This template is to be selected for use if your data for your research project is coming from secondary data sources only and does NOT involve a medical record/chart review.

**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A”. Do not deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

**PROTOCOL TITLE:**

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Primary Objectives** |  |
| **Secondary Objectives** |  |
| **Data Source** |  |
| **Study Population** |  |
| **Study Duration** |  |
| **Funding Source** |  |

**REVISION HISTORY:**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**PRIMARY OBJECTIVES:**

*Describe the purpose, specific aims, objectives, and/or hypotheses.*

*(There should be one or two primary objectives with additional objectives listed as secondary.)*

**SECONDARY OBJECTIVES:**

*Secondary objectives may or may not be hypothesis-driven, may include secondary outcomes, and general non-experimental objectives (e.g. to develop a registry, to collect natural history data).*

**BACKGROUND:**

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how this project will add to existing knowledge.*

*Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your thesis/dissertation proposal.*

**STUDY DESIGN AND PROCEDURES:**

*Briefly describe the study design and indicate, in general terms, how the design will fulfill the intent of the study.*

*Describe the source of the data/specimen: from whom? From where? Who “owns” it?*

* *If data/specimen is obtained via a third-party organization (e.g. via a web portal, tissue bank), provide the forms/application that must be submitted to access the data/specimen (or a link thereto) and any assurances you are asked to provide (e.g. a data use or materials transfer agreement).*

*Are there any identifiers associated with the data/specimen?*

* *If the data/specimen have identifiers associated with them now, but all identifiers will be removed prior to starting your analysis: who did or will de-identify the data/specimen?*

*Are the data/specimen linked to an individual by a code number? If yes, will anyone on the research team have access to the key linking the study ID to individuals?*

*Why were the data/specimens originally collected? If for a research study, provide IRB number(s) if applicable, and the informed consent/HIPAA authorizations signed by the subjects (so that the IRB can determine if the new proposed use of the data/specimen is within the scope of the original consent/authorization).*

*Describe any inclusion or exclusion criteria, if applicable.*

*Indicate if any data/specimens from vulnerable populations is included.*

**DATA COLLECTION PROCEDURES:**

*What will you do with the data/specimens?*

*Are there plans to store any data/specimens long-term? For what purpose? (May require a repository-specific IRB submission).*

**DATA ANALYSIS:**

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

*What sample size will you be able to get and is your suggested samples size sufficient for your primary objective?*

*Describe any procedures that will be used for quality control of collected data/specimens.*

**PRIVACY & CONFIDENTIALITY OF DATA:**

*Describe the plan to protect privacy of subjects and confidentiality of data/specimens.*

*What identifiers will be kept with the data/specimens?*

*If codes, where will the key linking the codes to identifiers be kept?*

*Will other parties help with statistical analysis, and if so, will identifiers be stripped off first?*

*What are plans for protecting the data/specimens or disposing of it once the study is completed?*

**SECURE STORAGE OF DATA:**

*Describe the steps that will be taken to secure the data/specimens (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.*

*Where and how data will be stored?*

*How long the data will be stored?*

*Who will have access to the data/specimens?*

*How data will be transported and/or transmitted?*

**STUDY TIMELINES:**

*Describe the estimated date that the investigators will complete the data analysis.*

**CONSENT PROCESS:**

*Many secondary data studies request a waiver of informed consent. Please state if you are doing so for your study.*

*If applying for a waiver, please address how your request meets the following criteria:*

* *The research involves no more than minimal risk to the subjects.*
* *The waiver or alteration will not adversely affect the rights and welfare of the subjects.*
* *The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)*
* *Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).*

*If your study does not meet the criteria for waiver of informed consent, explain how and when consent will be obtained.*

**HIPAA:**

*If applicable, list the specific HIPAA identifiers in your research dataset.*

* *Names*
* *Postal address* 
  + *All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, it contains more than 20,000 people.*
* *Dates* 
  + *All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89, except that such ages may be aggregated into a single category of age 90 or older.*
* *Telephone numbers/Fax numbers*
* *Electronic mail address*
* *Social security numbers*
* *Medical record numbers and/or Account numbers*
* *Health plan beneficiary number*
* *Certification/license numbers*
* *Vehicle identifiers and serial numbers, including license plate numbers*
* *Device identifiers and serial numbers*
* *Name of relative*
* *Web Universal Resource Locator (URL) and or Internet Protocol (IP) address number*
* *Biometric identifiers, including fingers and voice prints*
* *Full face photographic images and any comparable images*
* *Any other unique identifying number, characteristic, or code*

*HIPAA waiver: If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, state that you are requesting a HIPAA waiver.*

*If applying for a waiver, please address how your request meets the following criteria:*

* *The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:*
  + *An adequate plan to protect the identifiers from improper use and disclosure;*
  + *An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and*
  + *Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.*
* *The research could not practicably be conducted without the waiver or alteration.*
* *The research could not practicably be conducted without access to and use of the protected health information.*

**RESOURCES AVAILABLE:**

*Describe the resources available to conduct the research:*

*Describe the time that you will devote to conducting and completing the research.*

*Describe your facilities.*

*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.*

**REFERENCES:**

*Add references*