**Observational Study Protocol Template**

*Adapted from: National Institute for Dental and Craniofacial Research (NIDCR), Clinical Study (Observational) Protocol Template,* [*https://www.nidcr.nih.gov/sites/default/files/2018-02/nidcr-clinical-trial-observational-protocol-template.dotx*](https://www.nidcr.nih.gov/sites/default/files/2018-02/nidcr-clinical-trial-observational-protocol-template.dotx)

|  |  |
| --- | --- |
| **Purpose:** | To provide an instructional template for use in development of a protocol for observational studies involving human subjects |
| **Audience/User:** | Principal Investigators and Study Staff |
| **Details:** | In an observational study, the investigator does not assign participants to a specific intervention, but simply records observations and analyzes data. These studies may focus on identifying risk factors for a disease or health condition, or understanding the natural history or factors contributing to variations in disease progression or outcomes. Observational studies often assess specific health characteristics of the enrolled human subjects by collecting demographic or exposure data, quantitative or qualitative data, biospecimens (e.g., for biomarker or genomic analyses), or other measurements from research participants.  Observational studies that collect data from human subjects require Institutional Review Board (IRB) approval. This template will assist investigators in preparing a study protocol that includes all elements required for an IRB to assess study risks and benefits.  Changes to the protocol via an amendment cannot be implemented until IRB approval is received.  The template uses the terms “subject” and “participant” interchangeably, and a protocol author may use either or both terms. |

**Best Practice Recommendations:**

* In the template, instructions for each section are included in *{blue italics}*. Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired. As you complete a section, **delete the instructions.**
* Where sample text is included in standard font, you may include it in your protocol as written or modify as needed for your study. Sample text is set off by the introductory instructional text *{Begin sample text}* and closing instructional text *{End sample text}*. Remove this instructional text if you use the sample text.  
  Note: Sample text may contain additional embedded instructional text. As you complete a section, **delete the embedded instructions.**
* Required protocol text is set off by the introductory instructional text *{Begin required text}* and the closing instructional text *{End required text}*. Remove this instructional text while maintaining the required text in the document.  
  Note: Required text may contain additional embedded instructional text. As you complete a section, **delete the embedded instructions.**
* Text enclosed with < > is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
* It is not necessary to include text under a major numbered heading (e.g., 1, 2) that is immediately followed by numbered subheadings, (e.g., 2.1, 2.2). That is because certain numbered headings are used only for organizational purposes. Text should be entered under all numbered subheadings. See <Insert text> notations for guidance.
* It is easiest and cleanest to use the styles that are embedded in the document, rather than to create your own. In MS Word 2007: From the Home menu, select the bottom right arrow key to bring up the styles box, select “Options”, under “Select Styles to Show” select “in current document.”
* Protocol version control: Primary author controls version number and date, which appear on title page and header/footer of each protocol page. Use 0.1, 0.2, 0.3, etc., for early drafts of the protocol. Once all study team comments have been resolved, re-label last draft version 0.x as final version 1.0 for IRB submission. When drafting an amendment to an IRB-approved protocol, use the protocol whole version number with draft numbers in the decimal. For example, version 2.1 is the first draft of an amendment to protocol version 2.0. When the final draft of this amended protocol is ready for IRB review, change the version number to Version 3.0 before IRB submission.
* Versioning includes both a version number and version date. When the version number and date change, be sure to update them in the header of each section of the protocol.
* Remove these two Overview pages before use.

<Study Title>

Principal Investigator (PI):

**PI contact information:**

IRB Protocol Number:

Funding/sponsor:

Draft or Version Number: <x.x>

<Day Month Year>

STATEMENT OF COMPLIANCE

{If the study is being conducted in the community, and not in a clinical setting, delete the phrase “the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6),” from the paragraph below}

{Begin required text}

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46). All personnel involved in the conduct of this study have completed human subjects protection training.

{End required text}

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LIST OF ABBREVIATIONS

{Add all study-specific abbreviations/acronyms in this section. Modify this list as needed for your particular study and remove abbreviations that are not used in the document.}

|  |  |
| --- | --- |
| AE | Adverse Event/Adverse Experience |
| CFR | Code of Federal Regulations |
| HIPAA | Health Insurance Portability and Accountability Act |
| ICF | Informed Consent Form |
| IRB | Institutional Review Board |
| N | Number (typically refers to participants) |
| PI | Principal Investigator |
| US | United States |

PROTOCOL SUMMARY

{Limit to 1-2 pages; put key words in boldface in Protocol Summary}

|  |  |
| --- | --- |
| **Title:** |  |
| **Short title:** |  |
| **Overview:** | <A brief overview of the study design, including study groups, schedule for specimen or data collection, and analyses to be performed.>  {The overview should be only a few sentences in length. A detailed schematic describing all visits and assessments (schedule of events) should be included as Appendix A.} |
| **Objectives:** | <Insert objectives copied from the body of the protocol. Include the primary objective and secondary objectives and specify outcome measures. Objectives are the same as Specific Aims.> |
|  | Primary: |
|  | Secondary: |
| **Population:** | <Population information, including sample size, gender, age, demographic group, general health status, geographic location.> |
| **Study Sites:** | <Insert a list of sites if 3 or fewer sites; for more than 3 sites, insert the number of sites only, and list the sites in Section 1.> |
| **Study Duration:** | <Estimated time (in months) from when the study opens to enrollment until completion of data analyses.> |
| **Subject Participation Duration:** | <Time it will take to conduct the study for each individual subject.> |
| **Estimated Time to Complete Enrollment:** | <Estimated time from enrollment into study of the first subject to enrollment into study of the last subject.> |

**Schematic of Study Design:**

{The diagram below shows the preferred format and the level of detail needed to convey an overview of study design. Complete each text box with study-specific information and adapt the diagram to illustrate your study design. The time point(s) indicated in the schematic should correspond to the time point(s) in Section 6 of the protocol, Study Schedule, e.g., Visit 1, Day 0; Visit 2, Day 30 ± 7; etc.}

Total N: Obtain informed consent.

