# Instructions to use this template

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

Use the **U-M Non-FDA Regulated Clinical Trials 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 intervention/interaction(s) being utilized. The title must match the title entered in eResearch for the study.*

Study ID #: <HUM#, as applicable>

Current Protocol Version Number: v.<#>

Current Protocol Version Date: <DD/MM/YYYY>

*For protocol version history, see Section 16.3*

## 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

*Summarize the overall study plan. 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.*
* *The primary and secondary* ***objectives*** *of the research*
* *The primary* ***endpoint*** *of the study (i.e., what will be measured to assess whether an interaction/intervention will is beneficial)*
* *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.*
* *An indication of whether the clinical trial is a multi-site study (i.e., the participating sites are engaged in the research and using the same protocol)*

<insert text>

## 2.2 Schedule of Activities

*List or display the schedule of clinical trial activities (e.g., visits, contacts/touchpoints with participants, screening procedures, randomization/stratification 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-birth 1 month), as applicable to the study.*

*A table, abstract, or study schema (e.g., flowchart, CONSORT or STROBE diagram) 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] | [Weeks 12-20] | [Weeks 18-25] |
| [Recruitment / Eligibility Screening] | *x* |  |  |  |  |  |  |  |
| [Informed Consent] |  | *x* |  |  |  |  |  |  |
| [Interaction #1 - e.g., survey] |  |  | *x* |  |  |  |  |  |
| [Intervention #1 - e.g., biospecimen collection] |  |  |  | *x* |  |  |  |  |
| [Chart Review] |  |  |  |  | *x* |  |  |  |
| [Intervention #2 - e.g., biospecimen collection] |  |  |  |  |  | *x* |  |  |
| [Follow-up visit] |  |  |  |  |  |  | *x* |  |
| [Phone 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 the clinical trial, including any relevant literature or data that provides the clinical, epidemiological, or public health background or context for the clinical trial. Indicate the importance of the clinical trial and any relevant treatment issues or controversies.*

<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*
* ***Justification*** *for the use of any intervention/interaction, including the hypothesized target(s) of the interaction/intervention (i.e., the supposed cognitive, affective, behavioral, social, community, organizational, etc., target necessary to produce the behavior change relevant to the clinical outcome), and the clinical outcome of interest.*
* ***Objectives, hypothesis, or study aims***

<insert text>

## 3.3 Outcomes and Endpoints

*Study outcomes/endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested. List and describe the specific procedures and measurements, or observations used to assess the study’s interactions/interventions (e.g., specific diagnostic tests that define safety or efficacy, clinical assessments of disease status, assessments of psychosocial characteristics, patient reported outcomes, behaviors or health outcomes). Include the study visits or points of time at which data will be recorded or biospecimens will be obtained.*

*A table format is acceptable.*

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

|  |  |  |
| --- | --- | --- |
| **OBJECTIVES** | **ENDPOINTS/OUTCOMES** | **JUSTIFICATION FOR ENDPOINTS** |
| <Primary Objective> |  |  |
| <Secondary Objective(s)> |  |  |
| <Exploratory Objective(s)> |  |  |

<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*
* *Age range of the participants*
* *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 clinical study design, type, and methods (e.g., randomized, attention-control, multiple baseline, A-B-A design, dismantling, adaptive, SMART design, optimization, repeated measures, superiority, equivalence, noninferiority, exploratory, parallel groups, cross-over, factorial, single group, step-wedge, etc.).*

*This section should be consistent with the study summary, but be more detailed.*

*Specify, as applicable, the:*

* ***Type, design, and framework*** *of the study*
* ***Number of groups/arms*** *and, if applicable, stratification criteria*
* ***Duration*** *of study interaction/intervention 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*
* *Use of* ***blinding*** *(masking) to minimize performance/assessment bias and the type (e.g., single, double, etc.). If blinding will be used, specify:*
  + *Blinding methods and procedures*
  + *Plans for maintaining appropriate blinding*
  + *When unblinding may occur and who may unblind the study data, including the criteria and circumstances (e.g., serious adverse event) for unblinding.*
* *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. Indicate if the sites will be using the same study protocol (i.e., study is a multi-site trial).*
  + *Describe the plans for communicating data and protocol modifications among participating sites*

<insert text>

## 5.2 Interaction/Intervention Details

*Describe the study interaction(s)/intervention(s), including any control or comparison conditions being used in the clinical trial. Indicate 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/intervention in order to have evaluable data. As applicable, indicate how the participants’ adherence with study procedures will be tracked to assure active participation in the study.*

<insert text>

## 5.3 Permitted and Prohibited Alternative Procedures

*As applicable, identify any relevant alternative or complementary (i.e., concomitant) procedures, treatments, or therapies that will be permitted or prohibited for participants during the clinical trial or in place of a specific interaction/intervention. For permitted alternatives, detail:*

* *What data will be collected,*
* *When the information will be collected (e.g., screening, all study visits)*
* *How the concomitant might affect the outcome, and*
* *How the effects of concomitant can be ascertained from the effects of planned study interactions/interventions.*

*If applicable, identify and detail any plans for the use of a “rescue therapy” (i.e., type of treatment given to a participant if their condition doesn't respond to standard therapy).*

## 5.4 Investigator Fidelity

*Summarize the plans for the training of investigators and monitoring of interactions/intervention delivery to ensure consistent administration (fidelity) of the interaction(s)/intervention(s), especially if the study’s objectives involve variability in delivery of the interaction/intervention (e.g., comparisons of intensity, delivery by person vs. machine or remote application).*

<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 clinical trial, addressing both immediate and long-term risks and the likelihood of occurrence. Previous related research can assist in the identification of known risks for the study.*

<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 risks and potential benefits, addressing each of the following:*

