# Instructions to use this template

**Remove this page before finalizing and distributing this protocol.**

Qualitative research includes collecting and analyzing non-numerical data to understand concepts, opinions, or experiences. This contrasts with quantitative research, which includes collecting and analyzing numerical data for analysis.

Qualitative human subjects research is most common in the social sciences and humanities and often uses data collected from interviews, written responses, historical texts, and observation.

Use the U-M Qualitative Research Protocol Checklist in conjunction with this template to ensure that all required elements are represented in your research protocol.

## Formatting the Protocol Document

Where appropriate, use cross-references to sections of the protocol, rather than duplicating text. Do not reorder protocol sections or subsections, as the order provides consistency and aids IRB review.

If it is necessary to add subheadings in a section for clarification or emphasis, use the appropriate heading level (e.g., heading 2 or lower) so that they will be included when the table of contents is updated.

*Italic text* indicates **instruction or explanatory text** that provides information on the content to be included in the protocol. Delete this text prior to protocol submission to the IRB.

[Text in brackets] indicates **example text**. Modify the text to suit the research, or delete it if it is not relevant.

<Text in angled brackets> indicates **data entry**. Replace the text, removing the angled brackets.

If a particular section is not applicable to the research, indicate so by entering “N/A”.

Version control is important to track protocol development, revisions, and amendments, and to ensure that the most recently updated and IRB approved version of a protocol is used by all staff conducting the study. **With each revision, update the version number and date located in the header of each page**. When making changes to an IRB approved protocol, maintain the amendment history in the **Protocol Amendment History** section.

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# 

# 1. Study Information

## 1.1 Protocol Title and Version Information

<Study Title>

*The title should identify (as applicable) the study population, what is being evaluated, and interaction(s) being utilized. The title must match the title entered in eResearch for the study.*

Study ID #: <HUM#, as applicable>

Current Version Number: v.<#>

Current Version Date: <MM/DD/YYYY>

*For protocol version history, see Section 15.3*

## 1.2 PI Information

Principal Investigator: <Name>

PI Contact Information: <Address, email, phone>

PI Department Affiliation: <School/College, Department Name>

PI Responsibilities

<insert text>

Specialized Skills Required (as applicable)

*List any unique or specialized skills that are required of study team members to conduct the research.*

<insert text>

## 1.3 Sponsor Information

Study Sponsor: <Name>

Grant Title: <Name>

Grant Number: <PAF# or AWD #, as applicable>

## 

## 1.4 Statement of Compliance

*Provide a statement that the study will be conducted in compliance with the applicable regulations and guidelines. Indicate whether any study team members have any conflicts of interest and describe how these conflicts will be managed to reduce or eliminate bias to the study.*

[This study will be conducted in compliance with the protocol, the federal regulatory requirements of United States (US) Code of Federal Regulations (CFR) 45 CFR Part 46, and applicable state and local laws.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) will be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

All personnel involved in the conduct of this study have completed Human Subjects Protection training].

<insert text>

# 2. Protocol Summary

## 2.1 Study Description

*Provide a short description of the research. Details should be included in the body of the protocol. It may be useful to complete this section after the related sections in the protocol have been completed.*

*Include, as applicable:*

* *A brief study* ***description/synopsis****, including the hypothesis(es) or research question. A table, abstract, or study schema (i.e., flowchart, diagram) format is acceptable.*
* *The primary and secondary* ***objectives*** *of the research*
* *The primary* ***endpoint or outcome*** *of the study*
* *The study* ***duration*** *(estimated time in months from when the study opens to enrollment until completion of data collection). If applicable, label each* ***phase*** *of the project and list the duration of each phase.*
* *The* ***study population****,* ***sample size****, and key characteristics (e.g., gender, age, demographic group). Include other descriptive details (e.g., general health status, geographic location) as pertains to the research.*
* *A description of the study location(s)/center(s), including an indication of whether the participating sites are engaged in the research and using the same protocol (i.e., multi-site study)*

<insert text>

## 2.2 Schedule of Activities

*List or display the schedule of study activities (e.g., visits, contacts/touchpoints with participants, screening procedures, etc.). Include:*

* *Only those procedures that contribute to participant eligibility, study objectives and endpoints.*
* *The expected window of time for each activity (e.g., day 4 +/- 2 days, weeks 2-5, Month 1, 1st trimester, post-interaction 1 month), as applicable to the study.*

*A table, abstract, or study schema (e.g., flowchart) format is acceptable. Details about the procedures should be specified elsewhere in the protocol.*

