Qualitative Research Study Protocol Template

* **If you believe your activity may not meet the definition of “Human Research” subject to IRB oversight, complete and submit the Determination of Human Subjects Research Form in IRBNet.**
* **Be sure that all study materials/documents 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 *orange font.***
* **Note that, depending on the nature of your research, some sections below will not be applicable. Indicate this as “N/A.” Do not delete the section.**
* **Slight adjustments may be made to the section headings text to better reflect specific study design.**
* **Appendices, if used, should be added after the Reference section.**
* **Delete this “Instructions” section from your final protocol.**

**Study Protocol Title:**

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

*Your title should reflect the qualitative nature of your work. Qualitative research is not causal and the title should reflect that it is descriptive. Qualitative studies often have more creative titles than a quantitative study would, but that is not a requirement.*

**Study Sponsor:**

*AdventHealth is the default response. Please change if needed e.g., AdventHealth University. AdventHealth Central Florida, AdventHealth Midwest, AdventHealth West Florida, etc.*

*The sponsor is the person or organization 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.*

***Sample text****: AdventHealth or AdventHealth University*

*A site approval letter will be obtained from Ms. Samantha Jones, the practice manager at AdventHealth Medical Group Family Medicine, the site where potential subjects will be approached for study recruitment.*

**Principal Investigator:**

Principal Investigator: *Insert name here*

# List of Abbreviations:

*Include commonly used abbreviations and acronyms.*

# Introduction

*For any study, keep in mind that the IRB is focused on understanding your proposed work and that you are keeping participants safe and their information confidential. You do not need to make things complicated. A simple, clearly written proposal is what is required.*

*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 AdventHealth and AHU institutional research requirements. (insert any applicable regulations specific to this research)*

# Background Information and Scientific Rationale

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

*You are making a case for the relevance of your study. Many times, there is not much specific literature available for qualitative topics and that is why you are doing this type of study. You want to help people understand a particular phenomenon, gain insights into why people engage in a certain activity or have certain thoughts/feelings, etc. The purpose of your study is to explore, describe, discover, etc. Find literature that will help you build rationale to study and understand your chosen topic. Each paragraph should build on the previous one and by the final paragraph it should be clear why your study is relevant.*

*While there is no minimum number of required references, provide and summarize adequate published (or available unpublished) data in the literature to build enough rationale for the research question(s), study objectives, and research design.*

# Study Objectives

*In a general fashion, summarize the purpose, aim, or objective of the study. Qualitative research questions are typically a “how” or a “what” question.*

## Primary Objective/Aim/Goal

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

*Include the details of the study’s primary objective (this is the main purpose for performing this study and should be focused on* ***one question****).*

***Sample Text:*** *The primary objective of this study is to explore and describe the experience of a hospitalized patient working with a health advocate. Answering the question, “What is a hospitalized patient’s experience working with a health advocate?”*

## Secondary Objective/Aim/Goal

*Include secondary objectives (as many as relevant). These objectives may be dependent or independent of the primary objective. The secondary objective of the study may be something like: to identify variables for further study, discover themes that inform the process, determine recommendations for best practice.*

***Sample text:*** *The secondary objective will be to recommend changes to enhance the interaction of patient and health advocate.*

# Study Design

## Research Design

*Include the description of study type (qualitative) and any important study details. Type of analysis should be stated.*

***Sample text:*** *The research design is a qualitative design using a selected patient population that requested to have a health advocate. A thematic approach will be used for analysis of interview data transcripts.*

## Research Intervention Description

*In this section describe what you will be doing. This may be a semi-structured interview, participant observation, focus group or other technique. If you are using an interview method, please provide the initial interview questions.*

***Sample text****: Patients will be consented prior to interviewing. Interviews will be recorded using a recording device. Software will be used to provide transcripts of the interview. Because voice recording could be identified, these files will be deleted and only transcripts will be used for analysis purposes. Subject IDs will be assigned for documentation purposes.*

*The interview will have three initial starting questions. Subsequent questions will be determined based on patient response to these questions.*

1. *What was the reason that you requested a health advocate at this time?*
2. *What specific support did the health advocate provide for you and/or your family?*
3. *What other areas of support do you feel would be beneficial?*

***Analysis***

*The qualitative data will be analyzed according to the thematic analysis method based on that of Braun and Clarke (2006). This method has six phases. During the first phase the researcher becomes familiar with the data. In the second phase, the researcher focuses on coding the data, line by line and word by word. The codes will reflect the research question and are a semantic and conceptual analysis of the data. The third phase occurs after the data has been coded. The researcher will look for how different codes can be combined to create overarching themes. In the fourth phase the researcher will review the themes and analyze how the themes work together in relation to the whole data set. In the fifth phase of the process, the researcher defines and names the themes, so they reflect the essence of how that theme fits in the whole data set. Finally, the researcher will write a cohesive narrative about the data, contextualizing it in relation to the literature.*

