



U-M Qualitative Research Protocol Checklist

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The **bolded items below** represent information the institutional review board (IRB) expects in a protocol for this type of research. The non-bolded items should be included in the research protocol as applicable and are considered best practice.

STUDY INFORMATION

High-level detail about the study and Principal Investigator (PI)

Study title (must match title in eResearch)

Date of initial protocol version

Dates of subsequent protocol versions

Protocol version number

PI name, contact information, U-M department affiliation

PI responsibilities

Specialized training, skills, or qualifications required for study team members

Sponsor information

Statement of compliance

PROTOCOL SUMMARY

Brief overview of the study

Study description/synopsis (table or abstract), **including the hypothesis(es) or research question**

Primary study objective (include secondary objective, as applicable)

Endpoints (measurable outcome) **for the objectives**

Study duration

Study location(s)/centers (types, multi-site indication)

SCHEDULE OF ACTIVITIES

Display of procedures that will be accomplished for each interaction with study participants. Include visits, contacts/touchpoints and timeframes.

Schedule of Events (table, abstract, list, flowchart format acceptable)

BACKGROUND & RATIONALE

Overview of the relevant background information and rationale for the study. It should include a clearly stated research question or study purpose.

Study background (key information/data that contributed to the research question)

Research question, detailing as applicable:

Study rationale

Justification for interactions/interventions

Objectives, hypotheses, study aims

Outcomes/endpoints details

STUDY POPULATION

Description of study population.

Anticipated enrollment numbers (n) and attrition

Age range of study population

Inclusion/exclusion criteria and how they will be applied

Any expected changes in legal or cognitive capacity of participants (e.g., children coming of legal age, adults with dementia)

STUDY DESIGN

Description of the research methods and procedures.

Overview of study design

Randomization & allocation of participants

Interaction/Intervention details

Number of expected sites and list of participating sites

Plan for communicating among sites (data, protocol modifications, etc.)

RISKS & BENEFITS

Description of any physical, psychological, social, legal, economic, or other risks to participants and potential benefits to participants or others.

Known potential risks to participants and likelihood of their occurrence

Known potential benefits to participants, community or society

Assessment of risk/benefit ratio

Risk mitigation plan

RECRUITMENT

Description of how, when, and who will recruit, methods for recruitment, and where recruitment will occur. Note: DEI considerations should be incorporated.

Planned recruitment strategies

Identification and approach of potential participants

Pre-screening activities

Use of any established subject pools

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INFORMED CONSENT/ASSENT

Description of the process of obtaining consent and/or assent.

Informed consent/assent process (who, what, when, where, and how)

Recording/documentation of consent/assent

Justification for waiver of documenting consent/assent

CONFIDENTIALITY AND PRIVACY

Describe practices and strategies for preserving and supporting participant privacy and confidentiality of study data

Plans to ensure privacy during research activities

Plans to maintain confidentiality after collection of data

DATA ANALYSIS PLAN

Describe the general approach to data analysis, including the coding, interpretation and reporting of the study data.

Data analysis method(s)

Sample size/sampling strategies

Justification of sample size

Data identification, and plans for de-identification

Data organization methods (coding, identifiers, metadata)

Data storage methods and timeframes, including access and archiving considerations

Data collection and management responsibilities

DATA MANAGEMENT AND SHARING

Plans for sharing

Names of data repositories used for sharing

Description of data to be shared

STUDY COMPLETION/ OFF STUDY CRITERIA

Describe the criteria for the completion of the study and next steps.

Criteria for an individual participant's completion of the study

Plan for participant's data and/or specimens upon withdrawal

Subject replacement plan

Plan for early termination or suspension of the study

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ADVERSE EVENTS & UNANTICIPATED PROBLEMS

Identify how the study team will report adverse events, etc. to the IRB and/or others, as applicable.

AE Reporting Timetable

Grading and/or Adjudication regarding type of event

PROTOCOL DEVIATIONS

Describe protocol deviation reporting plan and planned deviations.

Deviation Reporting plan

Planned deviations

REFERENCES

Citations and References

List of abbreviations

Appendices