Screen potential participants by inclusion and exclusion criteria.

Prior to

Enrollment

Initial assessments

(list specimens to be collected, examinations or measurements

to be performed, questionnaires to be completed)

Visit 1

Time Point

Follow-up assessments

(list specimens to be collected, examinations or measurements

to be performed, questionnaires to be completed)

Visit 2

Time Point

Follow-up assessments

(list specimens to be collected, examinations or measurements

to be performed, questionnaires to be completed)

Visit 3

Time Point

**Final Assessments**

List analyses to be performed

Visit X

Time Point…

# KEY ROLES AND CONTACT INFORMATION

{Provide the following information for each individual:   
Name, degree, title  
Institution Name  
Address  
Phone Number  
Fax Number  
Email}

|  |  |
| --- | --- |
| **Principal Investigator:** | <Site investigator responsible for conducting the study> |
| **Medical Monitor:** | {if applicable} |
| **Site Investigators:** | <if applicable, investigator name, institution> |
| **Institutions:** | {List study sites, laboratory(ies), data coordinating centers, and other departments and/or institutions, as applicable.  Provide the following information for each organization or institution:  Institution Name Address Contact Person/Local Investigator Phone Number Fax Number Email} |
| **Other Key Personnel:** | {Consider listing, for example:   * Major collaborators, if not included as site investigators * Project manager * Statistician} |

# INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

## Background Information

<Insert text>

{This section should include brief background information for this study. Include:

* A brief description of the health problem that the study will address
* Discussion of important research relevant to the study that provides background and scientific justification for the study
* A brief description of the study’s overall goal}

## Rationale

<Insert text>

{Include a description of, and justification for, the need to collect biospecimens, images or other data, the means of collection, collection time frame and selection of study population. Include a statement of the hypothesis.}

## Potential Risks and Benefits

<Insert text>

{Include in Sections 2.3.1 and 2.3.2 a discussion of known risks and benefits, if any, to the participant. Be sure that information in these sections is consistent with your consent document.

NOTE: This information will be used to determine whether an event is “Expected” and therefore not an unanticipated problem requiring expedited reporting.}

### Potential Risks

<Insert text>

{Describe in detail any physical, psychological, social, legal, economic, or any other anticipated risks to study participants. Consider describing inconveniences to the participant, if relevant. Briefly describe measures taken to mitigate risks.}

### Potential Benefits

<Insert text>

{If the research is beneficial, describe any physical, psychological, social, legal, or any other anticipated benefits to participants. While it may not provide direct benefit to participants, the importance of the knowledge that may result from the study may be mentioned.

Note: Compensation to participants is not considered a “benefit.” See Strategies for Recruitment and Retention, Section 5.3.}

# OBJECTIVES

## Study Objectives

<Insert text>

{Provide a detailed description of the one primary objective and any secondary objectives of the study. An objective is the reason for performing the study in terms of the scientific question to be answered. The primary objective is the main question. This objective generally drives statistical planning for the study (e.g., calculation of the sample size to provide the appropriate power for statistical testing). Secondary objectives are goals that will provide further information on the health condition that is the focus of the study.

Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general or specific purpose, e.g., to evaluate biomarkers as physiologic correlates of disease, to determine genomic factors affecting oral health conditions, to determine risk factors for disease or condition, etc.}

## Study Outcome Measures

<Insert text>

{Specify the primary and any secondary outcome measures, i.e., the measurements or observations used to describe the patterns of diseases or traits or associations with exposures, risk factors, or treatment. Include the study visits at which the biospecimens, images or other data will be obtained and the specific laboratory tests or other analytical measures to be used.

Outcome measures should be prioritized and should correspond to the study objectives and hypotheses being tested.}

# STUDY DESIGN

<Insert text>

{Include a brief paragraph or bulleted text describing the study design. This section should include:

* A brief description of the type/design of study to be conducted [e.g., cross-sectional, cohort, case-control, case-only, case-crossover, ecological or community study, family-based or other (explain)]; state if it is a multicenter study
* A brief description of the study population (e.g., healthy/sick, inpatient/outpatient, demographic groups), sample size and characteristics of different study groups, if applicable. Do not list inclusion/exclusion criteria here, as these will be listed in Sections 5.1 and 5.2.
* A brief discussion of the rationale for design features
* A brief description of the study timeline, including approximate time to complete enrollment and expected duration of subject participation (details of study visit schedule will be included in Section 6, Study Schedule)
* A brief summary of methods for collecting data for assessment of study objectives (detailed methods will be included in Section 7, Study Procedures)
* Other protocol-specific details, such as centralization of evaluations (e.g., central laboratory)
* If the study requires that study staff (investigator, examiner, laboratory personnel, etc.) be masked with respect to the study group of a research participant, specimen, or image, state how masking will be maintained.}

# STUDY ENROLLMENT AND WITHDRAWAL

{In subsections 5.1 to **Error! Reference source not found.**, define the study population, describe subject recruitment and discuss issues related to subject withdrawal. Address the following in these subsections, as applicable:

* Provide the target sample size; identify anticipated number to be screened in order to reach the target enrollment.
* Specify approach(es) for inclusion of women and minorities. Include numbers of women and minorities expected to be recruited, or provide justification if women and/or minorities will not be recruited.
* Indicate from where the study population will be drawn (e.g., inpatient hospital setting, outpatient clinics, student health service, or general public).
* If the study intends to enroll children, pregnant women, prisoners, or other vulnerable populations, refer to applicable section of 45 CFR Part 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research (45 CFR Part 46.201-46.207); Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (45 CFR Part 46.301-46.306); Subpart D – Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46.401-46.409). Please refer to these regulations when choosing the study population. Note that these regulations apply if any subjects are members of the designated population even if it is not the target population (for example, if a subject becomes a prisoner during the study). Refer to: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46>

Use the following guidelines when developing subject eligibility criteria to be listed in subsections 5.1 and 5.2:

* The eligibility criteria should provide a definition of subject characteristics required for study entry.
* The risks of being in the study should be considered in the development of the inclusion/exclusion criteria so that risk is minimized.
* The same criterion should not be listed as both an inclusion and exclusion criterion (e.g., do not state age >32 years old as an inclusion criterion and also age ≤32 years old as an exclusion criterion).
* Identify and specific tests or participant characteristics that will be used as criteria for enrollment.
* If reproductive status (i.e., pregnancy, lactation, reproductive potential) is an eligibility criterion, provide specific contraception requirements (e.g., licensed hormonal methods).}

## Subject Inclusion Criteria

<Insert text>

{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.}

{Begin sample text}

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

Provide signed and dated informed consent form.

Willing to comply with all study procedures and be available for the duration of the study.

Male or female, aged XX to XX.

In good general health as evidenced by medical history *or* Diagnosed with specific condition/disease *or* Exhibits specific clinical signs or symptoms or physical/oral examination findings.

Laboratory results within a specific range.

Women of reproductive potential must use highly effective contraception *{specify methods of contraception acceptable for the study, e.g., licensed hormonal methods. See* [*ICH M3 Guidance*](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002941.pdf) *for information on highly effective contraception.}*

Men of reproductive potential must use condoms *{if appropriate for study}*.

{End sample text}

## Subject Exclusion Criteria

<Insert text>

{Provide a statement that all individuals meeting any of the exclusion criteria at baseline will be excluded from study participation and then list each criterion.}

{Begin sample text}

An individual who meets any of the following criteria will be excluded from participation in this study:

Medical condition, laboratory finding, or physical exam finding *{specify, e.g., vital signs outside of specific range}* that precludes participation

Use of disallowed concomitant medications *{specify}*

Presence of <specific devices, e.g., orthodontic appliances, dentures>

Recent febrile illness that precludes or delays participation *{specify time frame}*

Pregnancy or lactation

Participation in a clinical study that may interfere with participation in this study *{within a specified time frame}*

History of or current tobacco, drug and alcohol use *{define parameters for exclusion}*

Anything that would place the individual at increased risk or preclude the individual’s full compliance with or completion of the study.

{End sample text}

## Strategies for Recruitment and Retention

<Insert text>

{Identify strategies for participant recruitment and retention. If participants will be compensated for study participation, describe amount and schedule of payments. If the study requires long-term subject participation, describe procedures that will be used to enhance retention (e.g., multiple methods for contacting participants, visit reminders, incentives for visit attendance, etc.}

## Subject Withdrawal

<Insert text>

{Subjects may withdraw voluntarily from the study or the investigator may terminate a subject's participation.}

### Reasons for Withdrawal

<Insert text>

{Provide a list of reasons subjects may be withdrawn from the study.}

{Begin sample text}

Subjects are free to withdraw from participation in the study at any time upon request.

An investigator may terminate a study subject’s participation in the study if:

Any medical condition, event or situation occurs such that continued participation in the study would not be in the best interest of the subject.

The subject meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

{End sample text}

### Handling of Subject Withdrawals

<Insert text>

{Describe the efforts to follow subjects who are withdrawn from the study. It may be appropriate to collect safety data on a subject discontinued because of an unanticipated problem (UP) or serious adverse event (SAE).

This section should include a discussion of replacement of subjects who withdraw or discontinue early, if replacement is allowed.}

# STUDY SCHEDULE

<Insert text>

{Information outlined in this section should refer to and be consistent with the information in the Schedule of Events in Appendix A and in Section 7.

Provide a schedule of initial, intermediate, and final study visits, and include all contacts with participants, e.g., telephone contacts. State permissible time windows for study visits, e.g., Day 7 ± 1 day. When establishing visit intervals and windows, consider feasibility and relevance to study outcome measures, and take into account how weekends and holidays will affect the windows.

