**Observational Study Protocol Template**

**Version Feb 2025**

*Adapted from NIH protocol template and ICH Guidelines*

**Guidance for this Protocol Template**

This protocol template is to be used for observational research studies such as research involving analysis of data or specimen, observational studies where the investigator simply records observations and analyzes data, without assigning participants to a specific intervention or treatment.

For clinical trials, that is, research in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes use the Clinical Trial Protocol Template or the NIH Protocol Template on this page - [Links to Clinical Trial Protocol Template](https://www.uth.edu/ctrc/trial-conduct/protocol-development).

Do not delete any sections of the protocol template as all sections are important for all types of research studies.

This template contains two types of text: instructions/explanatory text and example text.

***Instruction/explanatory text*** *is indicated by italics and in blue font and should be deleted prior to finalizing the protocol. This text provides information on the content that should be included in the protocol.*

[**EXAMPLE text** is included to further aid in protocol writing and should be modified to suit the protocol and it may be deleted if it is not relevant. Example text is indicated by the word “EXAMPLE” and blue font within brackets*.*]

<Locations to enter study-specific text is indicated by black font and within angle brackets. Delete any instructional text and enter study-specific language.>

**Delete all language in blue/brackets [ ]/angle brackets < >/italics, and enter language specific to your research study.**

Version control is important to track protocol development, revisions, and amendments. It is also necessary 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, the version number and date located in the header of each page should be updated**. When making changes to an approved and “final” protocol, the protocol amendment history should be maintained.

**Additional Guidance and Tips**:

* [Michigan State University - Tips for Retrospective Chart Review Studies](https://research.chm.msu.edu/students-residents/retrospective-chart-reviews)
* [NIH IRB Protocol Templates](https://irbo.nih.gov/confluence/display/ohsrp/Protocol%2BTemplates)

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**<Title>**

*This title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.*

**Protocol Number: <Number>**

**Principal Investigator:** **<Principal investigator>**

**Funded by: <Name of funding agency, if applicable>**

*If not funded by any external entity, write department name, UTHealth Houston*

**Version Number: v.<x.x>**

**<Day Month Year>**

## PROTOCOL SUMMARY

|  |  |
| --- | --- |
| **Protocol Title:** | <Ensure that the protocol title matches the protocol title in iRIS.> |
| **Principal Investigator:** | <Name><Title><Department><School>*The same individual should be listed as PI on the protocol and in the IRB application in iRIS.* |
| **Co-Investigators:** | *For each collaborator/co-investigator:*<Name><Title><Department><School> *All of the individuals listed as collaborators/co-investigators should be listed in the IRB application in iRIS.* |
| **Study Design**  | <Study design, such as cohort, case-control, cross-sectional, chart review, etc.> |
| **Population:** | <State the sample size and briefly define population characteristics (e.g., 300 adults with cardiomyopathy).> |
| **Study Sites:** | <List the locations where the study will be done. For chart review studies, list which institutions’ data will be reviewed (e.g., UTHealth Houston, Memorial Hermann Health System).> |
| **Study Duration:** | <Estimated time from when the study opens to enrollment to completion of data analyses. Include Study Start Date and Study End Date (e.g., from Mar 2025 to Dec 2026).> |
| **Participant Duration:** | <Time it will take to conduct the study for each individual participant. For studies involving chart reviews only with no participant contact, state the time period from which charts will be reviewed (e.g., Jan 2024 to Dec 2026).> |

## Background Information

*State the problem or question (e.g., describe the population, disease, current standard of care, and limitations of knowledge). Provide an overview of the literature and data that is pertinent to the study design, as well as describe the background for the study. Include study hypothesis, summary of findings from studies that have potential significance to the proposed study, and a discussion of important literature and data that are relevant to the study and that provide background for the study. References for the cited literature should be provided in the references section.*