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

*Keep in mind 1 site may have multiple locations within that site.*

*AdventHealth sites (campus, physician offices, etc):*

*Estimated number of participants at AdventHealth* *o sites:*

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

*Estimated number of participants at external sites:*

*Total number of all sites:*

*Estimated number of participants at all sites combined:*

## Multi-Site Research Logistics/Communication Plan

 *Indicate n/a if this is not a multisite study.*

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

If this is a multi-site study where you are the lead investigator and AdventHealth 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 is a **participating** **center**, describe the processes to ensure communication with the **coordinating center**.

***Sample text:*** *N/A*

## 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.

***Sample text:*** *N/A*

# Participant 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.

***Example:*** *Due to our target population, it is possible that some of these patients will be cognitively impaired adults. If cognitively impaired patients are not enrolled, this would compromise the validity of the study because* ***<fill in the blank>***

*Include a description of additional safeguards in place to protect the rights and welfare of any of the vulnerable populations. Any populations lacking justification may NOT be included.*

Cognitively Impaired Adults: (If the research involves cognitively impaired adults, review the **“HRP-414 WORKSHEET: ADULTS LACKING CAPACITY”** 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) to ensure that you have provided sufficient information.)

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** 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) and address each of the criteria for approval.

*Employees:* ***(Refer to AH Policy 400.120 & AH SOP 400.120A)*** *When AH (or AH affiliate) employment status is part of the inclusion criteria, the AH Researcher must be able to provide a rationale other than convenience for selecting the AH employee as a subject. The recruitment method must not lead AH employees, especially when they are in a subordinate job position, to believe they will be compromised in any way by not participating. The compromised circumstances and fear of retribution, even subtle cues of compromise, can place AH employees in a position of involuntary participation in a research project. You must explain your plan to avoid coercion and make it clear that non-participation will not affect their employment status.*

*Recruitment through bulletin board advertisements (screened and approved by the IRB), or recruitment through a third party unassociated in a power/supervisory relationship with the employee are usually the best strategies.*

*NOTE: When an AH employee is recruited to be a study subject, but AH employment is not an inclusion criterion, it is suggested that during the consent procedure the relationship between the subject’s employment status and study participation be addressed so that it is made clear that non-participation will not affect employment status.*

Students: Provide a plan to avoid coercion when recruiting students and be clear that non-participation will not affect the potential subjects’ academic status.

***Sample text:*** *It is possible that an AH employee would be asked to participate. In this case, it will be made clear that for study purposes being an employee is secondary to the patient status and that declining to participate will in no way affect employment status or be communicated to anyone in any circumstance.*

## Inclusion Criteria

*Create a numbered list of criteria participants must meet to be eligible for study enrollment (e.g. age, gender, target disease, concomitant disease if required, etc.) Consider demographic and any clinical aspects that are appropriate for your protocol.*

***Sample text:***

1. *Age 18 – 89*
2. *Inpatient with a minimum of 3 days stay at time of enrollment*
3. *Has requested and met with a health advocate during this hospitalization*
4. *Willing and able to be interviewed and have interview recorded*

## Exclusion Criteria

*Create a numbered list of criteria that would exclude a participant from study enrollment. Consider demographic or clinical issues that are appropriate for your protocol such as ability to comply with study instructions or history of alcohol abuse.*

***Sample text:***

1. *Unable to provide answers in English*
2. *Cognitively unable to provide answers to research questions*

# Resources Available

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

Include your plan for ongoing discussion 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. 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.

Describe other resources available to conduct the research: For example, as appropriate:

* Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
* Describe the time that you will devote to conducting and completing the research.
* Describe your facilities.
* Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

***Sample text:*** *The principal investigator teaches qualitative methods and will instruct all team members in the interviewing process. The interviews will take place in the participants hospital room during an uninterrupted 45-minute interview time-period. The health advocate will not be present during the interview. Family members may be present in the room but will be asked to let the participant respond to questions.*

# Study Procedures

## Participant Recruitment and Screening

Describe the methods that will be used to identify potential participants keeping in mind safety, confidentiality and convenience of the participant.

Describe when, where, and how potential subjects will be recruited.

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements), describe those methods.

Describe materials that will be used to recruit subjects. (Include copies of these documents with the IRB submission. For advertisements, include the final copy of printed advertisements.

*Note: If you plan to access medical records for study development or feasibility, Reviews Prep to Research Form must be completed and submitted* ***PRIOR*** *to any access of medical records. If you plan to access medical records for screening and/or recruitment purposes prior to obtaining informed consent, Request for HIPAA Waiver of Authorization Form (HRP-220) must be completed and submitted* ***WITH*** *the initial application.*

***Sample text:*** *Participants will be recruited from patients admitted to AdventHealth Orlando. The list of health advocate consults will be used to review the inclusion and exclusion criteria prior to approaching the patient. This list will be updated weekly. The patient will be in a private room at the time of study introduction. Study will be introduced verbally and only after an initial acceptance will the written informed consent documents be introduced.*

## Consent Process

For Exempt Research: Confirm your plan to follow CW AHC 237 Process and Required Elements of consent for Exempt Research. NOTE: IRB makes the final determination on whether a study meets criteria for Exempt review.

For Non-Exempt Research:

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

If you are obtaining consent of subjects, check the box to confirm you will be following the below SOP or describe your consent process in similar detail.

🞏 CW AHC 216 Informed Consent Process and Written Documentation of Informed Consent .

## Subjects who are not yet adults (infants, children, teenagers)

* Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
* Describe whether parental permission will be obtained from:
	+ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
	+ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
* Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
* Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
* When assent of children is obtained describe whether and how it will be documented. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.

## Cognitively Impaired Adults

* Describe the process to determine whether an individual is capable of consent.

## Adults Unable to Consent

* 🞏 Check here to confirm that you will follow CW AHC 110 POLICY: Legally Authorized Representatives, Children, and Guardians when enrolling adults unable to consent.
* Describe the process for assent of the subjects. Indicate whether:
	+ Assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent, and which will not.
	+ If assent will not be obtained from some or all subjects, an explanation of why not.
	+ Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

***Sample text:*** *All participants will be consented prior to an interview.*

## Documentation of Informed Consent Process

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

*NOTE: Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.*

*In this section, describe how you will document the Informed Consent process in source documentation such as using a checklist or documenting via a progress note. This requirement is separate from obtaining signatures on the consent document. For help to create a checklist, review* **TEMPLATE – Informed Consent Process Checklist** *found on the IRB website.*

***Sample text:*** *A research team member will note in the source documentation the consent process, date consent was obtained, and that consent was obtained prior to initiating any research procedures.*

## 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.*

* 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
* Review the **“HRP-300 CHECKLIST:** [**Waiver Consent**](https://drupal02.floridahospital.org/irb/content/checklist-and-worksheets) **HHS”**

**Waiver or Alteration of HIPAA Authorization**

*Indicate n/a if you are obtaining Informed Consent/HIPAA authorization OR are not using or disclosing protected health information (PHI).*

* Indicate if you wish to request a Waiver or Alteration of HIPAA Authorization
* Indicate if you wish to request a Partial Waiver of HIPAA authorization for screening and recruitment. Complete/submit the “FORM: Request for Waiver of HIPAA Authorization (HRP-220
* If protected health information (PHI) is being used or disclosed, please complete and submit the **“FORM:** Request for Waiver of HIPAA Authorization (HRP-220)

## Non-English Speaking Subjects

* If you do not plan to enroll non-English speaking subjects, provide justification for the exclusion.
* If you plan to enroll non-English speaking subjects, consider the flow of the entire study and explain your plan to ensure that you are adequately prepared to conduct study procedures such as the consent process, study visits, directions, follow ups, etc., including how oral and written study material that is to be used will be presented.
* Indicate what language(s) other than English are understood by prospective subjects or representatives.
* For the consent process, indicate if you will have consent documents translated into a particular language or
* 🞏 Check here to confirm you will follow HRP-804 INVESTIGATOR GUIDANCE Short Form Consent Process

***Sample text:*** *Due to the study team only being able to converse in English, this study will not be able to include speakers of other languages. The iterative nature of interviewing does not allow for interpreter services to provide an alternative option.*

## Randomization

*Indicate n/a if you are not randomizing subjects to study groups.*

***Sample text:*** *N/A*

## Study Visits

*In this section, describe the setting as well as all study activities delineated by visit. If appropriate, create a study procedures flowchart/table depicting the activities and procedures to be followed at each visit. A study visit can consist of any subject contact for research purposes (e.g. face to face, phone, email) and in some cases may occur only once.*

***Example study grid:***

*The following table identifies the activities in relation to the study timeline.*

|  |  |  |  |
| --- | --- | --- | --- |
| *STUDY VISIT SCHEDULE* | *Visit 1**Screening* | *Visit 2 Interview* | *Visit 3 follow-up* |
| *Inclusion and Exclusion Criteria* | *X* |  |  |
| *Informed Consent* | *X* |  |  |
| *Semi-Structured Interview* |  | *X* |  |
| *Follow-Up Member check* |  |  | *X* |

