Quality Assessment & Strengthening of Qualitative Research

An example protocol

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1 Notes on This Protocol

1.1 Background

This protocol offers guidelines for conducting quality assessment and strengthening of qualitative research, as part of a broader process of quality assurance of a qualitative research project. In recognition of the absences of consistent and established guidance on assuring quality of qualitative research, the authors have sought to develop guidelines that are applicable to qualitative research conducted within the global health research context, and potentially beyond. We regard quality assessment and strengthening as comprising one stage of a quality assurance strategy, and through which qualitative research teams are able to received feedback on their research practice and guidance on how to strengthen its quality as the project progresses.

1.2 Overview of quality assurance

Quality assessment and strengthening of qualitative research, as described in this protocol, reflects a specific conceptualisation of quality assurance in relation to the principles and methods of qualitative research. This approach to quality assurance comprises two key perspectives:

1. *A process-oriented perspective*: a series of mechanisms adopted throughout the research process to assure quality, guided by a set of key principles of 'good practice' for qualitative research;
2. *An output-oriented perspective*: adopting techniques that can demonstrate to an external audience that the quality of the research has been assured.

These two perspectives reflect the conclusions of a review which explored the discourse around quality and quality assurance in qualitative research literature (Reynolds, Kizito et al. 2011). This review recommended that guidance be developed that facilitates the qualitative researcher to enact principles of quality at each stage of the research process, but which also offers opportunities for researchers to demonstrate to external audiences the credibility of their research. The quality assessment and strengthening exercise outlined in this protocol provides an opportunity to address both perspectives in the quality assurance process, at the stage of research when study design and planning have been conducted, and research activities are underway.

1.3 Defining quality assessment and strengthening

For this protocol we define 'quality assessment and strengthening' (QAS) as a process of assessing, by an external team, to what extent a qualitative study is being conducted in accordance with identified principles of quality for qualitative research, and to provide feedback and support for

improving the quality of the study. This may occur one or more times during the research process, and involves various stages of collaboration and engagement between the research team and external assessors. The QAS approach has parallels with the practices of monitoring and auditing commonly conducted within clinical trials research, typically guided by the *Good Clinical Practice* (GCP) guidelines (European Medicines Agency 2002). However, we draw several distinctions between these practices and the QAS approach which reflect the difference between the objective, positivist perspective underpinning clinical research, and the subjective, interpretive perspective underpinning the vast majority of qualitative research. In particular, the QAS approach recognises that:

- Interpretations of what constitutes 'quality' in terms of methods in qualitative research are varied and debated, reflecting different epistemological perspectives, and therefore quality assessment must be tailored to a definition and criteria of quality appropriate to individual studies;
- The flexible and subjective nature of qualitative research means that a check-list approach to assessing quality, chiefly through examining study documentation, is not suitable or helpful. More collaborative and discursive methods should be adopted to better engage with research staff and understand how to improve practice.
- Assessments should be an opportunity for researchers to reflect on their own practice and interpretations, serving either to strengthen researchers' points of view or to open their mind to other possible interpretations.

1.4 How to use this protocol

In this protocol we present a framework for designing and conducting quality assessment and strengthening of qualitative research, as part of a broader quality assurance strategy. It aims to offer researchers a way to elicit external assessment of their research practice, as it is being conducted, to indicate where and how to strengthen quality. This process can be used to demonstrate to external audiences that the quality of the project has been assured.

This protocol should be viewed as a flexible and adaptable guide to conducting quality assessment and strengthening, and is designed to be developed by investigators as part of the strategy for quality assurance for their own research. Suggested definitions, criteria and methods for assessing quality have been presented, as well as suggested tools for capturing the assessment process. These should be viewed as templates only, to be tailored and adapted by researchers to be applicable to the epistemological and methodological approaches underpinning their specific qualitative study.

Under each section, background information on how the section fits with the QAS approach is presented in boxes, and is to help researchers understand the process of planning for QAS. It is likely that researchers will want to delete this text from their final versions of the protocol. The text in italics is given as examples of how each part of the protocol might be completed – this text should be modified to be applicable and appropriate to the specific qualitative research study.

2 Preparation

2.1 Aims and objectives of quality assessment and strengthening

> Here, you should present the overall aims and objectives of the QAS process, reflecting the opportunities QAS presents not only for gaining external assessment and feedback on research activities, but also for supporting reflexivity among the research team. The objectives should also draw attention to the collaborative approach of QAS, whereby the research team leaders and external assessors decide together the specific priorities of the assessment process.

2.1.1 Overall aims

For example:

- *To provide constructive feedback to research team on how the study is being conducted and ways in which they can improve;*
- *To offer support to the research team through opportunities for reflection;*
- *To provide research teams with an opportunity to demonstrate to external audiences that the research has undergone a systematic assessment of quality.*

2.1.2 Specific objectives

For example:

- *Assessors to consult with principal investigators and study team leaders, plus study protocol, to identify priorities for the QAS process, and to develop a plan and timescale for the assessment, feedback and acting on recommendations;*

- *Assessors to visit the study site to conduct assessment of the agreed research activities;*
- *Assessors to assess quality of research activities against the principles and criteria for quality identified in planning with the research team.*
- *Assessors to provide feedback to research team on activities assessed, findings, areas for improvement and conclusions.*
- *Research team to consider and act up recommendations where appropriate, within timescale identified in planning stage.*

2.2 Definition of principles of quality

It is important at the outset of the QAS process to define the principles of quality, or 'good practice', that are applicable to the epistemological and methodological orientation of your qualitative research, and which will underpin the entire assessment and strengthening process. As demonstrated through the literature review, the notion of a set of principles of 'good practice' emerged as a key basis for guiding quality assurance of qualitative research, and underpins the *process-oriented perspective*. Rather than a check-list of activities that must be performed through the research process in order to achieve high quality research, the principles of 'good practice' reflect the subjective, interpretive nature of qualitative research, and the flexibility and variability of its methods. As such, we suggest that principles offer a framework for what it means to do good qualitative research, without compromising its epistemological underpinnings through a fixed, rigid set of standards. Although principles of 'good practice' for qualitative research may be debated within and across qualitative paradigms, we offer a set of six as the framework by which we have developed this protocol for quality assessment and strengthening (presented in example text below).

For example:

To define the concept of 'quality' that will inform the planning of the assessment and strengthening process, and against which, the qualitative research activities will be assessed, we will draw on six

key principles of 'good practice' that we believe should underpin our qualitative research, and are appropriate to the epistemological and methodological orientation of this study. These principles are reflected in our broader strategy for quality assurance of this qualitative study. These principles are:

- ***Reflexivity*** *- the researcher reflects upon their position, assumptions, biases and considers the influence of these on the research process and outcomes and findings.*
- ***Transparency*** *- honesty in relation to the representation of the data, and open presentation of decision-making and interpretation throughout the research process.*
- ***Comprehensiveness*** *- pursuing ideas to the fullest possible, to capture the richest data available within the confines of the study and to explore a wide range of interpretations of the data.*
- ***Responsibility*** *- understanding the role of each research team member in producing good quality data, and recognizing each person's responsibility to ensure this happens.*
- ***Ethical practice*** *- conducting research in a manner that does not bring harm, discomfort or distress to participants and which follows the ethical codes of the institution(s) that have approved the study.*
- ***Systematic approach*** *- a methodical and logical process for outlining and achieving each stage of the research process, in order to answer the research question in the most appropriate way.*

3 Methodology

3.1 Quality assessment approach

Here you should describe and define the approach to be taken for assessing the quality of your qualitative research, to outline assumptions underpinning the QAS process about what 'quality' is and how it can be assessed. This can help to clarify your expectations for the QAS process and demonstrate how it is appropriate for the epistemological perspective underpinning your qualitative research study.