* *Rationale for the necessity of exposing participants to risks*
* *The risk mitigation plan, summarizing 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

*Describe how, when, and who will recruit participants for the study. Identify 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) and indicate where recruitment will occur. Include rationale for why the strategy will be appropriate for reaching the targeted study population. Consider, as applicable:*

* *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 ensure the recruitment and retention of participants who are representative of populations impacted by the research*
* *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*
* *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.*

*Consider, as applicable:*

* *The anticipated number to be screened in order to reach the target enrollment indicated in the Study Population section.*
* *Providing a breakdown of the anticipated enrollment number by specific category (e.g., gender, race and ethnicity, age, group)*
* *Indicating the anticipated accrual rate over the course of the study, including a breakdown by any key participant characteristics such as by sex, age, or racial or ethnic minority group (e.g., 5 parent-child dyads per month over 24 months)*
* *How screen failures (i.e., participants who consented, but do not meet one or more criteria for participation) will be handled, including conditions and criteria for re-screening, if applicable.*

<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/assent process, where, and how. Include, as applicable:*

* *Any special circumstances regarding obtaining consent/assent, including considerations for children or other vulnerable participants*
* *Plans for obtaining consent/assent 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 and criteria (e.g., 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/assent 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 how participant privacy will be maintained during the process of identifying and contacting potential participants and during any study interactions/interventions.*

* *Consider what reasonable assumptions can be made about a participant's privacy given the study's methods and/or the location of intervention/interaction (e.g., research visits occurring in a home, school, online, lab, or exam room).*
* *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 to Ensure 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

*List and describe the statistical tests, assessments, and analysis plans, indicating how the study will answer the research questions with precision and with a minimum level of bias. If the study also includes qualitative data, describe how procedural and interpretive rigor will be monitored and maintained.*

*Specify:*

* *The type (e.g., descriptive, diagnostic, predictive, prescriptive, exploratory, inferential, casual, mechanistic), purpose and objectives of the data analysis,*
* *The sample size/accrual target. As applicable, provide a justification/power analysis describing how the study’s sample size/accrual target is adequate to address the research question.*
* *The sources and types of data used,*
* *Whether data is identifiable,*
* *The methods for coding and categorization,*
* *The techniques for data interpretation and synthesis,*
* *The formats for presenting and reporting the data,*
* *If applicable, state any plans for periodically analyzing collected data for safety, effectiveness, or other reasons (i.e., interim analysis).*

<insert text>

# 11. Data Management and Sharing

## 11.1 Data Management Plan

*Define the plan for the organization, documentation, storage, and* [*preservation*](https://nnlm.gov/guides/data-glossary/data-preservation) *of the clinical trial data. Indicate if you have a separate Data Management and Sharing Plan (DMSP), or describe the data management plan, specifying as applicable:*

* *The types and amount of data, including descriptive elements such as the modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing required,*
* *Whether data is identifiable and, as applicable, plans and methods for data de-identification,*
* *Data storage methods, including the tools, software and/or code needed to access, process, and store/archive the data,*
* *The associated metadata (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation),*
* *Data availability, including length of time data will be stored. As applicable, identify the availability for each subset of data.*
* *The name of the repository(ies) where data and metadata will be archived,*
* *Data access, distribution, or reuse considerations,*
* *Data collection and management oversight responsibilities, including frequency of monitoring, by whom (i.e., study team role), etc.*

<insert text>

## 11.2 Data Sharing Plan

*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 and/or biospecimens 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 noted in the Confidentiality and Privacy section of the protocol. As applicable:*

* *Describe the data and/or biospecimens to be shared*
* *Describe whether shared data and/or biospecimens will be identifiable or de-identified*
* *State any criteria that will be used to determine with whom data and/or biospecimens 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. Data Safety and Monitoring Plan

*As applicable, identify how the study’s conduct and progress will be* ***independently monitored for quality assurance*** *(e.g., who will conduct the monitoring, the type, frequency, and extent of monitoring, who will be provided reports of monitoring, whether audits of the monitoring will be conducted).*

* *Indicate if you have a separate Data Safety and Monitoring Plan (DSMP) or describe the monitoring activities intended to protect the safety of the research participants, the validity of the data, and the integrity of the research study.*
* *Indicate whether clinical monitoring/assessments will be conducted to evaluate the health and/or safety of the participants.*

*Consider the nature, size, risk, and complexity of the study to address the monitoring of the following:*

* *Participant safety to avoid or minimize risks (e.g., physical, psychological, or social).*
* *Data integrity to assure data is accurate and complete, and to assure adherence to the approved study.*
* *Participant privacy to assure individuals’ rights are protected.*
* *Data confidentiality to assure data is secured.*
* *Study documentation to assure that required documentation and reports are on file, accurate, and complete.*
* *Study coordination to assure that investigator delegation and communication with the research team is planned and systematic.*
* *Oversight responsibilities of and monitoring activities by an independent party/group such as a Safety Monitoring Committee (SMC), Data Safety Monitoring Board (DSMB), Safety Assessment Committee (SAC), and/or an Independent Safety Monitor (ISM).*

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

[Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB)/Safety Monitoring Committee (SMC) composed of individuals with the appropriate expertise, including <list expertise>. Members of the SMC will be independent from the study conduct and free of conflict of interest. The SMC will meet at least semiannually to assess safety and efficacy data from each arm of the study. The SMC will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the SMC needs to assess will be clearly defined. The DSMB will provide its input to <specify the study sponsor/National Institutes of Health staff/other>.]

<Insert text>

# 13. 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.*
* ***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>

# 14. 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>

# 15. 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>

# 16. References

## 16.1 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>

## 16.2 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>

## 16.3 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 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |