Qualitative Research Guidelines

These guidelines are to be used in conjunction with standard protocol templates. They are designed to provide guidance on issues that specifically apply to qualitative research projects.

These guidelines will be updated when we become aware of changes, however, it is your responsibility to ensure that your project meets regulatory, legal and ethical requirements related to each individual project.

This information is correct as at 31 July 2023 but is subject to change.

Questions?

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1. RESEARCH DESIGN

1.1 Is this a qualitative project?

Qualitative research is a process of collecting, analysing and interpreting non numerical data.
Types of research design – Quantitative v Qualitative.

Quantitative	Qualitative
▪ Measures, counts, scores ▪ Often uses a hypothetical deductive design, e.g. tests a hypothesis on a particular sample (intervention research) ▪ Seeks to identify correlations and causation ▪ Can often appear to be "atheoretical" ▪ Personal interests of the researcher are largely unstated ▪ Frequently asks "how many" questions	▪ Describes, interprets, explains ▪ Emphasis on people, experiences, understandings, meanings ▪ Frequently occur in naturalistic settings (not an experimental setting) ▪ Often more explicitly theoretical ▪ Often uses an inductive process - looks for patterns/themes in the data ▪ Frequently asks "how" and "why" questions

1.2 Methodology/research paradigm

- The methodology should be designed to answer the research question.
- Some common methodologies are detailed below:

Methodology	Explanation
Ethnography	Focuses on people as members of groups, or cultures
Phenomenology	Interested in the 'lived experience" – what if feels like to have a certain experience, how people understand their own experience
Grounded theory	Interested in meaning-making through interactions with others; aims to produce a theorised understanding of subjective personal experience, that is grounded (based) in the data. In original form, has strict rules for how to do data collection and analysis
Narrative inquiry (or narratology)	Focuses on telling stories as people's way of understanding of themselves and their experiences (regards the story as the natural form of meaning-making)
Case study	Interested in different perspectives on particular social phenomenon
Descriptive /Interpretative	Description of a phenomenon with a focus on rich description of the Who, What, Where, and Why from those who have the experience of that phenomenon

- Think about the time frame necessary for the chosen methodology and whether this is viable within the scope of the project. This also applies to all aspects of the project, e.g. participant numbers, recruitment strategies, analysis technique etc. (May be helpful to state a theoretical framework and why this is appropriate to your research question, including providing a reference)

- In order for research proposals to have merit and integrity, The National Statement on Ethical Conduct in Human Research (NS) states the that research must be:
    - *1.1 (b) designed or developed using methods appropriate for achieving the aims of the proposal;*
    - *1.1 (c) based on a thorough study of the current literature, as well as previous studies.*
- What this practically means for researchers is that in the background of the project and framing of the aims and hypothesis, the project should highlight how the design and methods were selected to best meet the aims of the study and how this is based on the current literature.

1.3 Sample

- Characteristics of intended participants, such as inclusion and exclusion criteria, and an indication of the anticipated number of participants should be included.
- Identify intended sampling strategy(s),e.g. purposive, convenience, stratified, snow ball and how this will be conducted.
- Anticipated participant numbers should consider: does the number suit the method, do you have sufficient participants to answer the research question(s) –is the method of assessing sufficient sample size (e.g. thematic saturation) adequately described, is it feasible to recruit the number suggested within the time frame of the project, what will happen if you recruit more participants than anticipated.
- To ensure the principle of justice is met (NS 1.4) the research must be designed in a way that does not unfairly burden or exclude particular groups. Where possible, the research should be designed in a way to minimise burden or exclusion. If this is not feasible then this must be clearly outlined, including how this might impact/bias research outcomes and how this will be mitigated in the future.
- Common examples of this are:
    - the exclusion of CALD participants due to lack of funding for interpreters
    - exclusion of vulnerable or minority groups because of the increased regulatory burden (e.g. project becomes greater than low risk)
    - excluding participants with disability due to access issues

1.4 Recruitment strategy/s

- Recruitment is the key to success of a research project and multiple methods of recruitment can be used to assist with this.
- Below are some specific issues to be considered when using different recruitment methods.

Method	Considerations
Accessing data to inform recruitment	Do you have permission to access a participant's data to see if they are eligible/obtain their contact info? If not do you need a waiver of consent See NS 2.3.10
Snowball sampling via networks	Does this bias your research findings by recruitment of a particular group?
Using personal networks	Can this create a sense of coercion if asking friends or family? (NS 3.1.18) Might this reveal sensitive information or viewpoints about yourself?
Unequal relationships	Could the patient feel obliged to say yes because they are worried that this may impact their care? How will you limit coercion? If asking HoD to assist with recruiting staff, could staff feel coerced to participate? How will you use reminders? Could they appear coercive?
Reimbursement	Could the reimbursement amount or value constitute an inducement? The amount must be justified as a reimbursement of participants time or covering reasonable costs of participating in the study. This should not be listed as a benefit of participation.
Respect	Is the recruitment method respectful of different cultures or backgrounds. See element 2 NS
Social media	Is this platform the most relevant for your target participant group? https://www.socialmedianews.com.au/social-media-statistics-australia-august-2020/ Does the advertising meet your organisations social media guidelines? RCH social media guidelines Does this have approval by the institution's comms team?