For each visit, identify the purpose and briefly describe what will occur at the visit.}

## Screening

<Insert text>

{Include any evaluations necessary to assess whether an individual meets eligibility criteria. Discuss the sequence of events that should occur during screening and the decision points regarding eligibility. List the time frame prior to enrollment within which screening tests and evaluations must be done (e.g., within 28 days prior to enrollment).

**This section must include instructions for obtaining** **signed informed consent. If screening procedures are required for eligibility (e.g., review of medical records, clinical examination or laboratory tests), they may be performed under a separate screening consent form. State if a separate screening consent will be used. If a separate screening consent form will not be used, the study consent form must be signed prior to screening.**

Confirm that the procedures listed are consistent with those included in the Schedule of Events (Appendix A).}

{Begin sample text}

**Screening Visit (Day -28 to -1)** *{include a window that is appropriate for the study}*

Obtain and document consent from potential participant on screening consent form.

Review medical history to determine eligibility based on inclusion/exclusion criteria.

Review medications to determine eligibility based on inclusion/exclusion criteria.

Perform any examinations needed to determine eligibility.

Collect blood/urine/saliva.

Schedule study visits for individuals who are eligible and available for the duration of the study.

Provide potential participants with instructions needed to prepare for first study visit *{specify instructions to be provided}*.

{End sample text}

## Enrollment/Baseline

<Insert text>

{Discuss evaluations/procedures necessary to assess or confirm whether an individual still meets the eligibility criteria and may be enrolled, and specify what will be recorded at baseline for comparison with later assessments. Discuss the sequence of events that should occur during the enrollment visit. List any special conditions (e.g., negative pregnancy test must be available prior to initiating study procedures).

Confirm that the procedures listed are consistent with those included in the Schedule of Events (Appendix A).}

{Begin sample text}

**Enrollment/Baseline Visit (Visit 1, Day 0)**

Obtain and document consent from participant on study consent form.

Verify inclusion/exclusion criteria.

Obtain demographic information, medical history, medication history, alcohol and tobacco use history.

Record results of any physical examinations.

Collect data and/or blood/urine/saliva/other specimen.

{End sample text}

## Intermediate Visits

<Insert text>

{List each visit, including visit number and visit window. For each visit, list the evaluations/procedures/specimen collections to be completed (in chronological order, if applicable).

Confirm that the procedures listed are consistent with those included in the Schedule of Events (Appendix A).}

{Begin sample text}

**Visit 2, Day X ± Y**

{Repeat for each visit, providing a study-appropriate window for the visit}

Record results of physical examinations.

Collect data and/or blood/urine/saliva/other specimen.

{End sample text}

## Final Study Visit

<Insert text>

{Define when the final study visit should occur and any special procedures/evaluations or instructions to the participant. Describe provisions for follow-up of any ongoing adverse events. If study results will be shared with participants, discuss when and how they will receive this information.

Confirm that the procedures listed are consistent with those included in the Schedule of Events (Appendix A).}

{Begin sample text}

**Final Study Visit (Final Visit, Day X ± Y)**

Record results of physical examinations.

Collect data and/or blood/urine/saliva/other specimen.

Provide final instructions to participant*.*

{End sample text}

## Withdrawal Visit

<Insert text>

{If subject withdraws early or investigator terminates subject participation, specify which of the evaluations required for the final study visit should be offered to the subject.}

# STUDY PROCEDURES/EVALUATIONS

{In the following subsections, describe procedures for collection of all study data including observations, laboratory results, biospecimens, images, questionnaire responses. Information outlined in this section should refer to and be consistent with the information in the Schedule of Events in Appendix A and in Section 6.

All procedures listed here should be specific to the study and not part of standard clinical care. Procedures completed during the study as part of normal standard of clinical care should be identified as such and summarized.}

## Study Procedures/Evaluations

<Insert text>

{Describe assessments to be done, such as baseline medical history, medications history, or other health status evaluations.}

## Laboratory Procedures/Evaluations

*{If laboratory testing will not be done in the study, Section 7.2 can be deleted}*

<Insert text>

{List all laboratory evaluations. Differentiate screening laboratories from evaluations required for study outcomes. Include specific test components and estimated volume and type of specimens needed for each test. Specify laboratory methods to provide for appropriate longitudinal and cross-comparison (e.g., use of consistent laboratory method throughout study). If more than one laboratory will be used, specify which evaluations will be done by each laboratory.}

## Study Specific Biospecimens

*{If biospecimens will not be collected in the study, Section 7.3 can be deleted}*

### Specimen Collection Procedures

<Insert text>

{If biospecimens will be collected in the study, specify what specimens will be collected specifically for the study and the general procedures for the collection.