*The schedule below in table format is provided as an example. Modify or replace as appropriate.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Data Collection  Procedures / Tasks / Touch Points | [Weeks 1-2] | [Weeks 2-5] | [Weeks 3-8] | [Weeks 4-10, 1 month] | [Day 70 +/- 7] | [Weeks 8 -12] |
| [Recruitment / Eligibility Screening] | *x* |  |  |  |  |  |
| [Informed Consent] |  | *x* |  |  |  |  |
| [Interaction #1 - e.g., survey] |  |  | *x* |  |  |  |
| [Interaction #2 - e.g., visit] |  |  |  | *x* |  |  |
| [Follow-up visit] |  |  |  |  | *x* |  |
| [Post project survey] |  |  |  |  |  | *x* |

# 3. Background & Rationale

## 3.1 Background & Significance

*Describe the existing key information or data that contributed to the development of the research question for this study, including any relevant literature or data that provides background or context for the study.*

<insert text>

## 3.2 Research Question

*State the problem or question being addressed with the research. Detail, as applicable, the:*

* ***Rationale*** *for conducting the research and the* ***justification*** *for the use of any interaction, including the hypothesized target(s) of the interaction (i.e., the supposed cognitive, affective, behavioral, social, community, organizational, etc., target necessary to produce the outcome of the research)*
* ***Objectives, hypothesis, or study aims***

<insert text>

## 3.3 Outcomes/Endpoints

*Study outcomes/endpoints should be prioritized and should correspond to the study objectives or hypotheses being tested. Define the specific criteria used to assess the study’s hypotheses or objectives.*

<insert text>

# 4. Study Population

*Describe the study population. Include, as applicable:*

* *Enrollment considerations, including anticipated enrollment numbers (n)*
* *Anticipated attrition rate or estimated number of participants who will not complete the study (required)*
* *Age range of the participants (required)*
* *Description of any vulnerable participants*
* *Expected changes in the legal or cognitive capacity of the participants*

<insert text>

## 4.1 Inclusion Criteria

*Inclusion criteria are the characteristics that every potential participant must satisfy to qualify for study entry. The number and type of criterion will depend on the research question and the complexity of the study. Some criteria to consider for inclusion are the demographic and/or geographic characteristics of the study population and community (e.g., age, gender, race, ethnicity, marital status, education, language, occupation). Additional criteria should be included as appropriate for the study design and level of risk with the goal of being broadly inclusive while still supporting the science and protecting subjects’ safety.*

* *Identify the criteria used to determine the study population and describe how the criteria will be applied.*
* *Provide a statement that individuals must meet all of the inclusion criteria in order to be eligible to participate in the study and then list each criterion.*

<Insert inclusion criteria>

## 4.2 Exclusion Criteria

*Exclusion criteria are characteristics that make an individual ineligible for study participation, such as factors that would cause harm or increased risk to the participant, or that preclude the participant’s full adherence with or completion of the study. Exclusion criteria should be appropriate for the study design and level of risk to participants.*

* *Provide a statement that all individuals meeting any of the exclusion criteria will be excluded from study participation and then list each criterion.*
* *Provide a justification if specific populations will be excluded from the study to establish that inclusion is inappropriate with respect to the health/safety of the participants or for the purpose of the research.*

<Insert exclusion rationale and justification>

# 5. Study Design

## 5.1 Design

*The scientific integrity of the study and the credibility of the data from the study depend substantially on the study design. Provide an overview of the study design and type and methods (e.g., single group, grounded theory, ethnographic, narrative research, phenomenological, participant observation). This section should be consistent with the study summary, but be more detailed.*

*Specify, as applicable, the:*

* ***Type/design*** *of the study*
* ***Number of groups/arms*** *and, if applicable, stratification criteria*
* ***Duration*** *of study interaction and follow-up period(s)*
* *Use of* ***control groups*** *with rationale for use and limitations*
* *Method for* ***randomization and allocation*** *of participants into study groups/arms. If randomization is used, specify the following:* 
  + *Specify allocation ratio, unit of randomization, allocation concealment, and timeline*
  + *Who (i.e., what role) will generate and implement the randomization schema*
  + *How randomization errors be handled*
* *Number of, name, and location of* ***participating sites*** *(i.e., site where someone will be engaged in the research, not limited to data analysis). Specify if the site is international.*
  + *Plans for communicating data and protocol modifications among participating sites*

<insert text>

## 5.2 Interaction/Intervention Details

*Describe the mode of interaction/intervention delivery, including the length, number, and frequency of participant contact. If an interaction/intervention has been adapted for a particular culture, provide justification for these adaptations being culturally relevant. Briefly describe the minimum-acceptable participation in, or exposure to, the interaction in order to have evaluable data.*

