**INSTRUCTIONS:**

*Before submitting to the IRB,* ***remove these instructions from the final protocol.***

*Depending on the nature of what you are doing, some section may not be applicable to your research. If so, retain the section heading and mark the section as N/A.*

*When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes to your study.*

***What template should I use?***

* The Biomedical Template Protocol should be used for studies involving clinical procedures or tests (except for behavioral studies where the only collected sample is obtained via a non-invasive method, for example saliva).
* For studies involving interviews, surveys, focus groups, or behavioral interventions, please use the Social Behavioral template instead.

For studies involving secondary data analysis only, please use the Secondary Analysis Protocol instead.

* For studies involving only a review retrospective data such as of medical charts, or case series, please use the Records Review template

**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 protocol.*

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| Revision # | Version Date | Summary of Changes |
|  |  |  |
|  |  |  |
|  |  |  |

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# Objectives

* 1. Describe the purpose, specific aims, or objectives. (There should be one or two primary objectives with additional objectives listed as secondary.)
	2. Describe the hypotheses to be tested or the study questions that will guide the research. If the study has more than one phase, clearly map out the different phases.

# Background and Rationale

* 1. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
	2. Describe the relevant prior experience and gaps in current knowledge.
	3. Describe any relevant preliminary data.

# Procedures Involved

* 1. *Describe and explain the study design.*
	2. *Please select the records that will be reviewed in this study (select all that apply).*

|  |  |
| --- | --- |
| [ ]  Record Review - Educational | [ ]  Record Review - Employee |
| [ ]  Record Review - Medical | [ ]  Record Review - Publicly Available Dataset |
| [ ]  Existing Specimen Analysis | [ ]  Record Review - Other  |

 *3.3 Accessing and/or collecting data, describe:*

* + - *The data that will be collected from the record (e.g., demographics, medical history, etc.). Attach the data capture sheet(s) on the IRB application.*
		- *How the data will be obtained, including how you have the authority to access the data.*

# Data Storage for Future Research

*5.1 If data will be banked for future use, describe where the data will be stored, how long it will be stored, how the data will be labelled and how it will be accessed, and who will have access to the data.*

*5.2 Describe the procedures to release data, including: the process to request a release, approvals required for release, who can obtain data.*

# Inclusion and Exclusion Criteria

* 1. Describe the criteria that define the records to be included or excluded in your study.
	2. Describe the criteria that define who will be included or excluded in your final study sample.

# Vulnerable Populations

* 1. *If the research involves records of vulnerable populations, describe additional safeguards included to protect their rights and welfare. More information can be found in SOP 128 Vulnerable Populations.*

# Statistical Analysis Plan

* 1. *Describe the data analysis plan, including any statistical procedures or power analysis.*

# Data Sources

* 1. *Indicate the source of the records.*

# Risks to Participants

* 1. List the foreseeable risks to privacy and/or confidentiality.

# Data Management and Confidentiality

* 1. *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.)*
	2. *Describe how data will be handled study-wide:*
		+ *What identifiable information will be included in the data or associated with the specimens (e.g., names, MRNs, dates, zip codes, accession number, etc.)?*
		+ *Where and how the data will be stored, including consent and/or HIPAA authorization forms?*
		+ *How long the data will be stored? Please refer to SOP 113 Data Management and Disposition for more information.*
		+ *How will the data be destroyed?*
		+ *If you plan to share confidential data with anyone outside of the research group (e.g., those not described in the consent and/or HIPAA authorization form), describe:*
			- *With whom you will share the confidential data, under what circumstances this will occur and explain how/whether participants will be informed.*
	3. *If you will review/access and/or collect/obtain Protected Health Information (PHI), select all that apply:*

|  |  |
| --- | --- |
| [ ]  Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | [ ]  Obtaining Signed Authorization |
| [ ]  Waiver of HIPAA Authorization for Entire Study (must be obtained from entity to owns the records/data) | [ ]  Data Use Agreement |
| [ ]  Business Associate Agreement (with the entity that owns the records/data) | ☐ Other (must describe/specify) |