For example:

The approach to be used for assessing the quality of our qualitative research reflects the interpretivist epistemological perspective underpinning the qualitative study. This perspective assumes that the world cannot be objectively measured or known but knowledge is constructed through interaction and is interpreted through values and assumptions (Green and Thorogood 2004) . Hence, for assessing the quality of qualitative research, the approach proposed does not attempt to measure whether the way a study is being conducted is 'right' or 'wrong', or to search for errors in practice against 'objective criteria'. Instead, we propose that the approach should interpret the progress and practice of our study against a defined set of values, underpinned by principles of 'good practice', which reflect the epistemological and methodological approaches of the study.

We will propose a range of methods to explore and interpret quality in relation to indicators specific to different research activities, developed from the principles of good practice presented in 2.2 above. The methods for assessment will include opportunities for discussion between the assessors and members of the research team, to facilitate reflexivity on the part of the researchers in relation to their practice during the research study - the decisions they have made and their interpretations and assumptions. As such, the assessment process will be a supportive and constructive one.

3.2 Quality strengthening approach

Here you should describe and define the approach to be taken for considering, reflecting and acting on the findings from the quality assessment process, and any recommendations made by the assessors. It would also be helpful to outline how the strengthening approach reflects the epistemological and methodological underpinnings of the study.

For example:

The second stage of the QAS process – quality strengthening – will involve the consideration of, and possible acting on, the findings and recommendations of the assessors' report following the assessment. Reflecting the interpretivist perspective underpinning both the qualitative study and

assessment approach, the assessors' findings and recommendations will be viewed as interpretations of the research practice against the defined principles of good practice. As such, these interpretations may or may not be considered by the investigators to be appropriate to the specific study and its aims; the strengthening process should include critical reflection on these interpretations, but without obligation to act upon them. It will be emphasised to the assessors that feedback should be constructive, highlighting both the positive aspects of the research and those areas that need improvement, and should offer practical recommendations for strengthening. The assessors' final report and recommendations will be viewed as a framework around which discussions and reflections on the quality of research activities can be generated, and an action plan of changes to be made to be developed. As such, the assessment report is to be used as a tool in the quality strengthening process.

3.3 Selecting the assessors

Outlining the process for choosing and training the assessors in the QAS approach outlined in this protocol will help to clarify your expectations of those conducting the assessment, the desired experience and/or credentials held by the assessors, and whether QAS is part of a reciprocal quality assurance process, akin to 'co-monitoring'. You should state how many people will be asked to conduct the assessment, how they will be approached and the nature of any existing relationship between them and the research team / institution.

For example:

3.3.1 Identifying suitable assessors

We will approach a team of three social scientists working at a partner institution, xxx, who are experienced in conducting health research using qualitative methods. They have some familiarity with the topic and methods used in our qualitative study, and we have discussed previously with them the possibility of establishing a reciprocal process for supporting the quality assurance of each others' research studies.

3.3.2 Training assessors on the QAS approach

Prior to beginning the prioritisation and detailed planning of the assessment process, the assessment team will be informed and trained in the QAS approach, using this protocol as a guide. In particular the training will focus on:

- *Comprehension of core principles of good practice appropriate for this qualitative research study, the methodology and approach to quality assessment and strengthening.*
- *An overview to the aims, objectives, design and methods of the qualitative study.*
- *The specific aims, objectives and timing of the QAS process for this study.*
- *The specific stages of the QAS process, including planning (preparatory work, prioritisation, timetabling), study site visit, assessment methods, reporting and feedback, and the strengthening approach.*

4 Prioritisation and planning

4.1 Selecting research activities to be assessed

There are many different stages and activities involved in the qualitative research process, from the initial design of the research question and study through to writing up and dissemination, and ideally each of these stages should be conducted in line with principles of good practice appropriate to the study. There is a list of the main study stages presented in *Appendix A*. However, it is unrealistic and perhaps unnecessary to aim to have all stages of the qualitative research process assessed. Assessment of many stages at multiple time points is likely to be highly intrusive to the research process and may have unwelcome and unintended influences on the progress and outcomes of the research. Furthermore, it could be considered a waste of valuable resources to assess a study excessively. Therefore decisions must be

made as to which activities to focus on during the assessment visit.

In this section, you should describe how research activities will be selected and prioritised for assessment, and the factors on which the decisions will be made. One way to do this would be for both the research team / senior researchers and the assessment team to identify their priority research activities separately, and then compare, discuss and compromise to develop an assessment plan that incorporates both. You may wish to use a tool to help reconcile the different priorities of the research team and the assessors, if it is difficult to form a compromise.

For example:

To decide which research activities will be assessed during the assessment visit, a process of prioritisation will be done. Both the senior researchers and the assessment team will, separately, consider the possible research activities through consultation of the study protocol and documentation, and decide which activities they think are priorities for assessing and strengthening quality. The following factors are likely to be influential in this prioritisation:

4.1.1 Timing

The timing of different research activities is likely to be an important factor, both for considering which activities will be occurring at a convenient time for the assessment to take place, from the perspectives of both the assessors and the research team.

4.1.2 Access and geography

When prioritizing activities for assessment it is important to consider the distance to and between study sites, the ease of access to sites and access to documentation. There is also need to consider the proximity of study sites where activities scheduled for assessment on a particular day are being conducted.

4.1.3 Availability of research team

In order to minimise the potential disruption of the assessment visit on the running of research activities, it may be important to take into consideration if/when members of the research team responsible for different research activities (for example analysis) are available to spend time meeting with the assessors. This could affect which activities are assessed and/or when the

assessment takes place. In addition, the principal or more senior investigators may prefer to be present during the assessment visit, if they are not 'on site' full time.

4.1.4 Potential for benefit

Some stages of the research process are potentially more subject to researchers' biases than others, and a research team could benefit more from the opportunity to think reflexively about these stages, and to receive feedback on their practice through the assessment. For example, data collection and analysis may be considered priorities for quality assessment to offer opportunities to reflect on the assumptions underpinning interpretations, and to what extent these activities are being conducted systematically and comprehensively. In addition, members of the research team may have concerns or questions about strengthening quality of particular activities, based on their experiences in conducting the study, and may identify these as priorities for the assessment.

4.1.5 Integrating and finalising priorities

The integration and finalisation of priorities for assessment is likely to come through discussion between the assessors and senior investigators, with input from the research team. If it proves difficult to reconcile differing priorities in this way, an assessment prioritisation scoring tool (Appendix B) will be used to help select activities to be prioritised for assessment. The tool takes into consideration the PI's priorities for assessment, the assessor's priorities and feasibility in terms of cost and time. Scores ranging from 1 to 5 are assigned to each activity and the activities with the highest total scores should be considered as priorities over those with lower scores.