<insert text>

# 6. Risks & Benefits

## 6.1 Known Risks

*Describe any physical, psychological, social, legal, economic, or any other risks to participants that the Principal Investigator (PI) foresees based on participating in the study, addressing both immediate and long-term risks. If identifiable information is collected, include any risk to a breach of confidentiality. For qualitative research involving behavioral or social interaction/intervention, review the relevant published literature for relevant risk information.*

<Insert text>

## 6.2 Known Potential Benefits

*Describe any physical, psychological, social, legal, or any other potential benefits to individual participants or society in general, addressing both immediate and long-term benefits. Previous related research can assist in the identification of known potential benefits for the study.*

*Payment to participants, whether as inducement to participate or as compensation for time and inconvenience, is not considered a benefit.*

<Insert text>

## 6.3 Risk/Benefit Ratio Assessment

*Include an assessment of known potential risks and benefits, addressing each of the following:*

* *Rationale for the necessity of exposing participants to risks*
* *A summary of the ways that risks to participants are minimized in the study design*
* *Justification as to why the value of the information to be gained outweighs the risks of participation in the study*

<Insert text>

# 7. Recruitment

## 7.1 Planned Recruitment Strategies

*Identify the general strategies for participant recruitment and retention (e.g. use of research participant pools, patient advocacy groups, online recruitment services, community advisors, national newspaper, local flyers). Include rationale for why the strategy will be appropriate for reaching the targeted study population. Consider, as applicable:*

* *Including strategies adapted to the cultural context of the study or population*
* *Strategies for ensuring an equitable study population*
* *If recruitment or data collection procedures occur in a public setting, or as community-based outreach, or other similar settings, describe a plan for ensuring participants’ and study staff’s safety*
* *Specific strategies that will be used to recruit and retain historically under-represented populations in order to target sample size and conform with sponsor or institutional policies and guidelines*
* *For multi-site studies, description and number of recruitment sites (e.g., inpatient hospital setting, student health service, community center), and anticipated number of participants to be recruited from each site*
* *If the study requires multiple visits, describe the procedures that will be used to enhance participant retention (e.g., multiple methods for contacting participants, visit reminders, incentives for visit attendance)*

*Specify as applicable:*

* *Use of established subject pools and anticipated number of participants from the pool*
* *Use of incentives to compensate participants (financial or non-financial), including the type, amount, and timing of such compensation in relation to study activities*
* *Steps to minimize coercion or undue influence*
* *Who, other than the participant, may receive the incentive (e.g., parent/guardian, legally authorized representative)*
* *The justification for the inclusion of vulnerable participants in the recruitment strategy. Include safeguards for protecting the vulnerable population(s).*

<Insert text>

## 7.2 Identification of and approach to potential participants

*Describe any pre-screening activities and the procedure(s) to be used to identify potential participants for eligibility.*

<Insert text>

# 8. Informed Consent/Assent

## 8.1 Informed Consent/Assent Process

*Prior to the beginning of the study, the investigator must have the IRB’s written approval for the protocol and the informed consent form(s) and other written information to be provided to the participants. Follow the applicable regulatory requirements for informed consent/assent (i.e., 45 CFR Part 46.116 and 46.117). This section should be consistent with the Recruitment section of the protocol.*

*Describe the procedures for obtaining informed consent of study participants and/or the procedures for obtaining children’s assent with parental or legally authorized representative (LAR)* *permission. Indicate who (study team role) will conduct the consent process, where, and how. Include, as applicable:*

* *Any special circumstances regarding obtaining consent, including considerations for children or other vulnerable participants*
* *Plans for obtaining consent from speakers of language other than English*
* *Procedures for determining competency and assessing comprehension/understanding*
* *Procedures for obtaining surrogate consent for those unable to consent on their own behalf*
* *Re-consent processes for children who become adults or are emancipated during a study*
* *Justification for a waiver of informed consent with potential participants*

*Example text, customize as needed:*

[Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study interaction/intervention.]

