Retrospective Research Study Protocol Template

* **Be sure that all study materials are correct and consistent with the information in this protocol.**
* **Instructions are provided in blue font to generate ideas of what should be included in some of the sections. This should be deleted and substituted with information that pertains to the actual study.**
* **An example protocol is given as sample text in green font.**
* **Depending on the nature of your research, some sections will not be applicable. Indicate this as “N/A.” Do not delete the section.**

**Study Protocol Title:**

Be consistent with the Title throughout your research application, protocol, and IRB documents.

**Study Sponsor:**

AdventHealth Orlando

AdventHealth Orlando is the default response. Please change if needed e.g. AdventHealth University.

The sponsor is the person or organization that employs the person who is responsible for the research study and may or may not be the funder. The sponsor develops/writes the study protocol, or has it developed on its behalf which may include collaboration with outside entities. The sponsor is responsible for satisfying all legal and regulatory requirements including but not limited to overseeing the conduct of the study, data integrity and analysis. The sponsor has the right to publish the results of the study.

**Principal Investigator:**

Principal investigator:

# List of Abbreviations:

Include commonly used abbreviations and acronyms.

# Introduction

The introduction should open with remarks stating this document is a research protocol and that the described study will be conducted in compliance with the following as applicable: institutional research requirements; Common rule; FDA; Good Clinical Practices (GCP) International Conference on Harmonization (ICH) Guidelines (E6) for GCPs standards. You must be familiar with the regulations governing this research.

Sample Text: This document is a protocol for a human research study. This study is to be conducted in accordance with institutional research requirements and (insert applicable regulations specific to this research).

# Background Information and Scientific Rationale

Provide and summarize published (or available unpublished) data in the literature to build a rationale for the research question(s), study objectives, and research design.

If none is available, include a statement that there is no available research data to date on the intervention being investigated.

This section must provide a justification for the conduct of this study based on existing knowledge and should include your research question.

You may include a summary of epidemiological data, if relevant.

# Study Objectives

In a general fashion, summarize the purpose, aim, or objective of the study.

## Primary Objective/Aim/Goal/Hypothesis

Select the appropriate term(s) (objective/aim/goal/hypothesis) for your research area and be consistent throughout the protocol

Include the details of the study’s primary objective (which is the main purpose for performing this study and should be focused on **one question**), outcome measures and method by which outcomes will be determined or state the hypothesis to be tested.

## Secondary Objective/Aim/Goal/Hypothesis

Include secondary objectives (as many as relevant). These objectives may be dependent or independent of the primary objective.

Sample text: To determine if BMI is related to length of time to oral pain medication usage in the appendectomy patient population.

# Study Design

## Research Design

Include the description of study type, number of study arms, and other study details. Type of study and design should be decided on the basis of primary and secondary objectives and availability of resources.

Sample text: This study is a retrospective correlational study examining factors associated between BMI and post-operative pain in patients undergoing appendectomy.

## Study Site(s)/Location(s) and Number of Subjects

Include the following information about number of sites and number of subjects. You can have 1 site with multiple locations within that site. For example, AdventHealth Orlando is a single site but can have multiple locations such as campuses, outpatient clinics, outpatient surgery, imaging centers, physician offices, or AdventHealth University.

AdventHealth-Orlando site locations (campus, physician offices, etc):

Estimated number of subjects at AdventHealth Orlando sites:

Name of external site(s) outside of AdventHealth Orlando:

Estimated number of subjects at external sites:

Total number of all sites:

Estimated number of subjects at all sites combined:

## Multi-Site Research Logistics/Communication Plan

Indicate n/a if there are no other sites other than AdventHealth Orlando.

This section will be applicable to research that is conducted at AdventHealth Orlando (any location) and external institutions or facilities not affiliated with AdventHealth Orlando.

If this is a multi-site study where you are the lead investigator and AdventHealth Orlando is the **coordinating center**, describe the processes to ensure communication among sites, such as:

* All sites have the most current version of the protocol, consent document, and HIPAA authorization.
* All required approvals have been obtained at each site (including approval by the site’s IRB of record).
* If an external site is not using their IRB of record or does not have an IRB of record to use, please describe what IRB will be used for that external site
* All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data as required by local information security policies.
* All local site investigators conduct the study appropriately.
* All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Describe the method for communicating to participating sites:

* Problems
* Interim results
* The closure of a study

If this is a multi-site study where AdventHealth Orlando is a **participating** **center**, describe the processes to ensure communication with the **coordinating center**.

## Community-Based Participatory Research

Indicate n/a if there is no community involvement in the design or conduct of the research.

Describe involvement of the community in the design and conduct of the research.

