Research Study Protocol Supplement

* **Use this document to provide information to supplement an external multi-centered research protocol. NOTE: If after IRB approval, any information in this supplement changes, resubmit a copy of this document with revisions for IRB review.**
* **Instructions and/or sample text is 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.**
* **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.**
* **Delete this “Instructions” section from your final protocol.**

# Study Protocol Title:

*Be consistent with the Title throughout your IRB documents.*

# Principal Investigator:

Principal investigator:

# 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.

# Drugs or Devices:

If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

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

*Include the following information about number of sites and number of subjects.*

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

*Estimated number of subjects at AdventHealth sites:*

*Estimated number of subjects study wide:*

# 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.*

***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, please contact the IRB. 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 a 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.

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# Recruitment Methods:

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 the methods that will be used to identify potential subjects.

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

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. When advertisements are taped for broadcast, include the final audio/video tape. (You may submit the wording of the advertisement prior to taping in order to avoid re-taping due to inappropriate wording but will still need the IRB to review the final audio/video tape.)

*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.*

*Note: If you plan to access medical records for recruitment purposes prior to obtaining informed consent,* Request for Waiver of HIPAA Authorization (HRP-220)*must be completed and submitted* ***WITH*** *the initial application.*

# 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, indicated, 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.

## 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) and provide sufficient information here 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”** and provide sufficient information here to ensure your study qualifies for the waiver.

**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 Partial Waiver of HIPAA authorization for screening and recruitment. Complete/submit the “FORM: Request for Waiver of HIPAA Authorization (HRP-220)”
* Indicate if you wish to request a Waiver or Alteration of HIPAA Authorization and 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

# 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.*

## 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, and 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 Investigator Obligations in Research for record retention requirements at AdventHealth.***

## 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 Sponsor Programs (OSP) or equivalent office 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.*

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

*This section does not apply to obtaining blood samples or other specimens for safety monitoring, screening procedures, and/or diagnostic purposes as part of this research study. 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 prospectively obtained materials of human origin (whether acquired from within AdventHealth or from another source) obtained as part of clinical intervention or prospective research study.*

*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 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?*

# 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.

# 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.*