1.4 Method/s of data collection (including approved devices) and storage

- Specify data collection methods and why that is appropriate for the research question.
- The nature of any recording devices used to record interviews with participants (or other research activities) in video or audio form should be specified in the Ethics protocol. Details of how the recordings will be moved from the recording device to a secure storage location, and where and how they will then be stored, shared and/or destroyed, should also be included.
- Researchers are reminded of the importance of ensuring that recording devices are adequately secure, in order to avoid any unauthorised access, use, loss or destruction of recordings. The below table sets out what methods of collection (including devices) and storage are currently approved by MCRI. Please note that this advice may change as platforms update so please consider the implications of this and contact MCRI IT or Legal as appropriate with any queries regarding the below requirements and how they apply to your project. This information is correct as at 12 June 2023.

Description	**What is approved?**	**Further comments** *(including IT and Legal considerations)*
Methods of data collection	Researchers can use the following: ▪ approved platforms: Teams (Office 365), Zoom. Only MCRI-allocated Zoom/Team (Office 365) accounts may be used. Personal accounts must not be used. ▪ approved hard disks (including USB sticks- see comments). ▪ approved devices (see below).	○ External hard disk (including USB sticks) should only be used if they are encrypted and with IT's prior approval. These devices are prone to failure even if they are encrypted. ○ Any other method of recording should be authorised by MCRI IT & Legal. ○ At the commencement of the interview, participant's verbal consent must be sought prior to using the recording function of any approved platforms. ○ If using a web conferencing platform participants must be reminded that they can turn their camera off and also use a pseudonym for the recording.
Devices	The following devices can be used with appropriate security settings: ▪ MCRI-owned devices (laptops, mobile phones, tablets); and ▪ Approved Bring your Own Devices (BYOD) (see the BYOD Policy for further information: https://intranet.mcri.edu.au/sites/policies/bring-your-own-device-(byod)-policy ▪ FACT SHEET: Using Dictaphones securely for research	○ **Personal devices such as mobile phones, or personal laptops which are not approved under the BYOD Policy are not sufficiently secure and must not be used.**
Storage location	Data must be transferred to the following: ▪ MCRI-approved and hosted data collection platforms (some research groups might use their own purpose-built databases/apps, others might use REDCap, MCRI Own Cloud, SharePoint (Microsoft 365) or OneDrive (Microsoft 365)); or ▪ MCRI Network group drive only.	○ Dropbox is not an approved platform. ○ Data must not be stored on any other third-party owned servers or cloud-based platforms or any external share drives (including RCH or the University of Melbourne), other than in accordance where an appropriate legal agreement is in place with the third party. ○ Data must be stored in accordance with the relevant Ethics approval. ○ The original file should be promptly and permanently deleted from the recording device.

Sharing data	Large data files such as videos may be transferred using the following approved platforms: • MCRI OwnCloud: allows files on network group to be shared with external users. SharePoint (part of the MCRI Microsoft 365 service offering): video files can be uploaded to a SharePoint site (that the user will need to create) and shared out to specific users of approved external collaborator domains.	○ Use of MCRI OwnCloud: Here is the Quick Start Guide, and IT Service Desk will need to be contacted to assist the team in setting it up for your project. ○ Use of SharePoint Information on this can be found here.

- Please ensure that the secure collection, storage and management of data (including recordings) is addressed in your data management plan as part of your protocol.
- Methods of data collection e.g., recording interviews, can be discussed with the REG team (who may then refer you to IT/Legal for further guidance) prior to an application being submitted.

1.5 Method/s of data analysis

- Specify data analysis methods, the analysis plan for the data, how this answers your research question, and why this is appropriate for the research design and methodology. You will also need to specify if software is being used, e.g., NVivo,
- Common analysis techniques include content analysis (inductive or deductive), thematic analysis, discourse analysis, narrative analysis.

1.6 Transcription

- Although many researchers transcribe their own recordings transcription services are commonly used by MCRI researchers for the purpose of their studies. If a third party transcription service is to be used, a reference to the use of that transcription service (including whether the data will be transferred outside Australia) must be included in the ethics protocol and in the plain language statements for participants. It is also important that the transcription company deletes recordings once they have been transcribed (and the researcher should check that this has occurred). The obligation to delete the recordings should be included in the agreement to be put in place with the transcription company (see also section 2 below). MCRI Legal must be advised prior to using an external transcription service and appropriate contractor agreement documentation arranged.

  MCRI has entered into Master Services Agreements with **Outscribe and Adroit Research** who are approved transcription services providers. An agreement in the form of a Work Order is required between MCRI and the transcription services

provider you will choose for each project. Contact qual.research@mcri.edu.au for a Work Order template and liaise with Legal to finalise the agreement.