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

# Subject Selection

## Vulnerable Populations (if applicable)

 Indicate n/a if there are no vulnerable populations in the study.

Provide justification if including any of the following populations in your study. For instance, consider whether the proposed research is directly important to the health and well-being of the vulnerable population; if it will answer a question affecting the health or welfare of the vulnerable population, or whether the study objectives can be met by using competent other subjects i.e. competent adults.

Cognitively Impaired Adults: If the research involves cognitively impaired adults, review the [**“HRP-414 WORKSHEET: ADULTS LACKING CAPACITY”**](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-05/HRP-414%20WORKSHEET%20-%20Adults%20Lacking%20Capacity.pdf)to ensure that you have provided sufficient information.

Children: If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the [[**“HRP-310 CHECKLIST: Children”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets)](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-05/HRP-310%20CHECKLIST%20-%20Children.pdf) to ensure that you have provided sufficient information.

Sample text: Appendicitis is a condition that affect children. If this population was not included, the validity of the study would be compromised because the study is based on the lack of knowledge for this patient population. The results of this research could lead to changes in the management of care for children undergoing appendectomy.

Pregnant Women: If the research involves pregnant women, review the [**“HRP-305 CHECKLIST: Pregnant Women”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) to ensure that you have provided sufficient information.

Neonates of non-viable or uncertain viability: If the research involves neonates of uncertain viability or non-viable neonates, review the  [**“HRP-306 CHECKLIST: Neonates of Uncertain Viability”**](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-05/HRP-306%20CHECKLIST%20-%20Neonates%20of%20Uncertain%20Viability.pdf) or **“HRP-307 CHECKLIST: Nonviable Neonates”** to ensure that you have provided sufficient information.

Prisoners: If the research involves prisoners, review the [[**“HRP-308 CHECKLIST: Prisoners”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets)](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-05/HRP-308%20CHECKLIST%20-%20Prisoners.pdf) and address each of the criteria for approval.

## Inclusion Criteria

Create a numbered list of criteria subjects must meet to be eligible for study inclusion (e.g., age, gender, target disease, concomitant disease if required, etc.) Consider clinical aspects that are appropriate for your protocol such as number of symptoms and length and/or severity of symptoms.

Sample text:

1. Age 12-18
2. Height and weight recorded in the medical record
3. Underwent appendectomy at study locations
4. Appendectomy between January 1, 2011 and December 31, 2011

## Exclusion Criteria

Create a numbered list of criteria that would exclude a subject from study inclusion. Consider clinical issues that are appropriate for your protocol such as abnormal lab results, or history of cancer.

Sample text:

1. Chronic pain condition noted in admission or H&P
2. Co-morbid condition with pain
3. Additional planned or unplanned surgical procedures at the same time of appendectomy
4. Patients with post-surgical complications of infection, bleeding, or return to surgery during hospital admission for appendectomy

# Resources Available / Study Team Qualifications

# Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the data collection procedures research procedures, and their duties and functions.

Include your plan for Investigator oversight and study team communication of issues throughout the duration of the study such as reportable new information, implementing amendments, study progress, etc.

Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. This will include students and their relevant coursework, along with confirmation of completed CITI. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.

# Study Procedures

Subject Inclusion and Screening

Describe the methods that will be used to identify potential subjects’ data to be included

If you plan to access medical records for study development or feasibility, **“HRP 221 FORM Review Preparatory to Research”** (access via IRBNet under “Forms and Templates”)Reviews Prep to Research Form must be completed and submitted **PRIOR** to any access of medical records.

Sample text: MRN numbers from all appendectomy patients who meet the inclusion criteria at the three campus locations will be provided to study personnel to be screened for inclusion and exclusion criteria.

## Consent Process

Indicate n/a if you are applying for a Waiver or Alteration of Informed Consent.

“PLEASE NOTE: If this study involves a consent process or for some reason you are not granted a waiver of informed consent by the IRB, you will have additional information to provide in this section.

## Waiver of Written Documentation of Consent or Waiver of Consent

**Waiver of Written documentation of Consent (consent will be obtained but signatures will not be required)**

Indicate n/a if you are obtaining Informed Consent with signature.

* Indicate if you wish to request a Waiver of Written Documentation of Consent
* Review the [**“HRP-303 CHECKLIST: Waiver of documentation of Consent”**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) to ensure your study qualifies for the waiver.

**Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

Indicate n/a if you are obtaining Informed Consent.