4.2 Planning the assessment visit

In this section you should outline the process for developing the timetable for the assessment visit, and how the assessors will prepare for the assessment. It will be important for the assessors to have time to familiarise themselves with the study in some detail before the visit, so should be sent copies of the study protocol and other relevant documents, with sufficient time before the visit takes place. During this time, the assessors should consult with the research team to develop a practical and feasible plan for the assessment visit, and to identify what resources (human, documentation, transport etc) the

assessors will need during that time. This will also help the research team plan to fit their own duties in and around the activities of the assessment. It might be helpful to develop a set of instructions or a standard operating procedure (SOP) to help the assessors and research team plan for the visit. An example SOP – *SOP 1: Planning Assessment Visit* – is presented in the appendices.

For example:

Following prioritisation of research activities for the QAS process, the timetable for conducting the assessment visit will be developed through consultation between the assessment team and senior investigators from the research team, guided by SOP 1: Planning Assessment Visit. As part of the preparation, the assessment team will be sent up-to-date versions of the study protocol and timetable of activities, no later than two weeks before the agreed start date of the assessment visit, so they can familiarise themselves with the study. The timetable for the assessment visit will accommodate both the prioritised research activities, and questions of logistics and timing relating to when and where assessment of particular activities can take place. This timetable will be shared among the research team, to ensure they are prepared and supported to accommodate the assessment visit activities in their day-to-day schedule. The timetable and record of resources needed for each part of the assessment will be recorded in the Assessment Visit Plan (see Appendix C).

5 Methods

5.1 Defining indicators of quality

Reflecting the principles of good practice defined at the outset of the QAS process, it is important to identify how quality will be assessed in relation to each research activity. Devising a set of indicators specific to each research activity can help assessors understand what it is they are looking for and what quality might 'look like' in the study in question.

These indicators should be reflective of the underlying principles of good practice. It is likely that the senior investigators will draft a set of indicators of quality for each of the prioritised research activities, and will then share this and consult with the assessors prior to the assessment visit to finalise the indicators. It should be emphasised that the indicators are not to be seen as a prescriptive, tick-box approach to assessing quality, but more a suggested guide of what the assessors should look for and ask about during their assessment.

For example:

Taking the principles of good practice as an overall framework for guiding the assessment, we will develop a set of indicators of quality for each of the research activities identified as a priority for the QAS process. These indicators will reflect the principles outlined in section 2.2, and will be presented as a suggested set of prompts for the assessors, to guide what they will ask and look for when assessing each activity, rather than as a prescriptive checklist of standards. A draft set of indicators will be shared with the assessment team prior to the visit to elicit feedback, and any revisions will be made and finalised before the visit start date. Appendix D presents definitions of quality and indicators for it can be assessed for different research activities.

5.2 Methods for assessment

There are several different methods that could be employed for assessing the quality of different research activities, and it is likely that a combination of two or more may be the most appropriate approach for assessing any one given activity. The methods selected should be appropriate for the underlying principles of good practice, as well as the epistemological and methodological perspectives of the study. It is recommended that discussion with the research team members is used as much as possible as well as other methods, as it reflects the interactive, supportive assessment approach outlined in this guide.

Discussion will provide an opportunity for research team members to reflect on their practice, and will enable assessors to explore in more detail why activities are done in a certain way, helping their assessment of the quality of the research. In this section you should describe the range of methods to be used in the assessment of your study.

For example:

Multiple methods will be used to assess the quality of each research activity against the appropriate indicators identified. Appendix E presents an overview of how the principles of good practice and indicators of quality will inform the methods selected to assess the quality of each activity. Further description and justification of each method is presented below.

5.2.1 Observation

Observation can be used as a method to understand and experience the research study 'in action', to see how the research team engage with participants and each other. It offers a good opportunity to assess to what extent the research process as outlined in the study protocol and SOPs is being conducted. It can also be a helpful method for assessing the enactment of certain principles of quality, including ethical practice, systematic approach and comprehensiveness. Acknowledging that the presence of the assessors may shape staff (and participant) behaviour, however, observation may not be considered suitable for certain activities, and this will need to be discussed carefully among the senior investigators and research team members prior to, and during the assessment visit. Observation will be used alongside other methods to capture the fullest picture possible of a study during the assessment visit.

Observation is likely to be used for:

- *Assessing the verbal and non-verbal communication of research team members with participants during recruitment and data collection activities.*
- *Observing research team debriefing meetings to assess how issues with the research process are raised and addressed and how comprehensively interpretations of the data are explored.*

5.2.2 Discussion

Discussions with members of the research team are an important method to explore why certain decisions were made during the research process, researchers' understanding of their role in producing quality research and the extent to which some of the less observable principles of good

practice – particularly reflexivity and responsibility – are understood and being enacted. Discussion offers a more consultative approach than observation or documentary analysis and also creates opportunities for the research team to reflect on their position and interpretations.

It is likely that discussion will be used in addition to other methods to assess a given activity, though could be used alone. A semi-structured topic guide will be used to frame the discussion, and may well be informed by questions and comments arising from other methods of assessment, such as observation.

Discussion is likely to be used for:

- *Exploring with relevant research staff the way interpretations of the data are made and justified during the data analysis process*
- *Exploring with data collection staff the reasons and assumptions behind questions in a topic guide, facilitating reflection on how they may influence the responses from participants.*

5.2.3 Documentary analysis

Analysis of study documents can help to clarify the progress of the study and assess how comprehensively and systematically the research process has been carried out. Analysing documents can range from checking that essential documentation, such as IRB approval and signed consent forms, is present, to a more in-depth analysis of meeting minutes and contact summary forms. This method can be particularly useful for assessing the principles of comprehensiveness, systematic approach and transparency, whereby detailed, complete documentation charting the progress of the study can help indicate its quality. In some circumstances, documentary analysis may offer insights into the reflexivity of the researchers, if they have records of discussions or thoughts about the study and justifications for decisions made. This method should ideally be used in conjunction with other methods, particularly discussion.

Documentary analysis is likely to be used for:

- *Review protocol, consent forms and information sheets to check for up-to-date versions, approval by an IRB and for any changes made since the approval.*
- *Review note-taker and contact summary forms following data collection to assess completeness, clarity and any evidence of reflexivity.*

5.3 Data collection tools

Here you should describe the types of tools you will develop for the assessment team to use to capture information about the quality of research activities during their visit. It is likely that you will need to tailor the tool to each specific research activity to be assessed, in order to capture the specific indicators of quality against which the activity will be assessed. As such, the tool can serve as both a guide for the assessors' appraisal, and as a resource for capturing data on the quality of the activities. Developing an SOP for assessing each activity and using the data collection tool might help inform this process. See the sample SOP for assessing focus group discussions (FGDs) in the appendices.

For example:

Assessment data collection forms will be developed to document assessors' notes, observations and judgments during the assessment of each activity. We have developed a series of SOPs to guide the assessment of each activity. The data collection forms will be structured so as to serve as a guide for the assessments, and will be based on the relevant indicators of quality for that activity. Although the format may be similar for each activity, the prompts and indicators to consider will always be tailored to the specific activity being assessed. The forms will have sufficient space for the assessors to record general comments, note things done well and areas for improvement, and to note any questions or queries that arise and which they wish to follow up through discussion. See Appendix F for example assessment data collection forms.

The questions arising when completing the data collection form can be used to structure any subsequent discussions with research team members about the activity being assessed. Not only will this help assessors clarify issues and make a better assessment of the quality, but will also serve as an opportunity for researchers to reflect on their practice.

Following the assessment, the data collection forms will form the basis of the assessors' assessment of quality, against each of the specified indicators. This will then be captured in the Activity Assessment Report From (see Appendix G).

5.4 Assessing quality

Here you should describe the process through which assessors will make analyse the data collected from the assessment of each activity, in order to generate an overall assessment of to what extent the activity demonstrated the specific indicators of quality, and the underlying principles of good practice. You should also outline how the assessment of each activity will be recorded and presented.

For example:

The assessment data collection forms will be used by the assessors to capture comments, questions and suggestions in relation to both good practice and areas for improvement following the assessment of each research activity (see Appendix F for examples of assessment data collection forms). The forms can then be used to guide further assessment of the same, or related activity, through similar or different methods. For example, if observing data collection, any questions noted by the assessors during the observation can be used to guide a subsequent discussion with the researchers about data collection.

Following assessment, and the completion of the data collection form, the information captured in the form will be analysed by the assessors through the comparison of comments, observations and questions against the indicators of quality defined for each activity. This is unlikely to be a simple 'yes/no' assessment, but will require the assessors to consider their perceptions of the extent to which standards have been met and that the principles of quality have been enacted and understood. This will be a largely interpretive approach to assessment, and so it is important that assessors are explicit in terms of the values against which they are assessing quality; specifically, the relevant principles and indicators of quality. The conclusions from this interpretation will be captured in the Activity Assessment Report Form (see Appendix G) and brought into the final feedback report (see Appendix H).

6 Feedback and Strengthening

Here you should describe and define the steps to be taken for considering, reflecting and acting on the findings from the quality assessment process, and any recommendations made by the assessors. It is important to identify prior to the assessment the process and timing for this, as well as the roles and responsibilities within the research team for implementing any changes agreed and for ensuring quality of the research is strengthened appropriately.

6.1 Assessors' feedback to the research team

For example:

As the assessment visit is underway, feedback will be provided to the study team informally, through the ongoing discussion and reflection built into the assessment process. This will be useful for prompting the research team to reflect upon issues arising while they are still fresh in their minds, and will also provide opportunities for the assessors and research team to discuss and clarify any misunderstandings or issues requiring further explanation. After each assessment, the assessors will complete the relevant Activity Assessment Report Form (see Appendix G for examples), to record their comments in line with observations or points raised in discussion. Following completion of all of the report forms, the assessors will prepare a summary report form capturing their formal observations, reflections and assessments from the entire QAS process (see Appendix H), and suggesting recommendations specific to the findings presented. This report should be produced and sent to senior investigators within four weeks of the completion of the assessment visit.

6.2 Strengthening the research

For example:

The detail of the assessors' report will be used as a series of prompts for a discussion between the senior investigators and wider research team on issues of quality, how to strengthen it, and reflecting on their roles and practice within the research process more broadly. The research team should consider each of the recommendations in the report, and to what extent it is feasible, appropriate and important to act upon it, with this discussion minuted for future reference. Further discussion with the assessors may be required, to clarify any findings or recommendations, or to seek further guidance on how to strengthen particular aspects of the research practice.

Following this, an action plan should be developed outlining what changes will be made to strengthen quality of the study, who is responsible for ensuring they happen and when and how these changes will be assessed. Finally, a copy of this action plan and the minuted discussion on the recommendations of the assessment will be shared with the assessment team, to help them understand how their findings have been considered and acted upon, where appropriate.

7 Ethical considerations

Reflecting the principles of good practice for qualitative research that underpin the approach to quality assessment, considering the ethics of conducting QAS is important. In this section you should detail the steps you will take to ensure that the QAS process does not compromise the ethical standards of your research.

For example:

In order to avoid compromising the ethical standards of our research, the following steps will be taken:

- *Assessors should check the consent form and information sheet for what participants are told about who will be able to see their data and to discuss this and their access to data with the PI, in relation to assessing the quality of data collection, management and analysis activities.*

- *Assessors and the senior investigators will consider carefully the appropriateness of assessment of data collection activities through observational methods. If it is considered appropriate, research team members will inform participants before observation takes place, explain the purpose of the assessment visit, and give participants the opportunity to decline to participate in that session.*

- *Assessors and senior investigators will agree a plan for addressing any unethical practice they observe during the visit, considering when it would be appropriate to feedback at the end of the assessment session or whole visit, and when it would be appropriate to intervene at the time. For example, if assessors decide that intimidation and rudeness by a facilitator/ interviewer towards participants is unacceptable practice, they could decide to pass a note to the researcher during the data collection if they observe this.*

- *Assessors should take care to note any major differences between what has been approved by the IRB/ethical committee in the protocol, consent and information sheets, and what actually happens in the roll out of the study, beyond the usual levels of flexibility expected for a qualitative study.*

8 Acknowledgements

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9 References

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10 Appendices and SOPs

Appendices

A. List of all Research Activities (Example)

B. Assessment Prioritisation Scoring Tool (Example)

C. Assessment Plan (Example)

D. Definitions and Indicators of Quality for Each Research Activity (Example)

E. Assessing Quality for Each Research Activity (Example)

F. Sample Assessment Data Collection Form (Focus Group Discussions)

G. Sample Activity Assessment Report Form (Focus Group Discussions)

H. Assessment Visit Final Feedback Form (Example)

I. Quality Strengthening Action Plan (Example)

Sample SOPs

SOP 1 – Planning for assessment visit

SOP 2 – Assessing data collection - focus group discussions

Appendix A –List of all Research Activities (*Example*)

Research Stage	Activity
Research design	Identifying research question
	Identifying theoretical orientation
	Acknowledging epistemological position and assumptions
	Choosing appropriate methodology/methods
	Choosing appropriate data analysis methods
	Defining appropriate sample population and sampling strategy
	Considering and addressing ethical issues
	Developing timeframe appropriate to the study design and methods
	Creating information sheets and consent forms
	Develop plan for quality assurance of research activities
Training	Training of entire research team on theoretical orientation, methodology, methods, and principles of qualitative research
	Ensuring and checking research team members' understanding and awareness of their own responsibility towards conducting high quality research
	Training of entire research team on quality assurance procedures
	Training research team members on SOPs
Preparation	(Where necessary) translate information sheets and consent forms into local language
	Check translation of information sheets/ consent forms through back-translation, and revise where necessary.
	Designing data collection tools, reflecting theoretical orientation
	Submission of protocol to ethical committee(s)
	Develop SOPs for each stage of the data collection and analysis process, to provide clear framework for conducting data collection
Piloting	Pilot recruitment forms & process
	Pilot information and consent forms, SOPs & process
	Pilot data collection tools
	Revise and refine recruitment & consent processes, SOPs and tools
Recruitment	Identifying, approaching and inviting to participate people who fulfil the eligibility criteria for participation
	Explaining the study and nature of participation using the participant information sheet, and answering any questions
	Requesting informed consent from the participant, using the approved consent form and witnesses were appropriate
	Recording details of all people invited to participate, those who consent and those who decline
Data collection	Conducting IDIs/FGDs/observations
	Changes to the protocol, tools or SOPs, beyond reasonable levels of flexibility associated with qualitative research
	Ongoing communication between members of the research team to

	discuss progress, challenges, emerging ideas, changes to topic guide or sampling
Transcription and translation	Transcription of audio files
	Translation of transcripts
	Process of checking transcripts and translations
Data analysis	Data management and coding of data
	Exploring different perspectives within the data through systematic analysis
	Interpreting and drawing conclusions
Writing up	Interpreting findings in relation to theory and other literature
	Condensing analysis and conclusions to fit into word count

Appendix B –Assessment Prioritisation Tool (*Example*)

Instructions:

1. List all potential research activities in column one – be as detailed as possible, for example for data collection distinguish between different methods.
2. Score each activity in terms of importance for assessors, importance for the research team and feasibility (including timing and ease of access). Scoring is on a scale of 1 to 5, where 1 is low and 5 is high.
3. Calculate the total score for each activity by adding up the scores across the row, and enter the total in the final column.
4. The activities with the highest scores should be prioritised over those with lower scores when planning the assessment visit.

Activity	Importance for assessors	Importance for research team	Feasibility	Total Score

Appendix C –Assessment Plan (*Example*)

Study title	
Location	
Study duration	
Principal investigator	
Field team lead	
Field team members	

Assessor(s)	
Institution(s)	
Dates of assessment visit	
Contact details of assessor(s)	

Purpose of assessment visit

Quality assessment and strengthening (QAS) as a process of assessing, by an external team, to what extent a qualitative study is being conducted in accordance with principles of good practice for qualitative research, and to provide feedback, which will inform a strategy to strengthen the quality of the study. The QAS process will involve a visit to the study site, discussion with research staff, looking at documentation, and observation of some research activities. The assessors will give informal feedback during the assessment visit and follow up shortly after the visit with a full report and recommendations, which will be used by the research team to inform their quality strengthening action plan.

Rather than being a 'fault finding' exercise, the assessment approach is a supportive and consultative one, and the assessment visit will provide a valuable opportunity for the research team to reflect on their practice and role in the research process. The QAS process can also be a useful way to demonstrate to others such as funders or peer reviewers that the research has undergone quality assurance measures.

Research activities to be assessed

The research activities described below have been identified as priorities for the assessment visit, based on a review of the protocol and SOPs, discussion between the senior investigators and assessors, and feasibility considerations. A scoring system was used to determine the activities of the highest priority for assessment, and can be seen below:

[*Insert completed 'assessment prioritisation scoring table' here*]

[*Example*]

Activity 1 – Assessing Focus Group Discussions

Aims:	To observe part of data collection process and assess levels of good practice and any areas for improvement
Methods:	Direct observation of one (or more) FGD; discussion with data collection team; review of relevant documentation
Resources needed:	Access to one (or more) FGD; copy of FGD topic guide; access to recruitment and participation documents
People involved:	Data collection team including FGD moderator and note-taker

Activity 2 – Assessing xxxx

Aims:	
Methods:	
Resources needed:	
People involved:	

Activity 3 – Assessing xxxx

Aims:	
Methods:	
Resources needed:	
People involved:	

[*continued*]

Timetable of Assessment Visit

[*Example*]

	Assessment Activities	
	AM	**PM**
Monday, 12th January	• Arrive at study site • Meet PI & field team • Discuss objectives for visit	• Review documentation on quality assurance plan • Discussion with team on quality assurance plan
Tuesday, 13th January	• Observe FGD in xxx	• Discussion with data collection team about FGD • Review documentation for FGD recruitment, consent and

		contact summaries
Wednesday, 14th January	• Review documentation on piloting • Discussion with team on piloting activities	• Review coding documents/files • Discussion with team on coding
Thursday, 15th January	• Observe research team debriefing meeting • Discussion with team following meeting	• Observe IDI in xxx • Discussion with interviewer following IDI
Friday, 16th January	• Review documentation on team communication, debriefing meetings and communication about analysis	• Final discussion with team and informal feedback of observations

Feedback report

The final report with feedback highlighting areas of good practice and areas for improvement with recommendations will be sent to the PI by xx/xx/xx, and to be shared with the research team and used to develop the strengthening action plan.

Other resources needed

- Transportation to FGD/IDI sites
- Desk or office space for reviewing documentation
- Quiet space to meet and discuss with research team members.

Appendix D –Definitions and Indicators of Quality for Each Research Activity (*Example*)

Research Activity	Definition of Quality	Indicators of Quality
Quality assurance plan	Systematic, comprehensive and detailed approach for assuring quality throughout the research process, and appropriate to methodology and theoretical approach	Existence of a quality assurance plan stipulating what measures will be taken to assure quality throughout the study and by whom. Comprehension amongst research team of how to implement quality assurance measures and individual responsibility towards assuring quality.
Training	Comprehensive training of research team covering all aspects of research process, and core methodological and epistemological principles	Well designed manuals tailored to the researcher's level of understanding and reflecting the objectives of the study. Opportunities for researchers to recap and consolidate their learning, and to demonstrate their understanding in relation to the research activities to be carries out.
	Effective training leading to comprehension amongst each team member of their role in the research process and how to conduct it to a high quality	Views and experiences of research team reflecting an understanding of their responsibility and importance of their role in conducting high quality research
Review and preparation	Appropriately designed data collection tools that reflect theoretical orientation and methodology, and research question	Existence of data collection tools, with indication of how they have been developed in line with research question, methodology, and theoretical orientation, eg through clear demonstration of links between questions and relevant theoretical domains. Evidence of research team's understanding of how data collection tools have been developed and their justification of how they will be able to answer the research question.
	Comprehensive and systematic process of translation of relevant documents	Evidence of choice and justification of translation approach, appropriate to study design, eg in protocol and/ or research team members' understanding. Transparent process of translation,

		checking and revision for all relevant documents (data collection tools, consent forms and information sheets). Consistency of meaning between translated documents and the original documents.
	Creation of comprehensive and detailed set of SOPs, appropriate to the methodology, and reflecting principles of qualitative research.	Existence of and familiarity amongst research team of SOPs addressing all relevant stages of the research process. Understanding amongst research team of how SOPs have been developed and how they reflect the methodology and principles of qualitative research. Clear consistency between detail of SOPs and research question, methodology and principles of qualitative research.
	Appropriate ethical review and approval of study protocol	Evidence of ethical approval by appropriate IRBs Consistency between IRB approval and most recent version of the protocol, consent forms and information sheets.
Piloting	Systematic process of piloting data collection tools, SOPs and other processes.	Clear documentation of process of piloting tools with appropriate sample populations. Clear recording of responses, challenges and experiences of piloting process.
	Reflective process of evaluating piloting and making revisions to processes and tools following piloting.	Comprehension and justification amongst research team for the rationale and basis of revisions and refinements made on consent forms and tools. Existence of minutes/notes from meetings held to discuss revisions and refinements to be made on consent forms and tools
Recruitment	Identifying, approaching and inviting people to participate in an ethical way and appropriate to the study design	Clear sampling procedure and documentation recording details of all people approached for participation, as well as details of those who agree and decline or withdraw. Consistency of activity with relevant SOPs.
	Clear communication of information about the study and answering of questions to enable informed consent, in	Evidence of information sheets being given and explained in an appropriate way and at an appropriate time and place for the participants, with opportunity for asking

	line with ethical standards.	and answering questions. Consistency with relevant SOPs. Evidence of consent being taken in appropriate way, place and time, and consistent with relevant SOPs. Consent forms signed and dated by participants, investigators and witnesses where necessary.
Data collection	Appropriate use of data collection tools and interviewing/ facilitating style.	Interviewer/facilitator/observer using data collection tools with awareness of influence of their own style on data collection, with modifications of style where appropriate. Interviewer/facilitator/observer responding to participants' verbal and non-verbal communication in an appropriate way. Evidence of a flexible approach to questioning and prompting, reflecting understanding of research question and theoretical orientation.
	Comprehensive recording of data	Reliable and consistent use of audio/video equipment to record data collection events. Systematic approach to recording non-verbal communication through note-taking.
	Comprehensive and reflexive process across entirety of data collection	Existence of minutes or notes of ongoing communication between members of the research team to discuss progress, challenges, emerging ideas, changes to topic guide or sampling. Reflection on researchers' practice and how it may influence data collection. Clear evidence of any changes made to topic guide or sampling with comprehension of why these were made among the research team.
Transcription and translation	Systematic process of transcribing data collection recordings.	Accurate and detailed transcripts consistent with audio files and note taker's notes.

		Standardized and consistent use of notation reflected in the transcripts.
	Comprehensive and systematic process of translation of transcripts.	Evidence of choice and justification of translation approach, appropriate to study design, eg in protocol and/ or research team members' understanding. Transparent process of translation, checking and revision for all transcripts.
Data analysis	Systematic, transparent and comprehensive data management and coding procedures.	Clear and consistent recording, filing and labeling of data with evidence of checks for completeness of data collection forms and audio files. Clear and consistent coding process, with evidence of how codes have been developed, discussed and refined.
	Systematic, transparent, reflexive and comprehensive data analysis process, appropriate to study design and methodology.	Clear process of development from coding to analytical categories and conclusions. Evidence of comprehensive approach to considering and testing multiple interpretations of the data. Evidence of reflexivity within analytic process regarding assumptions and interpretations of the data, and conclusions drawn. Relating findings to theoretical perspective and other theory and literature to further develop and refine interpretations

Appendix E –Assessment of Quality for Each Research Activity (*Example*)

Research Activity	Definition of Quality	Indicators of Quality	Assessment Activity to Assess Quality
Quality assurance plan	Systematic, comprehensive and detailed approach for assuring quality throughout the research process, and appropriate to methodology and theoretical approach	Existence of a quality assurance plan stipulating what measures will be taken to assure quality throughout the study and by whom. Comprehension amongst research team of how to implement quality assurance measures and individual responsibility towards assuring quality.	Check existing quality assurance plan of the study. Discussion with research team about understanding of plan and how they enact it. Assess through other assessment how well this plan is being followed.
Training	Comprehensive training of research team covering all aspects of research process, and core methodological and epistemological principles	Well designed manuals tailored to the researcher's level of understanding and reflecting the objectives of the study. Opportunities for researchers to recap and consolidate their learning, and to demonstrate their understanding in relation to the research activities to be carries out.	Documentary analysis of training manuals, learner's manuals, learner's assessments found in the study folder.
	Effective training leading to comprehension amongst each team member of their role in the research process and how to conduct it to a high quality	Views and experiences of research team reflecting an understanding of their responsibility and importance of their role in conducting high quality research	Discussion with the research team members' to check understanding and awareness of their own responsibility towards conducting high quality research.
Review and	Appropriately designed data	Existence of data collection tools, with	Documentary analysis of data collection

preparation	collection tools that reflect theoretical orientation and methodology, and research question	indication of how they have been developed in line with research question, methodology, and theoretical orientation, eg through clear demonstration of links between questions and relevant theoretical domains. Evidence of research team's understanding of how data collection tools have been developed and their justification of how they will be able to answer the research question.	tools, alongside protocol, to assess whether they reflect the theoretical orientation and study objectives. Discussion with research team members about how data collection tools have been developed and what they understand about how they will answer the research question.
	Comprehensive and systematic process of translation of relevant documents	Evidence of choice and justification of translation approach, appropriate to study design, eg in protocol and/ or research team members' understanding. Transparent process of translation, checking and revision for all relevant documents (data collection tools, consent forms and information sheets). Consistency of meaning between translated documents and the original documents.	Documentary analysis of protocol and discussion with research team members to explore justification for translation approach and awareness of how this relates to the study design. Check translation of information sheets/ consent forms by reviewing back-translation against the previous versions.
	Creation of comprehensive and detailed set of SOPs, appropriate to the methodology, and reflecting principles of qualitative research.	Existence of and familiarity amongst research team of SOPs addressing all relevant stages of the research process. Understanding amongst research team of how SOPs have been developed and how they reflect the methodology and principles of qualitative research. Clear consistency between detail of SOPs and research question, methodology and	Check SOPs for each stage of the data collection and analysis process to ensure they provide a clear and appropriate framework for conducting data collection and are consistent with the protocol. Discussion with research team members about the role of SOPs, how they reflect the study aims and researchers' responsibilities towards using them.

		principles of qualitative research.	
	Appropriate ethical review and approval of study protocol	Evidence of ethical approval by appropriate IRBs Consistency between IRB approval and most recent version of the protocol, consent forms and information sheets.	Check IRB approvals, amendments and previous versions of protocol.
Piloting	Systematic process of piloting data collection tools, SOPs and other processes.	Clear documentation of process of piloting tools with appropriate sample populations. Clear recording of responses, challenges and experiences of piloting process.	Observation of piloting activities, including recruitment of participants, data collection and evaluation activities. Documentary analysis of piloting data management documents and reflection documents.
	Reflective process of evaluating piloting and making revisions to processes and tools following piloting.	Comprehension and justification amongst research team for the rationale and basis of revisions and refinements made on consent forms and tools. Existence of minutes/notes from meetings held to discuss revisions and refinements to be made on consent forms and tools	Review of minutes/notes of team meeting following piloting and discussion with research team to understand the rationale and basis of revisions and refinements made on consent forms and tools.
Recruitment	Identifying, approaching and inviting people to participate in an ethical way and appropriate to the study design	Clear sampling procedure and documentation recording details of all people approached for participation, as well as details of those who agree and decline or withdraw. Consistency of activity with relevant SOPs.	Observation of recruitment activities, plus analysis of SOPs and recruitment logs.
	Clear communication of information about the study and answering of questions to	Evidence of information sheets being given and explained in an appropriate way and at an appropriate time and place for the	Observation of information and consent processes, alongside relevant SOPs.

	enable informed consent, in line with ethical standards.	participants, with opportunity for asking and answering questions. Consistency with relevant SOPs. Evidence of consent being taken in appropriate way, place and time, and consistent with relevant SOPs. Consent forms signed and dated by participants, investigators and witnesses where necessary.	
Data collection	Appropriate use of data collection tools and interviewing/ facilitating style.	Interviewer/facilitator/observer using data collection tools with awareness of influence of their own style on data collection, with modifications of style where appropriate. Interviewer/facilitator/observer responding to participants' verbal and non-verbal communication in an appropriate way. Evidence of a flexible approach to questioning and prompting, reflecting understanding of research question and theoretical orientation.	Observation of IDIs/FGDs/observations
	Comprehensive recording of data	Reliable and consistent use of audio/video equipment to record data collection events. Systematic approach to recording non-verbal communication through note-taking.	Analysis of contact summaries and note-taker notes.
	Comprehensive and reflexive process across entirety of data	Existence of minutes or notes of ongoing communication between members of the	Review of documentation for of ongoing communication between members of the