<insert text>

## Study Objectives and Outcome Measures

*Provide a description of the study objectives and outcome measures, optionally using the table below. Note that objectives are distinct from outcome measures, both defined below. Primary outcome measure(s) should correspond to the primary objective(s), and secondary outcome measures should correspond to the secondary objectives. If there are no tertiary or exploratory measures, delete from table. A document with further guidance on objectives and outcome measures is* [***at this link***](https://www.uth.edu/ctrc/regulatory/2021_02_21_outcome%20measure%20guidance%20b.pdf)*.*

* *An* ***objective*** *(sometimes also called an aim) is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate).*
* *An* ***outcome measure*** *(also called an* ***endpoint****) is a specific measurement or observation (e.g., specific laboratory test that defines safety or efficacy, clinical assessment of disease status, assessment of psychological characteristics, patient-reported outcome, behavior or health outcome) that is used to assess the effect of an intervention.* *Some observational studies don’t assess an intervention, in which case a study outcome might be a measurement or observation used to investigate the association between an exposure or risk factor and a disease or trait.*

*Of note, observational studies can be either descriptive or analytic (generally, descriptive studies describe the occurrence/presence of an outcome or exposure, whereas analytical studies evaluate the relationship between an exposure or treatment and an outcome). Considerations for purely descriptive studies are found in the table below.*

|  |  |
| --- | --- |
| **OBJECTIVES** | **OUTCOME MEASURES (a.k.a., ENDPOINTS),****with TIMEPOINTS for each** |
| **Primary** |  |
| *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, when appropriate).*[EXAMPLE A: To determine the effect of clinical recommendation for vaccination by healthcare provider on vaccination uptake among TMC Health Clinic patients during the 2024-2025 flu season.] [EXAMPLE B: To compare the efficacy of drug A and drug B for treatment of disease X]*For purely descriptive studies, the objective may be relatively broad; however, as much specificity as possible should be provided (e.g., rather than state “to study the natural history of disease X,” for instance state more specifically “to describe the progression of CNS lesions in disease X”).*<insert text> | *The primary outcome measure should be clearly specified, and a timepoint should be listed for each outcome measure. The primary outcome measure is the basis for concluding that the study met its objective, and the primary outcome measure’s role in the analysis and interpretation of study results should be defined in the statistical analysis section. Generally, there should be just one primary endpoint that will provide a clinically relevant, valid, and reliable measure of the primary objective.*[EXAMPLE A: Percentage of eligible patients seen at the TMC health clinic who received the flu vaccine. Timepoint: between October 1, 2024 through May 31, 2025][EXAMPLE B: Number of deaths. Timepoint: 30 days after treatment]*For purely descriptive studies, there may not be an outcome measure, as no effect or association is being examined, but provide an explanation of how you will determine when the study objectives have been met.*<insert text> |
| **Secondary** |   |
| *The secondary objective(s) are goals that will provide further information about the disease or treatment being studied.*<insert text> | *Secondary outcome measure(s) should be clearly specified, and a timepoint should be listed for each secondary outcome measure. Secondary outcome measures are those that may provide supportive information.*<insert text> |
| **Tertiary/Exploratory**  |   |
| *Tertiary/exploratory objective(s) serve as a basis for explaining or supporting findings of the primary analyses and for suggesting further hypotheses for later research.*<insert text, or delete this row of there are no tertiary/exploratory objective(s)> | *If applicable, specify exploratory outcome measure(s). Exploratory outcome measures may include clinically important events that are expected to occur too infrequently or outcome measures that for other reasons are thought to be less likely to show an effect but are included to explore new hypotheses.*<insert text, or delete this row of there are no tertiary/exploratory outcome measure(s)> |

## Study Design

*Provide an overview of the design of the study, including the research methods you plan to employ to meet your study objective. Describe in general terms how research objectives will be accomplished.*

<insert text>

## Study Population

*Describe the study population. This information is important even for research that does not involve any patient contact, for example research involving chart reviews.*

<insert text>

*Describe if any vulnerable populations will be included in this study. Describe additional protections for vulnerable populations.*

[EXAMPLE for research involving no participant contact (i.e., chart review):

Vulnerable populations (children, cognitively impaired persons, etc.) will be included in this study; however, no additional protections are needed beyond the data protection procedures described below, as this study does not involve interacting with participants or intervening in any way.]