* Indicate if you wish to request a Waiver or Alteration of Consent of Consent and/or a Waiver of HIPAA Authorization.
* Review the [**“HRP-300 CHECKLIST:** [**Waiver Consent**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) **HHS”**](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-11/HRP-300%20CHECKLIST%20-%20Waiver%20of%20Consent.pdf)
* If protected health information (PHI) is being used or disclosed, please complete and submit the **“HRP-220 FORM: Waiver of HIPAA Authorization Request”** (access via IRBNet under “Forms and Templates”)

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## Sample text: A waiver of informed consent and a waiver of HIPAA authorization are requested.

## Data Collection Process

In this section, describe the procedures required or your plan to collect and record data to ensure the data is collected in a consistent manner. This may include identifying the location to acquire data points for those that may be documented in more than one place, define terms and/or any symbols or abbreviations used in data collection sheets, etc.

Sample text: For patients meeting inclusion/exclusion criteria, records from AdventHealth Orlando, East, and Celebration campuses will be accessed by study personnel to gather BMI, time till pain medication and post op pain score information.

## Study Duration

Include a projected start date.

Include the estimated duration to collect data from all study subjects.

Provide an estimated date for investigators to complete the study (includes analysis).

Sample textIt is estimated to take 6 months to collect and analyze the data.

## Materials of Human Origin: Collection, Preparation, Handling and Shipping

Indicate n/a if you will not be using Materials of Human Origin.

This section should be used if the focus of the study utilizes stored materials of human origin.

Describe the process for obtaining access to the materials of human origin, and the plan for the physical security of the materials after they are obtained, including:

1. How and from where it will be obtained.
2. Where the biological materials will be stored.
3. Who will have access to the stored biological materials and how will such access be secured and controlled?
4. What chain of custody for the Materials of Human Origin will be used throughout the trial, and how will the transfer of custody between departments, people, and/or institutions be documented?
5. Will the biological materials be sent anywhere outside of the AdventHealth Orlando system? If so, identify all locations.
6. What are your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended?

# Study Outcome Measures (Endpoints)

Describe the primary and secondary study endpoints/outcome measures. In this section, provide a list of the endpoint/outcome measures to be studied along with a description of the endpoint/outcome measures and psychometric properties.

NOTE: Data listed here should mirror your data collection sheet or case report form.

Sample Text: BMI will be calculated using the stated Height in inches, as given during admission, and weight in pounds as measured in the pre-operative assessment. The formula for adult BMI calculation is as follows: lbs\*703/in2

Sample Text: Length of time in minutes, will be from the completion of the surgical procedure to the first oral pain medication dosage time.

Sample Text: Pain will be measured using standard pain scale for adults used on 10 Tower. Pain measurement taken at 8-10 hours post-op will be used for analysis.

# Data Management and Quality Plan

Throughout this section, address all mechanisms used to capture/store data including but not limited to paper copy, spreadsheets, databases, digital files (video or voice), device driven data collection, cloud storage.

## Data De-identification

Indicate n/a if you are not de-identifying data.

If data will be de-identified, there will be a process of developing a code to be used for study subject numbers. This code usually consists of numerals and may be a combination of numerals and letters. However, the code must not contain any unique identifiers. Please provide the following information related to this process.

* How are unique identifiers being generated? Describe the format or taxonomy of the chosen code.
* How is data being linked to subjects’ identifying information?
* How and when will the link be used?
* Where will the linked data be stored?
* Who will have access to the linked data?
* How long will the linked data be stored?
* Will the link ever be destroyed so that the data or the samples will become de-identified?
* Describe any circumstances under which the link between the subject’s identity and assigned study subject number could be used to break the code.

Sample Text: Variables of BMI, length of time and pain scores will be taken from the patient’s medical record. No identifying patient information will be retained. Date of surgery will be recorded for data verification compliance.

OR

Sample text: Patients will be identified by using a numeric code linked to the MNR number. PT visits, percentage of meals consumed, and length of stay will be calculated in an electronic spreadsheet with the numeric code only. The key (MRN and numeric code) will be locked in a secure office in a folder available to only the study team members. Once the data is cleaned and ready for analysis, the link will be destroyed.

## Data Confidentiality, Storage, and Retention

Describe how you plan to maintain confidentiality of study data.

* Describe how data and records of any media type (e.g., paper, electronic, audio recordings, video recordings, blogs, and photographs) will be stored during the study and after the study has been completed.
* Describe data security measures for the storage of records (e.g., locked filing cabinet, password protected computer, etc.)
* Describe who will have access to the data and records.
* Describe how long data and records will be retained\*
* Describe how data and records will be disposed.

**\*** AH policy requires study records be maintained a minimum of 7 years following study closure. **Refer to “POLICY 400.070 HRP-070 Investigator Obligations in Research”** **record retention requirements at AdventHealth.**

Sample text: Study documentation and patient information will be kept by the principal investigator in a locked drawer of their desk. Study records will be stored at the Orlando campus for a period of 7 years following study completion.