* Specimen source – Describe how the biospecimens will be obtained, e.g., from enrolled subjects or a biorepository.
* Pre-collection preparation – Provide information on how the subject will be prepared for collection of the biospecimen (e.g., pre-collection restrictions, collection site cleansing).
* Mode of collection – Describe how and when the biospecimen will be collected from the subject. Identify whether control specimens will also be collected, from where and how.
* Amount, frequency, and quality of specimen collection - Provide the maximum amount of biospecimen that could be obtained at each collection point and the total amount of specimen that could be obtained from each subject. Provide details of additional procedures to be done if the specimen is of poor quality or insufficient quantity.
* Specimen collection duration – Describe how much time the subject will spend in providing a biospecimen.}

### Specimen Preparation, Handling, and Storage

<Insert text>

{Describe where and how the specimens are processed after collection. Explain any special instructions for the preparation, handling, and storage of specimens. Include required temperatures for immediate and long-term storage, procedures for aliquoting specimens, where specimens will be stored, how they will be labeled and tracked for inventory, and measures taken to ensure sample integrity during storage. Include a discussion of long-term access and consent for future use of specimens.}

### Specimen Shipment

<Insert text>

{If specimens will be shipped to another location for analysis or storage, identify the receiver and provide destination and shipment information, including shipping frequency. Include here the contact information for laboratory personnel, days and times shipments are allowed, and any labeling requirements for specimen shipping. Also, include any special instructions such as dry ice or wet ice or the completion of a specimen-tracking log. Indicate how specimens will be labeled for tracking purposes and whether labels include subject identifying information. Provide information on the general mode of shipment and measures taken to protect specimen integrity.}

## Questionnaire Administration

*{If questionnaires will not be used in the study, Section 7.4 can be deleted}*

<Insert text>

{If questionnaires will be used in the study, describe the purpose and content of the questionnaire. Specify by whom and how the questionnaire will be administered and who will be the respondents. State whether the questionnaire has been previously validated. Attach the questionnaire as a protocol appendix.}

# ASSESSMENT OF SAFETY

{This section should be tailored for specific study characteristics.}

## Specification of Safety Parameters

<Insert text>

{Describe safety parameters that will be recorded during the course of the study. “Recording” refers to documenting data in the study database. Define what data will require reporting for protection of human subjects.}

{Begin sample text}

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

{End sample text}

### Unanticipated Problems

<Insert text>

{Begin sample text}

An unanticipated problem involving risks to subjects or others includes, in general, any incident, experience, or outcome that meets **all** of the following criteria:

unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

{End sample text}

{Per the definition, only a subset of adverse events would be characterized as unanticipated problems. There are other types of incidents, experiences and outcomes that are not considered adverse events, but are characterized as unanticipated problems (e.g., breach of confidentiality or other incidents involving social or economic harm).}

### Serious Adverse Events

<Insert text>

{Begin sample text}

A serious adverse event (SAE) is one that meets one or more of the following criteria:

Results in death

Is life-threatening (places the subject at immediate risk of death from the event as it occurred)

Results in inpatient hospitalization or prolongation of existing hospitalization

Results in a persistent or significant disability or incapacity

Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

{End sample text}

## Reporting Procedures

<Insert text>

{Institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (DHHS) must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and any supporting department or agency head of any unanticipated problem involving risks to subjects or others [45 CFR 46.103(b)(5)].

Describe the protocol-specific reporting procedures, including the individual responsible for each step (e.g., the investigator, the Data Coordinating Center, the Medical Monitor), which forms should be completed, timeframes for reporting, how reports will be distributed, and what follow-up is required.}

{Begin sample text}

Investigators should include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

appropriate identifying information for the research protocol, such as the title, investigator’s name, and the IRB project number;

a detailed description of the adverse event, incident, experience, or outcome;

an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;

a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline: *{IRB reporting timeframes may be modified according to local IRB rules.}*

Unanticipated problems that are serious adverse events will be reported to the IRB within 1 week of the investigator becoming aware of the event.

Any other unanticipated problem will be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.

All unanticipated problems should be reported to appropriate institutional officials (as required by an institution’s written reporting procedures) within one month of the IRB’s receipt of the report of the problem from the investigator.

{End sample text}

# STUDY OVERSIGHT

<Insert text>

{The method and degree of monitoring required varies, depending on the potential risk for subjects and the complexity of the clinical study. Monitoring activities may range from data and safety monitoring implemented by the principal investigator to independent data and safety monitoring boards.

Describe in this section the type of oversight for the study. Identify who is responsible, and note the expertise represented. State what outcomes will be monitored and the frequency of data and safety monitoring.}

{Begin sample text for PI oversight}

The investigator will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PI will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

{End sample text for PI oversight}

{Begin sample text for DSMB}

In addition to the PI’s responsibility for oversight, study oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of members with expertise in <appropriate clinical, statistical, scientific, ethical disciplines will be inserted>. The DSMB will meet <insert time interval> to assess safety, study progress and data integrity for the study. If safety concerns arise, more frequent meetings may be held. At this time, most data elements that the DSMB needs to assess will be clearly defined.

{End sample text for DSMB}

{Begin sample text for CSOC}

In addition to the PI’s responsibility for oversight, study oversight will be under the direction of a Clinical Study Oversight Committee (CSOC) composed of members with expertise in <appropriate clinical, statistical, scientific, ethical disciplines will be inserted>. The CSOC will meet <insert time interval> to assess unanticipated problems, study conduct, and progress. If major concerns arise, more frequent meetings may be held. At this time, most data elements that the CSOC needs to assess will be clearly defined.

{End sample text for CSOC}

{Begin sample text for ISM}

In addition to the PI’s responsibility for oversight, study oversight will be under the direction of an Independent Safety Monitor (ISM), <name the individual, and describe his/her expertise>. The ISM is independent of the study and will be available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

{End sample text for ISM}

# STATISTICAL CONSIDERATIONS

{The following subsections describing statistical considerations should be “self-contained” for coherence and ready reference. The statistical plan should show how the study will answer the most important questions with precision and a minimum of bias, while remaining feasible.

Some studies may be conducted to obtain preliminary qualitative data. The statistical section should describe this approach, including frequency reporting of variables, confidence intervals, etc.

This section MUST be completed prior to review by the GWCC Protocol Review and Monitoring Committee (PRMC) and the IRB. Protocols that do not have complete statistical analysis plans WILL NOT BE REVIEWED by the GWCC PRMC.}

## Study Hypotheses

<Insert text>

{State the formal, testable, null, and alternate hypotheses for the primary objective and key secondary objectives.}

## Sample Size Considerations

<Insert text>

{Provide all information needed to validate your calculations, and also to judge the feasibility of enrolling and following the necessary number of subjects.

Consider applicable items from the following list when describing sample size determination:

* Statistical method used to calculate the sample size
* Outcome measure used for calculations (almost always the primary variable)
* Test statistic
* Type I error rate
* Type II error rate
* Method for adjusting calculations for planned interim analyses, if any
* Assumptions used in calculations:
  + Assumed event rate for dichotomous outcome (or mean or variance of continuous outcome), justified and referenced by historical data as much as possible
  + Assumed dropout rates, withdrawal, missing data, etc., also justified
  + Approach to handling withdrawals and protocol violations, i.e., to what extent data from withdrawn subjects will be evaluable, whether withdrawn subjects will be replaced.

Present calculations from a suitable range of assumptions to gauge the robustness of the proposed sample size. Most assumptions are not accurate as point estimates.

Discuss whether the sample size also provides sufficient power for addressing secondary objectives or for secondary analyses in key subgroup populations.}

## Final Analysis Plan

<Insert text>

{Describe analyses for assessing the primary and secondary objectives. Plans must clearly identify the analyses, data stratifications, and methods to account for missing, unused or spurious data. Discuss how outcome measures will be assessed and transformed, if relevant, before analysis (e.g., Is the primary variable binary, categorical, or continuous?).

For complex data analyses (e.g., multiple secondary objectives), an overview of the statistical analyses may be provided here, with more details in a separate statistical analysis plan written prior to performing any analyses.}

# SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

<Insert text>

{Source data are all information, original records of clinical findings, observations, or other activities in a clinical research study necessary for the reconstruction and evaluation of the study. Examples of these original documents and data records include, but are not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ memory aid or evaluation checklists, recorded data from automated instruments, audio recordings of data collection events, copies or transcriptions certified after verification as being accurate and complete, photographs or digital photo files, x-rays, and subject files and records kept at the pharmacy, at the laboratories, and medico-technical departments involved in the study.

Describe how source documents will be managed in the study. Specify what will be considered source documents, how they will be maintained, and who will have access to records.}

{Begin required text; adapt as needed to specify what will be source documents for your study}

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of subjects. Study staff will permit authorized representatives of regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

{End required text}

# QUALITY CONTROL AND QUALITY ASSURANCE

<Insert text>

{This section will address the plans for local quality assurance and quality control.  
(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>).

Quality Management is the overall process of establishing and ensuring the quality of processes, data, and documentation associated with clinical research activities. It encompasses both quality control (QC), and quality assurance (QA) activities.

A quality management plan should describe:

* How data will be evaluated for compliance with the protocol and for accuracy.
* What materials will be reviewed (e.g., visit records, specimen tracking logs, questionnaires, audio or video recordings), who is responsible, and the frequency for reviews.
* Who will be responsible for addressing quality assurance issues (correcting procedures that are not in compliance with protocol) and quality control issues (correcting errors in data entry).
* Staff training methods and how such training will be tracked.
* If applicable, calibration exercises conducted prior to and during the study to train examiners and maintain acceptable intra- and inter-examiner agreement.}

# ETHICS/PROTECTION OF HUMAN SUBJECTS

## Ethical Standard

<Insert text>

{Include in this section the guiding ethical principles being followed by the study.}

{Begin required text}

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

{End required text}

{If the study is conducted at international sites, the statement could be as above and/or could reference compliance with the Declaration of Helsinki, CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), or another country’s ethical policy statement, whichever provides the most protection to human subjects.}

## Institutional Review Board

<Insert text>

{Each participating institution must provide for the review and approval of this protocol and the associated informed consent documents and recruitment material by an appropriate IRB. Any amendments to the protocol or consent materials must also be approved before they are placed into use.}

{Begin required text; modify as appropriate for a multi-site study}

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 must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

{End required text}

## Informed Consent Process

<Insert text>

{Identify different consent forms that are needed for the study (e.g., screening, study participation, future use of specimens, assent form for minors).

When a study includes participants who may be enrolled in the study only with the consent of the participant’s legally authorized representative (e.g., minors or participants whose cognitive impairment is such that they are unable to give informed consent), the participant should be informed about the study to the extent compatible with the participant’s understanding. If capable, the participant should assent and sign and personally date the written consent form. A separate IRB-approved assent form, describing (in simplified terms) the details of the study intervention, study procedures, and risks may be used. Assent forms do not substitute for the consent form signed by the participant’s legally authorized representative.

If non-English speakers will be enrolled, state that a translated consent document will be available and an appropriate person will conduct the consent process. Consider other special circumstances such as low literacy, braille, or web-based consenting.

For a multi-site study, each participating institution will be provided with a model informed consent form. Each institution may revise or add information to comply with institution consent templates, but may not remove procedural or risk content from the model consent form.}

{Begin required text; adapt as needed for a specific study}

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

{End required text}

## Exclusion of Women, Minorities, and Children (Special Populations)

<Insert text>

{Explain why any of these populations are excluded from study participation, or state that individuals of any age, gender or racial/ethnic group may participate.}

## Participant Confidentiality

<Insert text>

{Include procedures for maintaining participant confidentiality and any special data security requirements. Describe who would have access to records, including the investigator and other study staff, the clinical monitor, representatives of funding institutions, and IRB representatives. For some studies, it may be necessary to obtain a Certificate of Confidentiality. A Certificate of Confidentiality protects researchers and research institutions from being forced to provide identifying information on study participants to any federal, state, or local authority.}

{Begin sample text; include Certificate of Confidentiality and Data Sharing Policy text, only if applicable}

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to participants.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants.

Certificate of Confidentiality (if applicable)

To further protect the privacy of study participants, a Certificate of Confidentiality will be obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

NIH Data Sharing Policy for Genome-Wide Association Studies (GWAS) (if applicable)

This study is a genome-wide association study and will comply with the NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, which calls for investigators funded by the NIH for GWAS to 1) share de-identified genetic (genotypic and phenotypic) data through a centralized NIH data repository; and 2) submit documentation that describes how the institutions have considered the interests of the research participants, such as privacy and confidentiality. Submission of data to the NIH GWAS repository will be consistent with the permissions and limitations delineated on the study consent signed by study participants.

{End sample text}

## Future Use of Stored Specimens and Other Identifiable Data

<Insert text>

{Refer to Human Subject Regulations Decision Charts 2 and 5:  
<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2>.

If residual specimens or other identifiable data will be maintained after the study is complete, include the provisions for consent and the options that are available for the participant to agree to the future use of his/her specimens, images, audio or video recordings. Specify the location(s) where specimens or other data will be maintained, how long specimens or other data will be stored, if the site's IRB will review future studies, and protections of confidentiality for any future studies with the stored specimens or data (e.g., specimens will be coded, bar-coded, de-identified, identifying information will be redacted from audio recording transcripts, etc.). Include a statement that genetic testing will or will not be performed. A Certificate of Confidentiality may be obtained if genomic testing is planned.}

# DATA HANDLING AND RECORD KEEPING

<Insert text>

{Include instructions for data handling or record-keeping procedures required for maintaining subject confidentiality, any special data security or data transfer requirements and record retention.

Briefly describe steps to be taken to ensure that the data collected are accurate, consistent, complete, and reliable. The description should include reference to source documentation, instructions for completing forms, data handling procedures, and procedures for data monitoring.}

{Begin sample text}

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

{End sample text}

## Data Management Responsibilities

<Insert text>

{Include a general description as in the sample text below and add study-specific details and information about the role of a data coordinating center, if applicable.}

{Begin sample text}

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents and laboratory reports must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems must be reviewed by the investigator or designee.

{End sample text}

## Data Capture Methods

<Insert text>

{Provide details regarding the type of data capture that will be used for the study. Specify whether it will be paper or electronic, distributed or central, batched or ongoing processing, and specify any related requirements (e.g., password protection and data quality checks for an electronic data system).}

## Types of Data

<Insert text>

{Indicate the types of data that will be collected, such as safety (unanticipated problems), laboratory results (e.g., genetic sequences, biomarker levels, etc.), and outcome measure data (e.g., physical measurements, questionnaire responses). Specify if safety data are collected in a separate database.}

## Schedule and Content of Reports

<Insert text>

{Indicate, as applicable, the schedule and content for data review and reports. Examples include reports to monitor enrollment, reports to study oversight committee, reports of study conduct, and reports for interim data analysis and study progress. Identify plans for data analysis and interim and final study reports, steps for locking the database prior to analysis, and precautions related to masked data. Indicate whether and when coding is to occur.}

## Study Records Retention

<Insert text>

{Specify the length of time for the investigator to maintain all records pertaining to this study. Indicate whether permission is required (and from whom) prior to destruction of records. Generally, clinical records subject to the U.S. Health Insurance Portability and Accountability Act (HIPAA) must be retained for six [6] years from the date of creation or the date when the records were last in effect, whichever is later (45 CFR 164.530 (j))}

{Begin sample text}

Study records will be maintained until December 31, 20XX, which is approximately six years after the date at which data collection is scheduled to end.

{End sample text}

## Protocol Deviations

<Insert text>

{Begin sample text}

A protocol deviation is any noncompliance with the clinical study protocol requirements. The noncompliance may be on the part of the subject, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

All deviations from the protocol must be addressed in study subject source documents and promptly reported to the local IRB, according to their requirements.

{End sample text}

# PUBLICATION/DATA SHARING POLICY

<Insert text>

{Include the required text below, and provide study-specific policies on publication and data sharing, if applicable (e.g., authorship rules, registering the study on ClinicalTrials.gov, compliance with NIH GWAS data sharing policy, etc.).

Registering Observational Studies in ClinicalTrial.gov

Observational studies can be registered in ClinicalTrials.gov if human subjects are included. ICMJE issued a [clinical trial registration](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html) policy as part of the ICMJE [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](http://www.icmje.org/recommendations/) , which is followed by more than 1,000 journals. The ICMJE Recommendations encourage journal editors to require that all clinical trials be entered in a public registry before the start of participant enrollment for the trials to be considered for publication. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. However, investigators who are uncertain whether their study meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal.