***Sample text:***

*Pre-study Phase:*

*After the list of patients having seen a patient advocate has been provided, potential participants will be screened for inclusion/exclusion criteria prior to approaching patient. Patients will be approached in the private room and asked to participate. After signing informed consent, participants will be asked to provide a convenient time that day for a 45-minute interview.*

*Study Phase:*

*During the designated time, the interviewer will approach the participant and again ask about whether this time will work for the interview, after setting up the recorder, the interviewer will commence with the first initial question.*

## Study Duration

 *Include a projected start date. Include the estimated duration to enroll all study subjects.*

*Provide the total length of time participants will remain in the study, including the active intervention and follow up period.*

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

***Sample text:*** *The study will begin after IRB approval, OSP clearance and completion of all AHU procedural research requirements. The potential patient population for this study will allow the study to enroll participants within a 3-week period. Once the interview is conducted, no additional patient contact will be necessary. Analysis of results will take approximately 6 months. Results will be provided to the patient advocate manager.*

# Study Outcome Measures (Endpoints)

*In this section, provide a list of the endpoint/outcome measures/data elements to be studied along with a description of the endpoint/outcome measure.*

***Sample Text:*** *Number of hospitalizations: Count of the number of admissions during a 12-month period starting with patient enrollment in the study and counting back 12 months.*

 ***Sample Text:*** *Patient Interview: Information on the pros and cons of the intervention will be solicited from all patients in the study via a recorded transcript of the interview. This information will be gathered (audio recorded) by trained interviewers using three initial questions and follow-up questions will depend on prior responses. Interview will last approximately45minutes. Interview questions are provided in a separate document.*

# 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:*** *Patient Demographics: Patient information (Age, number of Health Advocate sessions, LOS) will be summarized from EMR but will not be paired with interview data. This information will only be used to describe the population of patients included in the study. This data will be recorded on paper.*

***Sample Text:*** *Patient Interview: Information on the interaction of the patient with the health advocate will be explored. This information will be gathered via an audio recording. An interview transcript will be obtained using transcription software and the audio recording will be deleted. No link will be retained. Only transcript information, which is de-identified, will be used for analysis. Each transcript will be assigned a subject number starting with 1 and ending with 10. Only transcript information, which is de-identified, will be used for analysis.*

## Data Confidentiality, Storage, and Retention

*Describe how you plan to maintain confidentiality of study data.*

* Describe how data and records of any type (paper, electronic, audio/video recordings, photographs) will be stored during the study and after the study has been completed. Include data security measures for the storage e.g., locked filing cabinet, password protected dedicated network space and/or

e-source tools/applications all as approved by the research department and per the research site’s policies.

* 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 CW AHC 112 POLICY Investigator Obligations in Research for record retention requirements at AdventHealth.***

***Sample Text:*** *Study regulatory records and transcript digital files will be retained as an electronic file for a period of 7 years following study closure. The electronic files will be stored on a secured AHU computer accessible to only study team members. Following the retention period, all files will be erased from the stored drive.*

## Data Quality

*Describe how the data quality is going to be checked. Indicate n/a if you do not have a plan for insuring data quality.*

***Sample Text:*** *Two audio recordings will be randomly selected, and transcription accuracy assessed prior to deletion of the source audio files.*

## Data Sharing

*Indicate n/a if you are not sharing data.*

*If information is going to be shared with any other individual, organization or institution, 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 site’s Office of Sponsored Programs (OSP) or equivalent office regarding appropriate legal documents.)*

# Sample Size Determination

*Describe how the sample size was determined for this study. Qualitative studies may have the number of participants selected based on saturation or other requirements. The sample size should be based upon adequate coverage of the primary outcome.*

***Sample text:*** *The sample size of 10 participants was selected based on insight perspectives and logistical constraints. It is believed that this number will provide insight to the most common attitudes related to the patient advocate role.*

# Potential Risks and Benefits

## Potential Benefits

*Describe potential benefits to the individual research participant (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:** The patient may benefit from having a voice and having someone listen to their interpretation of the patient advocate role.

## Potential Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the 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.

Although qualitative research usually has minimal risk, consider physical, psychological, emotional, social, legal, and economic risks, and other risks as applicable to the study and how you would address potential issues.

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

**Sample Text:** The only potential risk is that patient feels negative comments may affect their quality of care. This concern will be directly addressed with the participant.