<insert text>

### Inclusion Criteria:

[EXAMPLE:

1. Adult patients (ages 18-65) who received outpatient care at the TMC Health Clinic during the study period.
2. Patients who had a recorded flu vaccination status (either received or declined) in their medical chart.]

<insert text>

### Exclusion Criteria:

 [EXAMPLE:

1. Patients with documented contraindications to the flu vaccine.
2. Patients who are younger than 18 yrs.]

<insert text>

### Recruitment and Enrollment:

*For research involving participant contact:*

*Describe how participants will be identified and invited to participate in the research.*

*For research involving no participant contact, such as chart review studies:*

*Describe how relevant charts will be identified and by whom.*

[EXAMPLE: The study investigators will use slicer dicer to identify adult patients who had a clinic visit between October 1, 2024 and May 31, 2025.]

<insert text>

## Study Procedures

*For research involving participant contact:*

* *Describe the interaction with participants, including a description of the number of study visits, what procedures will occur at each visit, and how long each visit will take. Indicate the total amount of time required of each participant to participate in the project.*
* *Specify the type of information collected, along with the means for collecting and recording it.*
* *Describe the methods for collecting specimens and data, listing all laboratory evaluations, if applicable. Include specific test components and estimated volume and type of specimens needed for each test.*
* *If biological specimen are going to be stored, describe the plans for storage, duration of storage, and procedure to maintain confidentiality.*

*For research involving no participant contact, such as chart review studies:*

*Specify the source of the data that will be collected. Specify start date and end date of records that will be reviewed. Include a copy of the data abstraction sheet reflecting all the data elements you plan to abstract from each database as an appendix. Provide a list of the identifiers which will be used to meet the purpose of the study. The data you propose to collect must be relevant to the aims & objectives of the research and the minimum necessary to accomplish it. If applicable, explain when and how identifiers will be removed from the data collected.*

[EXAMPLE: UTP Epic Electronic Medical Records from October 1, 2024 to May 31, 2026 will be reviewed.]

<insert text>

## Risks Assessment

*Describe all risks and potential benefits to participants involved in this study.*

[EXAMPLE: for research involving no participant contact, such as chart review studies:

The risks to participants associated with their data being accessed and included in this chart review study stem from the potential for a confidentiality breach. While every effort will be made to ensure data security, there is always some level of risk that unauthorized individuals could access personal health information. If such a breach were to occur, it could lead to physical, psychological, economic, or societal harm.

For instance, individuals could experience psychological harm if sensitive health information were to be exposed, particularly if it reveals details about their medical conditions or treatments. There is also the potential for economic harm if the data leads to discrimination in areas such as employment or insurance. Specifically, exposure of health conditions could affect an individual's ability to obtain or maintain insurance coverage, resulting in reduced insurability or higher premiums.

Additionally, there is the risk of societal harm, such as stigmatization, particularly if personal health information, including mental health conditions or infectious diseases, becomes public. This could lead to social exclusion, judgment, or unfair treatment within a community or workplace.

While these risks are generally considered minimal in retrospective chart reviews, they should not be overlooked. Comprehensive safeguards will be in place to mitigate these risks, such as data encryption, restricted access to the study data, and ensuring that personally identifiable information is separated from the study outcomes.]

<insert text>

**Potential Benefits:**

*Include all of the potential benefits, if any to participating in this research study. List benefits that are direct benefits to the participants who participate in this study, as well as indirect benefits to society as a result of the knowledge to be gained.*

*For research involving no participant contact, such as a chart review study, there is no possibility of direct benefit to the participants whose data is collected, but some benefits that may be considered are:*

* *Identification of Trends: A chart review study may help identify trends or patterns in medical conditions, treatment outcomes, or vaccination rates across different populations or settings. These insights can inform future studies, treatment protocols, or healthcare practices.*
* *Evidence for Best Practices: The data gathered can support the development of evidence-based guidelines or help refine existing ones, improving patient care and outcomes over time.*