## Data Quality

Indicate n/a if you do not have a plan for insuring data quality.

Describe how the data quality is going to be checked.

Sample text: Quality control procedures for this research study include random selection of records by a second researcher that will compare entered data (Excel database) with the original source document (electronic medical records).

## Data Sharing (outside of AdventHealth Orlando)

Indicate n/a if you are not sharing data outside of AdventHealth Orlando.

If information is going to be shared with any other individual, organization or institution outside of AdventHealth Orlando, please complete this section. State the purpose of data sharing and provide a detailed description of all data elements that will be shared. (Note: Consult the Office of Sponsored Programs (OSP) regarding appropriate legal documents.)

Sample text: eCRFs will contain data pertaining to medical care and include the following PHI identifiers: Dates of diagnosis, surgery, discharge.

# Sample Size Determination

Describe how the sample size was determined for this study. The sample size should be based upon the primary outcome variable. If the authors have determined that sample size estimation was not computed, please provide the rationale.

Sample text: After obtaining IRB approval for Reviews Prep to Research, it was found that during a year time frame approximately 400 patients underwent appendectomy at the study locations. Based on the available sample size and estimating variation of time (6-12 hours) and BMI from 22 to 50, calculations determined there would be sufficient power (82%) to show differences in BMI and length of time to oral pain medication.

# Statistical Analysis Plan

Describe the statistical approach to the primary and secondary objectives of the study. This section should contain the key elements of the analysis plan. Describe how you will manage missing data.

## Primary Objective Analysis

Sample Text: A graphical display of BMI and length of stay will be used to check your specific statistical plan. If a possible linear relationship is visualized, a correlation coefficient will be calculated.

## Secondary Objective Analysis

Sample Text: The secondary analysis will be focused on post-operative pain and the BMI score. A graphical display of BMI and pain score (0 to 10) will be used to check your specific statistical plan. If a possible linear relationship is visualized, a correlation coefficient will be calculated.

# Potential Risks and Benefits

## Potential Benefits

Describe potential benefits to the individual research subject (economic, physical, or other) as well as the benefits to science for this research study.

Include the probability, magnitude, and duration of the potential benefits if these can be quantified or determined.

Indicate if there is no direct benefit.

##

Sample Text: There are no direct benefits to participants, as this is a retrospective study. However, the knowledge gained through this study may benefit patients in the future.

## Potential Risks and Mitigation of Risks

## List the reasonably foreseeable risks or hazards to subjects included in the research. Note that potential data breach is primary risk for retrospective research.

Include as many as may be useful for the IRB’s consideration, describe the probability, magnitude, duration, and reversibility of the risks if these can be quantified/determined.

Consider physical, psychological, social, legal, and economic risks, and other risks as applicable to the study.

If applicable, describe risks to others who are not subjects.

Describe what procedure(s) will be implemented to reduce subject risk(s) described above.

Sample Text: As this is a retrospective study, there are no physical potential risks to research subjects. Loss of confidentiality is a potential risk to patients, but patient information will be de-identified prior to analysis and only study personnel will have access to patient information.

## Provisions to Protect the Privacy Interest of Subjects

Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

Indicate how the research team is permitted to access any sources of information about the subjects.

Sample Text: There are no participant interactions in this study. Therefore, there are no further privacy concerns beyond what is being covered by HIPAA.

# Withdrawal of Subject/Data

## Investigator Withdrawal of Subjects

This section is **not** related to when a subject withdraws consent. If appropriate to your study, this section is designed to describe the scenarios under which the **investigator** may remove a subject from analysis prior to the expected completion of the study.

##

# Ethical Considerations

Indicate n/a if you do not have any Ethical Considerations.

Identify any ethical concerns and how you will address these. Note: If including or targeting vulnerable populations explain additional measures you will implement in order to protect their rights.

Sample Text: All members of the research team will adhere to standards of ethical conduct during the study. To ensure the integrity of the research, members of the research team will adhere to all components of the protocol.

## Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

# Funding Source

Indicate n/a if you do not have a funding source.

This section should describe how the study will be financed, but should not contain specific dollar amounts.

# Dissemination/Publication Plan

Describe the plan for dissemination of results. Note: To the extent possible, roles and responsibilities of each research team member should be determined in advance. Additionally, if the research study will be published, there should be an additional plan that describes assignment of authorship and the contributions of each author. International Committee of Medical Journal Editors (ICMJE) has a policy to guide authorship.

# References

This is the bibliography section for any information cited in the protocol. It should be organized as any standard bibliography.

1. Author, Title of work, periodical and associated information.
2. Author, Title of work, periodical and associated information.