## Mitigation of Risks

*Describe what procedure(s) will be implemented to reduce subject risk(s) described above. Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

**Sample Text:** Patients will be reassured that neither their participation in this study nor any comments made will impact the level and quality of care they receive.

## 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.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

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

**Sample Text:** The interview will be conducted in a private room and will be stopped and restarted if medical procedures or monitoring needs to be done. If the subject shows any apprehension about the interview questions, the interviewer will ask the participant if they would like to continue or end the session.

# Early Withdrawal of Subjects

## Investigator Withdrawal of Subjects

*NOTE: This section is* ***not*** *related to when a subject withdraws consent. This section is designed to describe the scenarios under which the* ***investigator*** *may withdraw a subject prior to the expected completion of that subject (e.g. safety reasons, failure of subject to respond, etc.) Describe the process to determine when a subject is lost to follow-up (e.g. number of phone calls to subject, phone calls to next-of-kin if possible, certified letters, etc.).*

***Sample text:*** *Subjects may be withdrawn from the study if the interviewer determines the participant is not able to provide answers to interview questions.*

## Subject Request for Withdrawal from Study

*Describe the process in which a subject may request withdrawal from the study.*

***Sample text:*** *Subjects may withdraw from the study by indicating they would like to terminate the interview session prior to completion.*

## Data Collection and Follow-up for Withdrawn Subjects

*Even though subjects may be withdrawn prematurely from the study, it is important to describe how data will be handled for withdrawn subjects and be sure that this is consistent with information in the Informed Consent form.*

***Sample text:*** *Patients who request to be withdrawn from the study or are withdrawn by the investigator will not be included in the study analysis. These subjects will be replaced.*

# Adverse Event Reporting

*Include methods and timeline for assessing, recording, managing and reporting adverse events and safety parameters*

***Sample text:*** *No adverse events are expected, but if a patient has a physical or emotional reaction to being interviewed, this will be promptly reported to the IRB.*

# Ethical Considerations

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

*Identify any ethical concerns and how you will address these. Including but not limited to the following:*

***Deception:*** *If distress or deception must be experimentally induced, as in some psychological and physiological measurement research, the research design usually requires withholding certain information from the consent process in order to obtain unbiased results. After the subjects have completed participation, it is important to provide this information to subjects from whom it was withheld and to provide an opportunity for subjects to express their concerns and ask questions about the research. If the research design includes deception, please describe why it is needed. Describe the debriefing process of how subjects will be debriefed with a description of what really happened and why the research could not otherwise have been conducted.*

## *Sharing of Results with Subjects: Describe whether results (study results or individual subject results, such as results of 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.*

***Sample text:***

*Ethical considerations in qualitative research are sometimes represented as less overt than other study designs. Orb, et.al. (2000) assert, “The nature of ethical problems in qualitative research studies is subtle and different compared to problems in quantitative research.” They go on to point out “The literature provides few examples of ethical issues in qualitative health research.”*

*Morse (2001) concurs with a nod to principles of informal consent and adherence to confidentiality: “In the 10 years of publication of Qualitative Health Research, some authors have referred to the potential risks to investigators inherent in fieldwork… and in working with qualitative data. However, we have been silent about the risk to participants—possibly because if the principles of informal consent are adhered to and promises of anonymity and confidentiality respected, the risks are very low indeed.”*

*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.*

*Members of the research team will ensure that all potential participants are provided with informed consent, consent is obtained, and all participants have all questions answered prior to performing any study procedures. Members of the research team will ensure that participation is voluntary by noting that participants may withdraw from the study at any time without consequence. Members of the research team will assure all safeguards that respect the confidentiality and anonymity of research participants.*

# 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.*

***Sample Text:*** *This study is supported by funding from National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research (RO1 NS050506). AdventHealth has received a subaward from Duke University, who is the Prime Recipient of this grant. The IRBNet # for this grant is 412345.*

***Sample Text:*** *This study is funded in part by a gift given to the AdventHealth Foundation.*

# Subject Stipends or Payments

*Indicate n/a if you are not providing subject stipends or payments.*

*Describe any subject stipend, payment or gift here. Describe the amount, method, and timing of any payments to subjects*

***Sample text:***Subjects will receive a $10 stipend for their participation and a parking voucher if needed at conclusion of the interview.

# 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.*

*Note: Review the Clinical Trials.gov guidelines on the Research Services website to determine if your study is required to be registered. For those studies of which it is not required by law, registration may still be required by your publishing journal.*

***Sample text:*** *It is anticipated that these results will only be reported to the patient advocate care manager. The study is primarily intended as an educational activity in qualitative research.*

# 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.

***Sample format:***

Braun, V., Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3, 77-101.