The Observational Study Type (see [Study Type data element](https://prsinfo.clinicaltrials.gov/definitions.html#StudyType) on ClinicalTrials.gov) can be used to register studies of human beings in which biomedical and/or health outcomes are assessed in predefined groups of individuals, but the investigator does not assign specific interventions to the study participants. This will provide access to the [Observational Study Design data elements](https://prsinfo.clinicaltrials.gov/definitions.html#ObsStudyDesign) on ClinicalTrials.gov, including Observational Study Model, Time Perspective, and Biospecimen information.

The Patient Registry Observational Study Subtype (see [Study Type data element](https://prsinfo.clinicaltrials.gov/definitions.html#StudyType) on ClinicalTrials.gov) can be used to indicate that an observational study is also considered to be a Patient Registry. The [Agency for Healthcare Research and Quality (AHRQ)](https://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=401) defines a Patient Registry as including an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single-purpose or ongoing data collection programs that address one or more questions.

Observational study records in ClinicalTrials.gov should be updated and maintained in the same manner as interventional study records.}

{Begin required text}

This study will comply with the [NIH Public Access Policy](http://publicaccess.nih.gov/policy.htm), which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](http://www.pubmedcentral.nih.gov/) upon acceptance for publication.

{End required text}

{Begin sample text for GWAS data sharing, if applicable}

This study will comply with the NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS). Genotype and phenotype data will be submitted to the Database of Genotypes and Phenotypes (dbGaP), with a certification that the IRB has verified that

* the submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
* the investigator's plan for de-identifying data is consistent with the Policy standards;
* it has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
* the genotype and phenotype data to be submitted were collected in a manner consistent with 45 CFR Part 46.

{End sample text}

# LITERATURE REFERENCES

<Insert text>

{Include a list of relevant literature references in this section. Use a consistent, standard, modern format, which might be dependent upon the required format for the anticipated journal for publication (e.g., N Engl J Med, JAMA, etc). Use of bibliographic software, such as EndNote or RefWorks ([available to all GW faculty, staff and students at no cost through Himmelfarb Library](http://www.refworks.com/refworks2/?r=authentication::init&groupcode=RWGWUMC)), is highly recommended.}

SUPPLEMENTAL MATERIALS

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

{These are examples of documents that you should consider including in the protocol as Supplemental Materials. Many of these materials will be required by the IRB.

* Site Staff Roster (especially for multi-center studies)
* Repository Instructions (if applicable)
* Laboratory Handling (if applicable)
* Quality Management Plan
* Data Management Plan
* Statistical Analysis Plan}

APPENDICES

{In this section, include the list of documents that are officially affiliated with the protocol and will be submitted to the IRB as a part of the protocol. As such, changes to these items require a protocol amendment. When including items in this section, it is useful to number them (e.g., “Appendix A: Schedule of Events”).

These are examples of documents you may want to include as Appendices:

* Schedule of Events diagram or table (must match with Section 6)
* Recruiting materials (e.g. flyers, text of social media announcements, advertising)
* Consenting scripts
* Consent form(s)
* Questionnaires that will be used in the study (if applicable)
* Scripts for focus groups (if applicable)
* Observational Coding Schemes (if applicable)

Include a cover page for each listed Appendix. The following page includes an example.}

APPENDIX A: Schedule of Events

{Create a detailed schematic describing all visits and assessments, consistent with those listed in Sections 6 and 7.}

{Begin sample text}

| Procedures | | Screening  (Day –X to –Y) | | Study Visit 1  (Day 0) | Study Visit 2  (Day X ± Y) | Study Visit 3  (Day X ± Y) | Study Completion  (Day X ± Y) | Premature Discontinuation |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signed Consent Form | | X | | X |  |  |  |  |
| Assessment of Eligibility Criteria | | X | | X |  |  |  |  |
| Physical Examination | Height | | X |  |  |  |  |  |
| Weight | | X | X | X | X | X | X |
| Vital Signs | | X | (X) | (X) | (X) | (X) | X |
| Clinical Lab | Urine Pregnancy Test | | X |  |  |  |  |  |
| Research Laboratory | Biomarkers  \_\_mL saliva (or blood) | X | | X |  |  | X |  |
| Sample for Genetic Analysis | X | |  |  |  |  |  |
| Other Procedures | Questionnaire | X | | X | X | X | X | X |
| Focus group | X | |  |  |  |  | X |

{End sample text}

{Specify time points for intervention or intermediate visits in days, weeks, or months, as appropriate for protocol. For each visit, provide a window during which the visit can occur. The window should be appropriate for the parameters to be assessed at the visit.

(X) – As indicated/appropriate.

Note: List the tests applicable to your specific protocol.

Provide a list of Clinical Laboratory tests, e.g.:

* **Pregnancy Test** – urine or serum test to establish eligibility

Provide a list of Research Laboratory tests and the required specimen types, e.g.:

* **Gene sequencing** – X mL blood
* **Biomarkers** – X mL saliva, blood, urine

Provide a list of other procedures done to evaluate outcome measures (e.g., anthropometric measurements, photographs, questionnaires, quality of life assessments).}