<insert text>

## 8.2 Informed Consent/Assent Documentation Process

*Describe the procedures for recording/documenting the informed consent of study participants and/or parental or legally authorized representative (LAR)* *permission.*

*Include as applicable:*

* *An indication of the use of special documents or materials (e.g., Braille, another language, audio recording).*
* *Justification for a waiver of documenting consent with participants (i.e., signatures of participants are not collected during the consent process)*

<insert text>

# 9. Confidentiality and Privacy

## 9.1 Plans to Ensure Participant Privacy

*Describe the processes that will be used to protect participant privacy during the recruitment process and the interactions/interventions.*

* *Consider what reasonable assumptions can be made about a participant's privacy given the study's methods (e.g., focus group or other observational method) and/or the location of intervention/interaction (e.g., research visits occurring in a home, school, or online).*
* *If the research data will be protected by a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH) or other federal agency, include information about the CoC.*

*Example text provided as a guide, customize as needed:*

[To further protect the privacy of study participants, this study will be/has been issued a Certificate of Confidentiality (CoC) to all researchers engaged in the research. The CoC protects researchers and institutions from the forced disclosure of participants' individually identifiable information, sensitive research information, records, or data to anyone not associated with the research, except in certain instances when federal, state, or local law or regulation requires disclosure. The study team will inform research participants of the protections afforded to them by the CoC through the informed consent process.]

<insert text>

## 9.2 Plans for Participant Data Confidentiality

*Identify and describe the procedures for maintaining the confidentiality of the participants’ data throughout and after the study. Indicate:*

* *Who (general study team roles) will have access to records, data, and samples*
* *Data security measures and requirements*
* *The record retention requirements per the sponsor, funding agency, and/or institution.*
* *Whether identifiers will be attached to data/samples, or whether data will be coded or unlinked*

*Consider:*

* *If additional information is available that might make identification of unlinked or coded data identifiable.*
* *If research data/samples will be coded, describing how access to the “key” for the code will be limited. Include description of security measures (password-protected database, locked drawer, other) applied to protect the code key. List the positions of persons with access to the code key.*
* *Describing any situations in which personally identifiable information will be released to third parties*
* *If monitors or auditors outside of study investigators will need access to records, data, and/or samples*

<insert text>

# 10. Data Analysis Plan

*Describe how procedural and interpretive rigor will be monitored and maintained. Outline the organization, management, coding, interpretation, and reporting of qualitative data. Specify the:*

* *Type (content analysis, thematic analysis, narrative analysis, grounded theory analysis, or discourse analysis), purpose and objectives of the data analysis,*
* *Estimated number of participants and observations. As applicable, justify how the numbers are adequate to address the research question.*
* *Sources and types of data used,*
* *Whether data is identifiable and, as applicable, plans and methods for data de-identification,*
* *Procedures for data management and storage,*
* *Methods for coding and categorization,*
* *Techniques for interpretation and synthesis,*
* *Formats for presenting and reporting the data.*

<insert text>

# 11. Data Management and Sharing

*Identify the circumstances in which study data and/or biospecimens will be shared with other researchers (i.e., who will have access, how the data will be shared). Indicate if you have a separate Data Management and Sharing Plan (DMSP), or describe the plan for the sharing of participants’ data in accordance with the confidentiality and privacy measures. As applicable:*

* *Describe the data that may be shared outside of the study team. This includes sharing with sponsors, companies, other researchers, or any entities not on the study team.*
* *Describe whether shared data will be identifiable or de-identified*
* *State any criteria that will be used to determine with whom data may be shared*
* *Identify any relevant publication and data sharing policies (federal, sponsor, and/or institutional) by which the study will abide (e.g., NIH Data Sharing and Management plan). Refer to the study’s contract, grant, or agreements, as applicable.*
* *If details of the publication policy will be described in the study’s Manual of Operations (MOP), refer to it here.*
* *List any data repositories that will be used to store, maintain and share the data.*

<insert text>

# 12. Study Completion/Off Study Criteria

*List the criteria used to determine:*

* ***Participant completion*** *of the study. This information should be consistent with the informed consent documentation.*
* ***Participant withdrawal/discontinuation by the PI/study team****. If there are distinct withdrawal criteria for one or more cohorts, list them separately by adding a subheading for each and clearly state the difference(s) between the groups.* 
  + *State any methods the study team will implement to verify that participants are attentive (i.e., attention check questions in a survey) or are human (i.e., methods to screen out bots or artificial intelligence) that may lead to withdrawal of participants.*
  + *Indicate how the participant discontinuation/withdrawal will be recorded.*
  + *Describe how the data from withdrawn participants will be handled in the analysis of study data.*
  + *Indicate whether withdrawn participants will be replaced to maintain the sample size.*
  + *If a study uses online data collection, indicate criteria that will be used to identify and remove automated form fillers (e.g., bots) or bad-faith actors as participants.*
* ***Early termination or suspension of the study*** *(e.g., study closure based on the decision of the PI, sponsor/funder, or regulatory or other oversight body; the review of serious, unexpected, and related AEs; noncompliance; futility).* 
  + *Describe the plan to inform the study participants, the IRB, and the sponsor of the early termination or temporary suspension of the study.*

*Example text provided as a guide, customize as needed:*

[Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:

* <list reasons>

The reason for participant discontinuation or withdrawal from the study will be recorded on <specify documentation>.]