- Whilst transcription companies will endeavour to make their transcribed documents as accurate as possible researchers should check each transcribed document against the audio recordings prior to starting analysis. This is called data cleaning.
- Researchers should be aware that even if a professional transcription company is used, individual recordings may still need to be transcribed by the researcher if the individual record contains sensitive information.

1.7 Data sharing

- Specify if the data will be shared with any third parties and whether the data will be disclosed to an overseas entity. If personal information (that is, any information about an identified individual or someone who is reasonably identifiable) is disclosed to an overseas entity, participant's express consent to such a disclosure should be sought. Disclosure in this context does not necessarily include a physical or electronic transfer – for example, allowing access to a database hosted by MCRI will amount to a disclosure. Speak to the MCRI legal team to discuss disclosure of any personal information to an overseas entity.

1.8 Legal considerations

- If your study involves working with a third party, whether it is (i) a collaborator involved in the research activities, (ii) a site responsible for recruiting participants and collecting data or (iii) a company supplying goods or services (such as transcription companies referred to above), please contact MCRI Legal team legal@mcri.edu.au who will assist you in setting up the relevant agreement with the third party and initiate the CAB process if your project involves a data transfer **https://intranet.mcri.edu.au/staff-resources/change-advisory-body/data-transfer**.
- The agreement will cover the transfers of data between MCRI and the relevant third party and will include key provisions including confidentiality and privacy obligations, liability and insurance terms, and arrangements regarding the intellectual property generated in the course of the project and/or performance of the services (e.g. transcripts can be protected by copyright, and it is important that MCRI owns the IP in the transcripts).

2. ETHICAL CONSIDERATIONS

2.1 Burdens and risks to participants, and risk management strategy for participants

- Do you have appropriate referral pathways for potential clinical concerns? Who will clinical concerns be directed to in the first instance?

- Is psychological or counselling support available for participants and researchers (if appropriate)?
- Have the risks been clearly articulated?

2.2 Any potential benefits to participants

- These must be realistic. If there are no direct benefits to participant or the community then that is sometimes ok, but you must be clear about this and ensure the risk- benefit relationship is favourable.
- Reimbursement of time cannot be considered a benefit.
- Any e.g. MCRI/RCH policies on gift cards. If e gift cards are to be provided as a token of appreciation these must be identified in the protocol.

2.3 Confidentiality

- You must outline the methods used for protecting privacy of participants and their data (such as the means used to securely store personal information (hard copy or electronic); limiting the amount or restricting access to personal information on a need-to-know basis; the use of study IDs; the storage of identifying information separate from personal/health information)
- Where data will be stored and for how long should be specified.
- How the data will be destroyed at the end of the required period should also be included.

2.4 Informed consent – how consent will be obtained, from whom (participant or parent/guardian/proxy) and by whom.

- Try and tell the complete story about how consent will be obtained. If using different methods e.g. verbal, written, opt-out or implied make sure you tell the ethics reviewer how this will occur from initial approach, consent discussion and any follow up.
- If using verbal consent, how will this be documented?
- Proposed methods of obtaining consent can be discussed with the REG department prior to an application being submitted.

2.5 Any risks to researchers, and researcher safety plan

- A risk management plan should be included in the protocol. This plan should address processes for participant safety and staff safety.

3. PEER REVIEW

- Qualitative and mixed methods research projects should ideally have peer review by a researcher with qualitative experience. A list of researchers who have made themselves for peer review is available from qual.research@mcri.edu.au

4. REPORTING STANDARDS AND APPRAISAL TOOLS FOR QUALITY IN QUALITATIVE AND MIXED METHODS RESEARCH

- The following checklists are available. Please refer to these documents before you start your project.
    - **COREQ** Consolidated criteria for reporting qualitative research
    - **SRQR** Standards for Reporting Qualitative Research
    - **CASP** Critical appraisal skills program checklist
    - **GRIPP2** Reporting checklists: tools to improve reporting of patient and public involvement in research

5. SOME HELPFUL HINTS FOR FOCUS GROUPS BASED ON FREQUENTLY ASKED QUESTIONS

5.1 Focus groups

- Can use non-written consent processes. If audio recording, record the reminder that it is a research project, participants have the right to withdraw prior to the interview commencing and the ground rules of the focus group.
- You do not have to make it possible to identify individual participants for the purposes of enabling participants to withdraw their data later. Just need to inform participants that after you have participated in a focus group it is not possible to withdraw data later.
- Protocols including focus groups should include a paragraph about the limitations to confidentiality (example from RCH PICF Standard wording document)

5.2 Statement about confidentiality in focus groups for inclusion in ethics protocols

Confidentiality

We will ask that you and the other participants keep the group discussions private. In other words, you and the other participants should not share anything that is said in the group discussions. However, we cannot guarantee that everyone will keep these discussions private. You should keep this in mind when you share things with the group.

6. FACTSHEETS

Several factsheets and resources have been developed to support researchers with qualitative research.

You can find links here:
Factsheet:ChatGPT - some interim guidance
Using Dictaphones securely for research
Using human transcription companies
Web based transcription services