	collection	research team to discuss progress, challenges, emerging ideas, changes to topic guide or sampling. Reflection on researchers' practice and how it may influence data collection. Clear evidence of any changes made to topic guide or sampling with comprehension of why these were made among the research team.	research team to discuss progress, challenges, emerging ideas, changes to topic guide or sampling. Discussion with research team following data collection to raise questions and offer an opportunity for reflexivity about influence of researchers' practice on data and outcomes.
Transcription and translation	Systematic process of transcribing data collection recordings.	Accurate and detailed transcripts consistent with audio files and note taker's notes. Standardized and consistent use of notation reflected in the transcripts.	Checking transcripts against the audio files and note taker's notes (for FGDs) Check transcripts for standardized notation (e.g pauses, laughter, emphasis, gestures)
	Comprehensive and systematic process of translation of transcripts.	Evidence of choice and justification of translation approach, appropriate to study design, eg in protocol and/ or research team members' understanding. Transparent process of translation, checking and revision for all transcripts.	Documentary analysis of protocol and discussion with research team members to explore justification for translation approach and awareness of how this relates to the study design. Check translation of transcripts by reviewing back-translation against the previous versions.
Data analysis	Systematic, transparent and comprehensive data management and coding procedures.	Clear and consistent recording, filing and labeling of data with evidence of checks for completeness of data collection forms and audio files. Clear and consistent coding process, with	Reviewing databases and coding documents. Discussion with research team members about how codes were developed and refined.

		evidence of how codes have been developed, discussed and refined.	
	Systematic, transparent, reflexive and comprehensive data analysis process, appropriate to study design and methodology.	Clear process of development from coding to analytical categories and conclusions. Evidence of comprehensive approach to considering and testing multiple interpretations of the data. Evidence of reflexivity within analytic process regarding assumptions and interpretations of the data, and conclusions drawn. Relating findings to theoretical perspective and other theory and literature to further develop and refine interpretations	Discussion with the research team to understand their perspectives and conclusions from study findings. Review of analysis reports and discussion with research team to explore how they have interpreted their findings in relation to existing literature.

Appendix F – Sample Assessment Data Collection Form (Focus Group Discussions)

Protocol ID: **FGD no.:**	**Study site:**		**Date of visit:**	
Study staff present at this visit, including assessor(s):				
Name	**Role**		**Affiliation**	
Indicators of quality	**Comments**	**Questions**	**Positive observations**	**Negative observations**
Meeting place Location, size, accessibility and how this could have affected the discussion and interactions throughout the discussion				

FGD data collection tools
• Topic guide:
  ○ Appropriateness of range of questions in relation to topic and research question
  ○ Appropriateness of format and style of questions in relation to methodological approach
• Contact summary form
• Note-taker form				

Consenting participants • Reading and explanation of the consent form • Response to questions raised by participants • Signing of consent forms				

• Completion of appointment logs and participant logs				

Dynamics of the FGD participants
• Number of participants present
• Composition of the group
• Level of participation
  ○ Dominant participants
  ○ Passive participants
  ○ Interest and engagement levels				

Communication and interaction of moderator, note taker and participants
• Verbal communication
• Non verbal communication
  ○ Research team's body language
  ○ Moderator's responsiveness to participants' verbal and non verbal communication				

Use of topic guide
• How questions were asked
  ○ Closed questions
  ○ Open questions
  ○ Tone
• Probing skills
• Comprehensiveness of questioning
• Flexibility of approach
• Responsiveness and interpretation of participants' comprehension				

Moderator control of the group • Handling dominant and passive participants				
Use of FGD data collection tools • Levels of detail captured in contact				

summary / note-taker form • Levels of reflection on process of FGD and researchers' roles • Reflection on data collected in relation to previous data collection				
Debriefing meeting • Levels of input from research team members on process of FGD • Reflection on input • Interpretation of data collected in relation to theoretical orientation and other data collection • How well researchers address any concerns or questions raised by assessors following observation of the FGD				

Appendix G – Sample Activity Assessment Report Form

1. Activity assessment report form – focus group discussions

Activity assessed:	
PI:	Study site:
Protocol ID:	Date of visit

Staff present at this visit (including assessors)		
Name	Role	Affiliation

FEEDBACK FROM QUALITY ASSESSMENT	
1. Preparation and planning	
1.1 Appropriateness of meeting place	
Strong points	Areas for improvement
1.2 Data collection tools	
Strong points	Areas for improvement
1.3 Consent process	
Strong points	Areas for improvement
1.4 Composition of the FGD group	
Strong points	Areas for improvement
General comments	
2. Moderation of the discussion	

2.1 Use of the topic guide to frame the discussion	
Strong points	Areas for improvement
2.2 Responsiveness to discussion and probing skills	
Strong points	Areas for improvement
2.3 Responsiveness and interpretation of non-verbal communication	
Strong points	Areas for improvement
2.4 Management of group dynamics	
Strong points	Areas for improvement
General comments	
3. Data collection and reflection	
3.1 Use of other data collection tools (contact summaries, note-taking)	
Strong points	Areas for improvement
3.2 Interpretation of discussion in debriefing meeting	
Strong points	Areas for improvement
3.3 Reflection on research team's inputs	
Strong points	Areas for improvement

3.4 How assessors' questions were addressed	
Strong points	Areas for improvement
General comments	

Recommendations for the research team

Assessor's name_____Signature_____Date_____

Assessor's name_____Signature_____ Date_____

Appendix H –Assessment Visit Final Feedback Form (*Example*)

Study Title	
Study Location	
Principal Investigator	
Field Team Lead	
Study Duration	

Dates of Assessment Visit	
Assessors (names/institutions)	
Date of Feedback Form	

1. Overview of Assessment Visit

[Here, recap on the original aims and objectives of the assessment visit, and give an overview of the assessment in reference to the planned visit and timetable. Describe the visit dates, times, any challenges faced meeting assessment objectives, and any modifications to the timetable and assessment activities that had to be made, with reasons.]

2. Description of Activities Assessed

[Here, give a description of each of the activities that was assessed, with reference to the methods used for assessment, the resources used, which research team members were involved, the time taken, and any specific challenges faced in assessing these].

3. Assessment of Quality for Each Activity

[Give an overview of general interpretations of the quality of the research. Then, with reference to the specific activity assessment report form, summarise the strengths and areas to improve for each of the activities assessed. This assessment should also refer to the specific indicators of quality defined for each activity, to show clearly how the assessment has been made.]

4. Recommendations for Improvement

[This section should begin by outlining the strengths of the qualitative research, followed by practical recommendations to improve the weaker areas of the research. These recommendations should be

specifically linked to the assessments of quality outlined above and should be feasible and appropriate for the study design and research context.]

5. Further Contact

[In this section, you should give the contact details of the assessors and offer the researchers the opportunity to discuss the findings and recommendations in more detail, should they wish.]

6. Attachments

[Attach the original assessment plan document, and all the completed assessment activity report forms for each of the research activities assessed, for the information of the research team.]

Appendix I – Quality Strengthening Action Plan (*Example*)

Date of discussion:	
Discussion led by:	
Team members present:	
Minutes taken by:	

A) Reflections on assessors' recommendations:

1a) Assessors' recommendation:
1b) Team's reflection:
1c) Action to be taken:

2a) Assessors' recommendation:
2b) Team's reflection:
2c) Action to be taken:

3a) Assessors' recommendation:
3b) Team's reflection:
3c) Action to be taken:

[*continue as necessary*]

B) Dates and Responsibilities

	Action to be taken:	Responsibility of:	Resources needed:	Date to be reviewed:
1				
2				
3				
4				
5				

Sample SOP 1: Planning the assessment visit

1. Title

Planning the assessment visit

2. Purpose

To describe how to prepare, plan and communicate details of the assessment visit, in terms of timing, activities to be assessed and resources needed.