<insert text>

## Data Collection and Management

*Describe the plan for maintaining source documents and whether it includes paper and electronic formats. Include a statement that all data and records generated throughout the course of the study will be kept confidential in alignment with UTHealth Houston policies. State that only the study team members will have access to the study data and records for the purposes of conducting the study.*

*Describe whether identifiers will be attached to the data or whether they will be coded:*

* *If coded, but additional information of the subjects (e.g., age, ethnicity, sex, diagnosis) is available, discuss whether this might make specific individuals or families identifiable.*
* *If coded, describe how access to the “key” for the code will be limited. Include description of security measures (password-protected database, locked drawer, other, etc.). List positions of persons with access to the key.*

[EXAMPLE: Paper case report forms will be stored securely in a locked filing cabinet, with access limited to the Principal Investigator (PI) and the designated Clinical Research Coordinator (CRC).

Identifiers collected as part of the study will include [list any identifiers such as patient ID, date of birth, etc.]. These identifiers will be stored separately from the study data to maintain confidentiality. Paper records containing identifiers will be securely locked away, and electronic records will be encrypted and stored in a password-protected system. All data will be handled in compliance with applicable privacy regulations to ensure confidentiality and data security.

If the data will be shared with any outside entities, state whether any identifiers will be shared, specify who the data will be shared with and which agreements will govern the sharing of data (for example, data use agreement, data and material transfer agreement, subcontract, sponsored research agreement, etc.—work with Sponsored Projects Administration to determine the appropriate agreement).]

*State where data will be stored and how it will be secured.*

[EXAMPLE: All study data will be securely stored on a password-protected UTHealth Houston computer. Any paper documents with research data will be kept in a locked filing cabinet, with the key remaining in the possession of a designated study team member.

Data will be entered in UTHealth Houston instance of REDCap. The REDCap system has user authentication, restricted access based on specific roles, and audit trail functionality that records all user activity, including data entry, modification, and access, ensuring complete accountability and the ability to track any changes made to the data. This audit trail helps maintain the integrity and confidentiality of the study data throughout the research process.]

*Summarize the record retention plan applicable to the study. Describe when identifiers will be destroyed. (link to records* [*Records Retention Schedule*](https://inside.uth.edu/it-administration-and-finance/records-management/records-retention-schedule) *).*

[EXAMPLE: Study records and linking logs will be stored securely until 6 years after publication of study results.]

*For studies involving sensitive data, consider a* [*certificate of confidentiality*](https://www.uth.edu/cphs/policies/coc)*.*

[EXAMPLE: Certificate of Confidentiality is issued by the National Institutes of Health (NIH) for all federally funded research. 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, 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 participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.]

<insert text>

## Statistics

*Describe the statistical methods to be employed, including timing of any planned interim analysis.*

*Indicate the number of participants planned to be enrolled. In multicenter trials, the numbers of enrolled participants projected for each trial site should be specified.*

*Describe the reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.*

*Indicate the level of significance to be used.*

*Discuss the selection of participants to be included in the analyses.*

<insert text>

## Safety Monitoring

*State if adverse events are expected. If yes, describe how these events will be identified, assessed, and graded.*

*Describe plans for reporting unanticipated problems (including adverse events, protocol deviations, and/or other problems).*

*Describe the safety-monitoring plan (e.g., periodic review by research team, external review, formal data and safety monitoring board).*

[EXAMPLE TEXT:
Unanticipated Problems; 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 Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied; and
* 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 participants or others (which many include research staff, family members or other individuals not directly participating in the research) at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or expected.

The investigator will report unanticipated problems (UPs) to the IRB as per reporting policy.

It is the responsibility of the investigator to use continuous vigilance to identify and report deviations and/or non-compliance to the IRB. The investigator is responsible for knowing and adhering to the reviewing IRB requirements.

Protocol Deviations: A protocol deviation is any changed, divergence, or departure from the IRB-approved research protocol.