* 1. *Describe the PHI that will be disclosed to or received from individuals outside of the research group (e.g., those not described in the consent and/or HIPAA authorization form), and your plan to maintain an accounting of disclosures.*
	2. *If you have selected an alteration or waiver in the table above, describe:*
* *The inclusion criteria you will utilize to identify the records (e.g., diagnosis codes (ICD 10), treatments received, etc.).*
* *The time interval of the charts/records involved, if applicable.*
* *The plan to protect identifiers collected under the waiver or alteration from improper use and/or disclosure.*
* *The plan to destroy the identifiers collected under the waiver or alteration at the earliest opportunity consistent with the conduct of the research.*
* *Provide written assurance that the PHI will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.*
* *Why it is not practicable to obtain signed HIPAA Authorizations from the subjects before using or disclosing their PHI in your study.*
* *Why your study cannot be conducted without access to and use of subjects’ PHI.*

# Provisions to Protect the Privacy Interests of Subjects

* 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 with whom they interact or to whom they provide personal information. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.

# Prior Approvals

* 1. Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

# Consent Process

* 1. Select the consent options you will use during the study. Each selection below must have a description in the subsequent section(s). Choose all that apply:

|  |  |
| --- | --- |
| [ ] Obtaining Signed Consent (Subject or Legally Authorized Representative) | [ ] Obtaining Consent Online (Waiver of Written Documentation of Consent) |
| [ ] Obtaining Signed Parental Permission | [ ] Obtaining Verbal Consent (Waiver of Written Documentation of Consent) |
| [ ] Obtaining Signed Assent for Children or Adults Unable to Consent | [ ] Waiving Consent and/or Parental Permission (Waiver of Consent Process) |
| [ ] Obtaining Verbal Assent for Children or Adults Unable to Consent | [ ] Waiving Assent/Assent is Not Appropriate |

* 1. If you will be obtaining signed consent from the subject or legally authorized individual (LAR), or will be obtaining signed parental permission, describe:
		+ Where the consent process will take place.
		+ Any waiting period available between informing the prospective participant, participant’s LAR, or participant’s parent about the study and obtaining the consent/parental permission.
		+ The process to ensure ongoing consent.
		+ Describe:
			- The roles of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
			- 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.

13.3 If you will be obtaining consent online or verbally (no signature), provide justification for the requested waiver. Also, please describe:

* + - Where and/or how the consent process will take place.
		- Any waiting period available between informing the prospective subject and obtaining the verbal or online consent.
		- The process to ensure ongoing consent (if applicable, e.g., for studies involving multiple visits).
		- The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
		- 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.

13.4 If you will **not** obtain consent/parental permission for any part of the study, provide justification for the requested waiver.

13.5 If you will obtain consent from non-English speaking subjects, indicate the different language(s) of the prospective subjects, and describe the process to ensure that the oral and written information provided to those subjects will be in their primary/native language, including who will act as translator.

13.6 If you will enroll individuals who have not attained the legal age for consent (children) or individuals who are unable to provide legal consent (e.g., cognitively impaired individuals or individuals requiring a LAR), describe:

* The criteria that will determine whether a prospective subject has not attained the legal age for consent or is unable to provide legal consent to treatments or procedures involved in the research under the applicable law where the research will be conducted.
* Whether parental permission will be obtained from:
	+ *One parent even if the other parent is alive, known, competent, available, and shares legal responsibility for the care and custody of the child.*
	+ *Both parents unless one parent is deceased, unknown, incompetent, or not available, or when only one parent has legal responsibility for the care and custody of the child. Signatures from both parents are required for studies that are greater than minimal risk with no prospect of direct benefit.*
* *Whether permission will be obtained from individuals other than parents, and if so, how you will determine that the individual providing consent has the authority to do so.*
* *For subjects with a LAR, 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.)*
* *The process for obtaining assent from the subjects. Indicate whether:*
	+ *Assent will be required of all, some, or none of the subjects. If some of the subjects, indicate which subjects will require assent and which will not.*
	+ *If assent will not be obtained from some or all subjects, provide an explanation of why not.*
	+ *Assent of the subjects will be documented and the process to document assent.*

# Statistical Considerations

* 1. *Specify when, where, and how data will be analyzed, and by whom.*
	2. *Describe the statistical methods to be used for determining the sample size, stating the rationale for the number of charts/records that will be reviewed.*

# Setting

Describe the sites or locations where your research team will conduct the research and obtain the data.

# Literature References

Add References

1. **Appendices**

*Examples include:*

* *Schedule of Events*
* *Schematic of Study Design*
* *Case Report Forms (CRFs)*
* *Data Collection Forms*