3. Rationale

Quality assessment and strengthening (QAS) is one part of the broader quality assurance process for this qualitative research study, much of which is researcher-led and implemented throughout the day-to-day research process. Assessment of qualitative research activities, carried out by an external party, can offer valuable insight, feedback and support to the research team. Assessment can identify aspects of the research process that can be strengthened, and can provide an opportunity for the researchers to discuss, make explicit and reflect upon their practice. The QAS process is also a useful mechanism for demonstrating to external audiences (funders, sponsors, peer reviewers) that the quality of our research has been assured.

This SOP will describe the process for preparing for assessing and strengthening a qualitative study.

4. Resources needed

- Latest version of study protocol
- Timetable of study activities
- Description of study activities, including where, by whom etc
- Latest version of study SOPs
- Activity prioritisation scoring table
- Assessment plan document

5. Target audience

- Assessment team member(s)
- Principal investigators and study team

6. Definitions

- *Assessment* - an event or series of events during which a team external to the qualitative study visit the study site to appraise, discuss and provide feedback on the quality of the research activities, through a variety of methods.

7. Procedures

A. Approaching the assessors

1. The PI or appropriate senior investigator should identify suitable people external to the study who have knowledge of social science and qualitative research methods. They should approach them to explain the process and timescale for the QAS process, including the assessment visit, and invite them to consider acting as assessors.
2. Assessment of the study could be offered as part of a 'co-assessment' strategy, whereby two research teams take it in turns to assess and offer feedback on each others' studies.

B. Familiarisation with the study

1. Once the assessors have agreed to conduct the QAS process, the research team lead should provide the assessors with copies of the latest version of the protocol, timetables and documents describing research activities, and SOPs. When these are received, the assessment team should read all the documentation and make preliminary notes of any questions, areas of interest for assessment, areas of concern and any areas requiring clarification.
2. The research team lead should arrange a call or meeting with the assessment team and any other senior investigators from the study, to discuss any questions arising from the documentation and to discuss their expectations for the assessment visit. Both the assessors and senior investigators should state which activities within the research process they consider to be priorities for assessment, and should discuss the most convenient time for the assessment visit to take place.

C. Selecting activities to be assessed

1. The priorities for assessment identified by both the research team and assessment team should be brought together by the research team lead, and considered in terms of feasibility and appropriateness for the QAS process.

2. If the priorities are very different, and/or if a compromise cannot easily be reached, the prioritisation tool should be used to allocate scores to each activity selected, to identify those that are most important and feasible to assess. The potential activities should be listed in the first column. In the second column, the assessors should rate each activity in terms of its importance for assessment, using a score of 1 (low importance) to 5 (high importance). The research team lead should do the same in column three, 'importance for research team', and the assessors and research team lead should agree scores of feasibility of assessment for each activity in column four (1 is low feasibility, 5 is high feasibility). The total score for each activity is the sum of scores in each column; those activities with the highest scores should be considered as the priorities for the assessment visit.

3. The research team lead, consulting the assessors, should then draft the Assessment Plan, detailing the timetable of activities to be to be assessed during the assessment visit, and the list of resources needed by the assessors for each, including access to documentation, transport, space and time to talk to the PI/study lead/field team, opportunities to observe data collection etc.

4. This draft should be shared with the PI and assessment team, any necessary revisions made and then agreement sought from both parties. The finalised Assessment Plan should be shared with the PI, study lead and all the field team in good time before the assessment visit, to help the research team prepare for the visit.

Sample SOP 2: Assessing data collection – Focus Group Discussions

1. Title

Assessing data collection - FGDs

2. Purpose

To describe how to assess FGDs, and the resources needed.

3. Rationale

Quality assessment and strengthening (QAS) is one part of the broader quality assurance process for this qualitative research study, much of which is researcher-led and implemented throughout the day-to-day research process. Assessment of qualitative research activities, carried out by an external party, can offer valuable insight, feedback and support to the research team. Assessment can identify aspects of the research process that can be strengthened, and can provide an opportunity for the researchers to discuss, make explicit and reflect upon their practice. The QAS process is also a useful mechanism for demonstrating to external audiences (funders, sponsors, peer reviewers) that the quality of our research has been assured.

Assessment of data collection activities is potentially beneficial for strengthening the quality of the research as it can help the researchers to understand how their position, actions, and assumptions influence the data collection process, outcomes and findings. This SOP will describe the process for assessing FGDs.

4. Resources needed

- Assessment plan
- Latest version of study protocol
- Latest version of SOP(s) for conducting SOPs
- FGD topic guide
- FGD assessment data collection form
- Activity assessment report form

5. Target audience

- Assessment team members
- Principal investigators and research team

6. Definitions

- *Assessment* - an event or series of events during which a team external to the qualitative study visit the study site to appraise, discuss and provide feedback on the quality of the research activities, through a variety of methods.

- *Focus group discussion* - A qualitative research method with the primary aim of describing and understanding perceptions, interpretations, and beliefs of a select population to gain understanding of a particular issue from the perspective of the groups' participants.

7. Procedures

A. Brief meeting with research team before FGD begins

1. At the outset of the assessment visit, the assessors and research team members should meet to discuss the plan for the visit, and check understanding of and expectations for the QAS process.
2. Prior to assessing the FGD, the assessors should meet with the field team / data collectors to remind them of the objectives of the assessment activity, and to discuss how to minimise any potential disruption of the FGD by nature of the assessors' presence. They should agree an appropriate place for the assessors to sit to observe the FGD and any confirm how the assessors' presence will be described to the participants, before the FGD begins.

B. Assessing the FGD

1. The FGD moderator should introduce the assessors to the FGD participants and explain the purpose of their visit and assessment. They should highlight the continuing confidentiality of the discussion and address any concerns raised by the participants.
2. When observing the FGD, the assessors should be guided in their assessment by the indicators of quality detailed in the data collection forms, and the underlying principles of good practice defined for the study being assessed. The assessors should remember that the list of indicators of quality is not a fixed or exhaustive one, but a guide for interpreting whether the principles of good practice are being enacted.
3. After the FGD, the assessors should also review the tools and documentation related to the FGD, including note-taker's notes, contact summary form and any other notes or logs.

Again, these should be assessed in line with the indicators and principles of quality relevant to FGDs.

4. If appropriate, the assessors should observe the debriefing meeting following the FGD to assess how the team reflect upon the activity. This can also be an opportunity for the assessors to raise any questions they have about the activity they have observed and to offer an opportunity for team members to reflect on their practice.
5. In cases where no debriefing meeting is held after the FGD, the assessors may invite the study team to have a discussion about how the FGD went and to extend their assessment of the quality through discursive methods.

C. Feeding back

1. At the end of the assessment activity, the assessors can give informal feedback to the research team on their assessment of quality of the FGDs. They should then complete the Activity Assessment Report Form for FGDs.
2. At the end of the entire assessment visit, the assessors should incorporate their assessment of the FGDs into their overall feedback on the quality of the research activities assessed. This should be captured in the Assessment Visit Report Form, and shared with the PI and research team, to inform the development of their quality strengthening action plan.