Major deviations: Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.

Minor deviations: Deviations that do not have the potential to negatively impact the rights, safety or welfare of subjects or others, or the scientific integrity or validity of the study.]

<insert text>

## Ethics

*State that the study will be initiated only after IRB approval and any other applicable approvals (e.g., MHH CIRI or Harris Health Clinical Research).*

*Describe the consent process, including: who will be responsible for obtaining consent; where the consent process will occur; how participant privacy will protected; how much time participants will be given to review the consent form; how the consent process will be documented; how consent will be documented; what steps will be taken to ensure that participants understand the stud; and any measures that will be implemented to prevent coercion.*

*If waiver of consent or waiver of documentation will be sought, justify the waiver of consent by providing protocol-specific determination for each of the following criteria:*

1. *The research involves no more than minimal risk to the participants;*
2. *The research could not practicably be carried out without the requested waiver or alteration;*
3. *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;*
4. *The waiver or alteration will not adversely affect the rights and welfare of the participants; and*
5. *Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.*

[EXAMPLE: A waiver of informed consent is requested due to the minimal risk nature of this retrospective chart review, which involves no direct patient interaction. Requiring informed consent would necessitate contacting each patient individually, increasing the risk to patient privacy. Additionally, obtaining a signed consent form would introduce further risks to data confidentiality, as it would create an extra document containing patient identifiers. Furthermore, requiring consent could result in a loss of patients who may not participate, thereby reducing the study's sample size and overall impact. A smaller sample size might also necessitate contacting more potential participants or extending the enrollment period, further increasing privacy and confidentiality risks. The rights and welfare of patients will remain unaffected by this study.]

EXAMPLE 2: We have no ongoing interactions with the participant for the purposes of this research.

The required sample size is so large, including only those participants data who we are able to reach and obtain new consent from might bias the sample. Identifiable information is required in order to collect the corresponding data from the electronic health records at UTP and MHH. The research is minimal risk, and the only risk is a breach of confidentiality. The research team is experienced with ensuring procedures to protect the confidentiality of patient data. We do not intend to have any contact with the participants or data we will use in this study to share the findings of this research.

<insert text>

## Reporting Problems

## Conflict of Interest Statement

*State whether all study personnel have submitted a financial disclosure statement within the last year. If any study team member has a financial interest related to this research study, then explain the conflict and state whether a management plan is in place.*

<insert text>

## Data handling and record keeping

*Discuss access to source documents.*

*Discuss procedures for maintaining participant confidentiality, including where will data be stored, how access will be controlled, and how long data will be retained. Specify where electronic records will be stored.*

*State how the data will be linked to the participants during the study.*

*Indicate whether data be shared with any outside entities*—*if yes, specify what will be shared and with which entities.*

<insert text>

## Quality control and assurance

*Describe steps to be taken to assure that the data collected are accurate, consistent, complete, and reliable (e.g., source data verification, audits, or self-assessment).*

*Describe whether there are plans to have ongoing third party monitoring.*

<insert text>

## Publication Plan

*Describe plans for publication of research results.*

*State if results will be returned to research participants.*

<insert text>

## Protocol Amendments

*Include a summary of Protocol Amendments. Include version number, date of the version and summary of changes. You may use a table here for clarity.*

<insert text>

## References

*Include at least two references that support the study.*

<insert text>

## Attachments

*These may be standalone documents that are submitted separately in iRIS.*

[EXAMPLE:

1. Consent Document if applicable - [Template](https://www.uth.edu/cphs/templates-and-forms/)
2. Case Report Form or Data Collection Form – [Template](https://drive.google.com/open?id=1EdKCyYe7KDlK4rVscSM7LPlkf3CAoPCh) (or for chart review studies, list of variables to be collected)
3. Linking Log - [Template](https://docs.google.com/spreadsheets/d/1EIxBQlX9p2Us7W23sL_J2zH3aF1gCe-3/edit?usp=drive_link&ouid=111435455462881673528&rtpof=true&sd=true)]

<insert list>