[Participants who sign the informed consent form but do not receive the study interaction/intervention may be replaced.

Subjects who sign the informed consent form and receive the study intervention, and subsequently withdraw voluntarily, or are withdrawn or discontinued from the study by the study team, <will> *or* <will not> be replaced.]

<insert text>

# 13. Adverse Events and Unanticipated Problems

*Indicate whether the study will use a Standard U-M IRB AE* ***reporting timetable*** *(e.g.,* [*IRB-HSBS timetable*](https://research-compliance.umich.edu/sites/default/files/resource-download/ae_standard_timetable_2.7.2020_final_0.pdf)*,* [*IRBMED timetable*](https://az.research.umich.edu/sites/default/files/Adverse%20Event%20Reporting%20Guidelines%20for%20INTERNAL%20AEs%20Occurring%20at%20UM_1152018%20OUTWARD%20facing.pdf)*) or a study-specific AE reporting plan.*

*If the latter, provide details below or include as a separate document.*

* *As applicable to the study, define the adverse events. Consider the risks of the study interactions/interventions, other study procedures, and the characteristics of the study, including but not limited to the following:*
  + *Risks to individuals other than research participants (e.g., household or intimate contacts, communities, study personnel)*
  + *Mandatory reporting requirements for certain events (e.g., suspected child abuse or substance abuse) that may be discovered because of the study population or study design characteristics*
  + *The study is conducted at multiple sites, and will require centralized safety oversight*
  + *The study involves a population at heightened risk of serious adverse events (e.g., participants at heightened risk of suicide, clinical deterioration, etc.)*
* *How an adverse event will be* ***assessed****, including the criteria to determine the AE’s severity and its relatedness to the study intervention/interaction, the method of assessment, and identify who is responsible for the assessment. Examples of methods include a binary assessment (e.g., related/not related) or a scale of relatedness (e.g., definitely related, probably related, possibly related, unlikely to be related, not related).*

<insert text>

# 14. Protocol Deviations Reporting Plan

*Specify the protocol deviation reporting plan.*

*Example text provided as a guide, delete or customize as needed:*

[It will be the responsibility of the study investigators to use continuous vigilance to identify and report deviations to appropriate individuals. All deviations will be addressed in study source documents. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.]

<insert text>

# 15. References

## 15.1 Citations and References

*List the relevant literature and citations for all publications referenced in the text of the protocol. Use a consistent, standard, modern format, which might be dependent upon the required format of the anticipated journal used for publication of the study.*

*Example text provided as a guide, customize as needed:*

* **[Journal citation**  
  Veronesi U, Maisonneuve P, Decensi A. Tamoxifen: an enduring star. J Natl Cancer Inst. 2007 Feb 21;99(4):258-60.
* **Whole book citation**  
  Belitz HD, Grosch W, Schieberle P. Food chemistry. 3rd rev. ed. Burghagen MM, translator. Berlin: Springer; 2004. 1070 p.
* **Chapter in a book citation**  
  Riffenburgh RH. Statistics in medicine. 2nd ed. Amsterdam (Netherlands): Elsevier Academic Press; c2006. Chapter 24, Regression and correlation methods; p. 447-86.
* **Website citation**Complementary/Integrative Medicine [Internet]. Houston: University of Texas, M.D. Anderson Cancer Center; c2007 [cited 2007 Feb 21]. Available from: http://www.manderson.org/departments/CIMER/.
* **Electronic Mail citation**

Backus, Joyce. Physician Internet search behavior: detailed study [Internet]. Message to: Karen Patrias. 2007 Mar 27 [cited 2007 Mar 28]. [2 paragraphs]]

<insert text>

## 15.2 Abbreviations and Special Terms

*List any abbreviations and their definition used in this protocol. Special terms are those terms used in a specific way in the protocol. A table format or a bulleted list is acceptable, but use a consistent format.*

<insert text>

## 15.3 Protocol Change Log

*The table below is intended to capture changes to the IRB-approved versions of the protocol, including a description of the change and rationale. Add rows to the table as needed.*

*Version control is important to track protocol development, revisions, and amendments. Always ensure that the most recently IRB approved version of a protocol is used by all staff conducting the study. With each revision, update the version number and date located in the page header.*

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Version | Date of Change | Description of Change | Brief Rationale |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |