIMPs and for other research.

Qualitative research provides an in-depth understanding of human behaviour, human action and human interaction and the reasons governing this behaviour, action and interaction \(^{(1)}\). As a result qualitative researchers are interested in the how and why, not only in the what, where and when and use smaller but more focused samples, to clarify social world data.

Qualitative research uses a variety of open ended data collection methods to provide an “in-depth understanding of human behaviour, human action and human interaction and the reasons governing this behaviour, action and interaction” \(^{(1)}\). As a result qualitative research explores not only the what, where and when but also the how and why, and generally includes data collection from smaller samples but in greater depth and with a less structured approach, to clarify social world data.

Qualitative approaches to data collection and analysis are increasingly being incorporated into trials to complement quantitative methods in a mixed methods approach. This SOP describes best practice in designing and carrying out qualitative components of trials & the roles, responsibilities and actions of individuals developing and approving SOPs. However, it does not give detailed information on different approaches to data collection and analysis, and expert advice should be sought in line with the needs of the particular study.
4 Purpose

To specify the process of designing, planning and reporting qualitative components of trials and to set best practice standards for carrying them out.

5 Roles & Responsibilities

The Chief Investigator (CI) is responsible for ensuring that this SOP is put into practice.

The Trial Qualitative Researcher (TQR), Trial Manager (TM) and Trial Data Manager (TDM) should assist with its planning and implementation if needed. There may be more than one qualitative researcher in the trial. Only one will have overall responsibility for the qualitative component of the trial, and others who are involved in the day to day running of it will report to that person.
6 Procedure

6.1 Qualitative Components in Trials Flow Chart

CI discusses research questions with Trial Qualitative Researcher to see if qualitative component needed, appropriate and feasible

Qualitative methods appropriate and feasible - research design planned with input from TQR, & service users with complementarity in mind at all times

Qualitative research questions (objectives) agreed between TQR, CI and TDG

Qualitative methods agreed - advice provided by TQR, agreed with CI and TDG

Complementarity of qualitative and quantitative objectives and methods assessed by TDG

Qualitative data analysis plan drafted by TQR, agreed by CI and TDG

TQR to draft full documentation of qualitative component in trial protocol to include: research questions (objectives); methods of data collection; plan of analysis; management arrangements; timetable/milestones; resources required

Undertake qualitative data collection and analyses

Report qualitative findings to TMG

TMG to consider qualitative and quantitative results together with advice from TQR and trial statistician and synthesise findings

TQR to write up (or supervise write up of) all aspects of qualitative component to include research questions/objectives; methods; findings; and to contribute to write up of synthesised interpretation in discussion and conclusions of trial report and main paper(s)

Papers related to qualitative component including findings and methods to be drafted by TQR or with advice/under supervision of TQR for submission to peer reviewed journals
6.2 Identifying the purpose of the qualitative component of the study

When the trial is designed and a qualitative component is proposed, it is important that a clear purpose for the qualitative component is identified and actioned right from the beginning with early expert involvement. This purpose might be one or more of the following:

- Developing research instruments or interventions for use during the course of the trial (qualitative component takes place at the beginning of the trial)
- Gathering complementary information which contributes to answering the main research question(s) in a way not covered by the outcome measures used in the quantitative component of the trial (qualitative component takes place in parallel with quantitative component)
- Seeking explanation for unexpected findings or unexplained associations (qualitative component takes place at the end of the trial)
- Developing or responding to a hypothesis (at appropriate stage)

If there is no clear purpose for a qualitative component to the trial, it should not be included. The complementarity of qualitative and quantitative methods should be considered to ascertain if a mixed methods approach is the most suited to the needs of the study.

In some cases, it may be appropriate to carry out a qualitative study complementary to, but independent of, the main trial.

MRC guidelines for developing and testing complex interventions should be considered when assessing the relevance and purpose of the design of any qualitative components\(^2\). Qualitative methods are particularly suited to the feasibility/piloting and evaluation phases of the research process.

6.3 Appointing a Trial Qualitative Researcher

At the time when the trial team is brought together to plan the trial, a TQR will be appointed. The TQR will have expertise in designing and managing qualitative research. (S)he will work under the overall direction of the CI, and his/her role would normally be equivalent to that of the senior statistician.

When a qualitative component is agreed to be relevant, and is to be
included in the trial design, the TQR will have input into the protocol design and will oversee all aspects of the qualitative component of the trial, with the support of the TM and other team members. In this case the TQR may be included as a co-applicant on the bid.

6.4 **Designing the qualitative component of the study**

The TQR takes responsibility for designing the qualitative component of the study, with input from other team members and service user representatives, and also takes responsibility for overseeing all work related to collection, management and analysis of qualitative data undertaken by researchers during the trial. The qualitative component should be described in detail in the trial protocol.

The qualitative component may use one or more established methods of data collection and analysis (e.g. semi-structured and unstructured interviews, focus groups, observation, and analysis of written data sources) to meet defined objectives. The trial protocol should give references for the use of the method chosen. A clear rationale should be set out for using the method chosen. If more than one method is to be used, the trial protocol should clearly describe why more than one method has been chosen, and how each will add to the study.

Consideration should be given to the inclusion of methodological objectives relating to the advancement of learning about qualitative or trial methodologies.

The trial protocol will set out the following details of the qualitative component of the research:

- Objectives/research questions for this component of the research
- Sampling strategy/process
- Sample size and justification with an explanation of any issues relating to sampling
- Research settings
- Methods for data collection
- Methods for data recording and management
- Methods for analysis
• Plan for synthesis of qualitative and quantitative findings

• Timescale for the qualitative component within the overall study

Once the qualitative research components have been identified, these must be verified against the trial protocol to ensure they are consistent with it, and agreed with the CI.

The TQR should provide advice related to resources and timescales required to complete the proposed qualitative components of the trial, and should agree costing and management arrangements with the CI.

6.5 Conducting the qualitative component of the study

The qualitative component of the research will be conducted in line with the following good practice principles:

Practical issues:

• Ethical approval must be in place and extended to cover fully informed consent to the use of recordings and verbatim quotation (see WWORTH SOP14 Ethical & Research Governance approval)

• Participants will be given an Information Sheet and asked to provide their informed consent in writing before the start of data collection (see WWORTH SOP05a Producing participant informed consent & WWORTH SOP05b Obtaining participant informed consent)

• Participants will be offered full out of pocket expenses (see WWORTH SOP09 User Inclusion)

• Participants may be offered an incentive (e.g. a gift voucher) to acknowledge their time and input

• If interviews or focus groups are conducted, they will normally be recorded and generally transcribed in full. This should be clearly indicated in the consent form with agreement to use direct quotes. Whichever research method or combination of methods is chosen, these should be piloted before use.

• Training of staff must be put in place to ensure as great a consistency of application of the data collection instruments as possible. Training notes and other interview guides must be prepared and verified by the TQR
Data storage, data handling and data labelling must be taken into consideration at the outset of each study (see WWORTH SOP22b Data Protection & Confidentiality).

Analysis:

- Analysis of qualitative data will be carried out in line with recognised good practice. To avoid research bias, at least two researchers should have input into analysis of all data(3)

- Field researchers carrying out qualitative data collection and analysis will have been appropriately trained.

- The PI or TQR should identify specific qualitative costs, which may include a computer analysis software package (e.g. NVIVO, Ethnograph, ATLAS ti) to support data management and analysis, if analysis is not being undertaken by hand.

- The PI or TQR should work with the CI to work out plans for the integration of qualitative and quantitative findings, but integration can only take place after quantitative data collection is complete and quantitative data are analysed.

Reporting:

- Participants should be provided with a lay summary as feedback at the end of the study, and should be offered the chance to have a copy of the main publication if they wish.

- No individual will be identifiable in transcripts, analysis, reports or research papers. Participants will be identified only by a code name or ID number.

