

PROTOCOL TITLE:

INSTRUCTIONS:

- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”.*
- *Attach the entire sponsor’s protocol. Unless otherwise specified, provide only site-specific information below.*
- *When you write a single site supplement, keep an electronic copy. You will need to modify this copy when making changes. When you make changes, use the Track Changes feature.*
- *As you are writing the site supplement, remove all instructions in italics so that they are not contained in the final version of your site supplement.*

PROTOCOL TITLE:

Include the full protocol title.

PRINCIPAL INVESTIGATOR:

*Name
Department
Telephone Number
Email Address*

VERSION NUMBER/DATE:

Include the version number and date of this site supplement.

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?

PROTOCOL TITLE:

Table of Contents

1.0	Study Summary.....	2
2.0	Study Intervention/Investigational Agent.....	2
3.0	Data and Specimen Banking*.....	3
4.0	Sharing of Results with Subjects*.....	3
5.0	Inclusion and Exclusion Criteria*.....	4
6.0	Vulnerable Populations*.....	4
7.0	Local Number of Subjects.....	4
8.0	Local Recruitment Methods.....	4
9.0	Withdrawal of Subjects*.....	5
10.0	Data Management and Confidentiality.....	5
11.0	Provisions to Protect the Privacy Interests of Subjects.....	5
12.0	Compensation for Research-Related Injury.....	5
13.0	Economic Burden to Subjects.....	5
14.0	Consent Process.....	6
15.0	Process to Document Consent in Writing.....	8
16.0	Setting.....	8
17.0	Resources Available.....	9

1.0 Study Summary

Study Title	
Study Design	
Primary Objective	
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	
IND/IDE #	
Study Population	
Sample Size	
Study Duration for individual participants	
Study Specific Abbreviations/ Definitions	

2.0 Study Intervention/Investigational Agent

2.1 *If the research involves drugs or device, 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.*

PROTOCOL TITLE:

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*
- 2.2 *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*
- *Identify the holder of the IND/IDE/Abbreviated IDE.*
 - *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

FDA Regulation	Applicable to:		
	IND Studies	IDE studies	Abbreviated IDE studies
21 CFR 11	X	X	
21 CFR 54	X	X	
21 CFR 210	X		
21 CFR 211	X		
21 CFR 312	X		
21 CFR 812		X	X
21 CFR 820		X	

3.0 Data and Specimen Banking*

- 3.1 *The sponsor’s protocol may require banking data or specimens for future use and both storage and use will be determined by the sponsor. If additional data or specimens will be banked locally for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.*
- 3.2 *List the data to be stored or associated with each specimen banked locally.*
- 3.3 *Describe the procedures to release locally banked data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

4.0 Sharing of Results with Subjects*

- 4.1 *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.*

PROTOCOL TITLE:

5.0 Inclusion and Exclusion Criteria*

5.1 Describe any inclusion or exclusion criteria that will differ for your local site compared to the sponsor's protocol. For example, if the sponsor's protocol allows the enrollment of children but your site will not enroll children, indicate that here.

6.0 Vulnerable Populations*

6.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (OCR-412)" to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review "CHECKLIST: Neonates (OCR-413)" to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (OCR-415)" to ensure that you have provided sufficient information.*
- *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 "CHECKLIST: Children (OCR-416)" to ensure that you have provided sufficient information.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (OCR-417)" to ensure that you have provided sufficient information.*

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects to be accrued locally.

7.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

8.0 Local Recruitment Methods

This section is for recruitment methods under the control of the local site and not central recruitment managed by the sponsor.

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

8.2 Describe the source of subjects.

8.3 Describe the methods that will be used to identify potential subjects.

PROTOCOL TITLE:

8.4 *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

8.5 *Describe the amount and timing of any payments to subjects.*

9.0 Withdrawal of Subjects*

9.1 *Describe procedures that will be followed locally, if different than the sponsor's protocol, when subjects withdraw from the research.*

10.0 Data Management and Confidentiality

10.1 *Describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

11.0 Provisions to Protect the Privacy Interests of Subjects

11.1 *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.*

11.2 *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.*

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

12.0 Compensation for Research-Related Injury

12.1 *If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.*

12.2 *Provide a copy of contract language, if any, relevant to compensation for research-related injury.*

13.0 Economic Burden to Subjects

13.1 *Describe any costs that subjects may be responsible for because of participation in the research, e.g., fuel, parking, childcare.*

14.0 Consent Process

14.1 Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following “SOP: Informed Consent Process for Research (OCR-090).” If not, describe:*
 - *The role of the individuals listed in the application as being involved in the consent process.*
 - *The time that will be devoted to the consent discussion.*
 - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
 - *Steps that will be taken to ensure the subjects’ understanding.*

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

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

- *Review the “CHECKLIST: Waiver or Alteration of Consent Process (OCR-410)” to ensure you have provided sufficient information for the IRB to make these determinations.*

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.)*
 - *For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (OCR-013)” to be aware of which individuals in the state meet the definition of “children.”*

PROTOCOL TITLE:

- *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (OCR-013).”*
- *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.*

Cognitively Impaired Adults

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

Adults Unable to Consent

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
 - *For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (OCR-013)” to be aware of which individuals*

PROTOCOL TITLE:

in the state meet the definition of “legally authorized representative.”

- *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (OCR-013).”*
- *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.*

Adults Unable to Consent

- *For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

15.0 Process to Document Consent in Writing

15.1 Describe whether you will be following “SOP: Written Documentation of Consent (OCR-091).” If not, describe whether and how consent of the subject will be documented in writing.

16.0 Setting

16.1 Describe the local sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*

PROTOCOL TITLE:

- *For research conducted outside of the organization and its affiliates describe:*
 - *Site-specific regulations or customs affecting the research for research outside the organization.*
 - *Local scientific and ethical review structure outside the organization.*

17.0 Resources Available

17.1 Describe the 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.*
- *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.*