### 6.6 Presentation of research findings

Findings from the qualitative arm of the study should be integrated into the main publication from the study, since the aim of a mixed methods study is to produce more learning than the findings from each component individually. The TQR is responsible for write up of qualitative findings, and will contribute to the integration of findings with those from the quantitative trial components, in consultation with the CI and research team. In addition, papers may be produced reporting aspects of the qualitative component of the study according to the trial publication plan, agreed by the TMG.
Researchers presenting qualitative data should be aware of the research review guidelines such as RATS\(^4\) for certain targeted journals (see for example BMJ requirements), and should take these into consideration at the planning stages.

### 6.7 Critical review

After each trial, WWORTH staff will evaluate strengths and weaknesses of the approach taken to qualitative components of the trial, and develop learning for future trials. Lessons learned will be included in future training and development and incorporated into SOP reviews where appropriate.

### 7 Training Plan

All WWORTH staff involved with trials must undertake the appropriate generic and trial-specific training to ensure that they meet with the specific employers' mandatory training requirements and the specific requirements of the trial. For example, for SU staff, all new employees must attend induction, fire and safety training (as well as role-specific training courses, e.g. laboratory safety). For new staff, additional training requirements should be identified alongside the specific role requirements and the WWORTH Unit Manager should make provision for the new staff member to attend the necessary courses as soon after appointment as is practicably possible.

It is the responsibility of the WWORTH Unit Manager (alongside the CI or TM) to identify all the SOPs that are relevant to a specific trial and in which the new member of staff should be trained. The WWORTH UM or the SOP author will provide group training for trial staff and/or one-to-one training, as required for new staff in relation to the specific SOPs identified. Training records should be filed both by the main employer and the staff member, in accordance with the specific employer requirements. Trial specific training should be filed in TMF or TSF as appropriate and every individual involved in a trial should have an individual training record (see WWORTH SOP02 Training).

Where the tasks specified in the individual SOPs are delegated to WWORTH staff, CIs/PIs or TMs, these delegated staff must ensure that they have attended a training course on GCP and keep up-to-date through attending refresher courses.

It is the responsibility of the CI/PI to ensure that all staff allocated duties on the study delegation log template of responsibilities are suitably trained in the activities linked to those duties (see WWORTH SOP16 Site Setup, Appendix 9 and Appendix 10).

Each trial should maintain a central training log and ensure that WWORTH has access to that log, not least to integrate the logs of staff who work on more
than one trial. Similarly trials should ensure that each site maintains a local training log, not least to integrate the logs of staff who work for more than one sponsor.

In principle, the trainer should be one of the authors of the write up of findings. Training will be in two stages. First training in the principles of the SOP will take place during monthly meetings of JSOPGs. Second training in using the SOP in practice will take the form of regular supervision by an experienced qualitative researcher, culminating in approval of the SOP. Both trainer and trainee will sign the log (Appendix 1) to confirm that training is complete. To help individual staff record training for the purpose of their Continuing Professional Development, and help individual trials and WWORTH record training for quality assurance, WWORTH will aggregate training logs by individual within trial. Training may be necessary, in some cases, for those service users involved in the qualitative element of a trial.

WWORTH should consider the possibility of employing a qualitative researcher who could work on all the different studies as required and be involved in the training process.

Research staff recruitment, training, and retention will aim to ensure that WWORTH has a sustainable and skilled team with the necessary qualitative research method expertise to deliver rigorous, consistent and appropriate qualitative evaluation alongside RCTs.

WWORTH should promote a policy of prioritising the extension of current staff contracts over the appointment of new staff in order to promote career planning, employment security and a critical mass of increasingly experienced staff. This means that research staff should be flexible and willing to move from one project to another. In addition, WWORTH will pursue sustainability through:

- Enhancing its national and international profile (e.g. promotional activities, networking, website, publications and presentations at relevant conferences).
- Seeking resources to enable research staff to undertake short courses (e.g. mixed method research alongside RCTs, qualitative research principles and good clinical practice).

### 8 References


9 Related SOPs

WWORTH SOP02 Training
WWORTH SOP05a Participant Informed Consent
WWORTH SOP5b Obtaining Participant Informed Consent
WWORTH SOP09 User Inclusion
WWORTH SOP14 Ethics Research Governance approval
WWORTH SOP22a Data Collection Management
WWORTH SOP08 Archiving
WWORTH SOP22b Data Protection & Confidentiality