***Instructions***

*This protocol template is most appropriate for use when the research involves data collection only with no interactions or contact with the human subjects*.

*This protocol template is to be used as a guide. You may use a different format, order, or add additional information as needed.* ***Information provided in this template is intended to be a prompt,*** *if something does not apply to your study, delete it.*

*Use good version control of your document as you make edits. Keep an electronic copy of your final draft. You will need to modify this copy when making future changes.*

***Delete all instructional text*** *from the final copy, indicated by italics.*

**Protocol Title:** *<Include full protocol title as listed in the IRB application forms>*

**Principle Investigator:** *<Include the principle investigator’s name as listed in the IRB application forms>*

**Student Investigator:** *<If this is a student project, include the student’s name as listed in the IRB application forms.>*

**IRB Review History: <**If you have submitted this protocol for review to another IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information. This section would be applicable if you are performing research at another institution and that institution’s IRB has approved it. If this applies, explain the situation. If not, delete this section.>

**Study Objectives: <**In this section, provide your study hypothesis/objectives. What is the question to be answered? Describe the purpose, specific aims or objectives as concise as possible. If multiple aims, number then and include them all.>

**Background: <** *This section should describe what is known about your area of interest in relation to your research question. What does current literate say about the topic? Summarize the available study data (published and available unpublished data) with relevance to the protocol – if none available, include a statement that there is no available research data to date. Are there any gaps in current knowledge and what is the importance of this study to fill in those gaps?*>

**Study Recruitment: <**Describe the study’s recruitment plan, i.e. identify where and how you will obtain the data for this study>

* Data Source:

[ ]  Data is publicly available at: <enter where you can locate the data>.

[ ]  Data has already been collected from a previous research study and will be reused for this study. IRB # of original study: <enter IRB number under which the data was originally collected.>

[ ]  Data will be obtained: <enter source of the data and how it will be obtained, i.e., Data will be requested from the registrar’s office through their request process. >.

**Inclusion/Exclusion Criteria:**

* Describe criteria that will define who are included or excluded.
* *Describe the method for identifying candidates for the study*
	+ For a non-human subjects determination is it CRITICAL you explain how the data being collected by the study team is not identifiable to any member of the team.
* If you will exclude certain populations include scientific justification for that exclusion. For example, if excluding men or women a scientific justification may be that the disease being studied is not found in men/women. If excluding non-English speaking persons, a scientific justification may be that the study survey has not been validated in other languages.
* If you are including vulnerable populations, state what additional safeguards will be in place to minimize the potential for coercion. Example: If recruiting employees, what measures are in place that they do not feel forced to participate? How are you ensuring their supervisors do not know whether they chose to participate or any outcome of their participation?

*Example: The data source for this study is PHIS, which is an administrative database that contains inpatient, emergency department, ambulatory surgery and observation encounter-level data from 47 not-for-profit, tertiary care pediatric hospitals in the United States. These hospitals are affiliated with the Children’s Hospital Association (CHA). Data quality and reliability are assured through a joint effort between the CHA and participating hospitals. Portions of the data submission and data quality processes for the PHIS database are managed by* ***Truven Health Analytics*** *(Ann Arbor, MI). For the purposes of external benchmarking, participating hospitals provide discharge/encounter data including demographics, diagnoses, and procedures. Nearly all of these hospitals also submit resource utilization data (e.g. pharmaceuticals, imaging, and laboratory) into PHIS. Data are de-identified at the time of data submission, and data are subjected to a number of reliability and validity checks before being included in the database.*

*Example text: Investigators will ask X Records department to run a query from <database name> to generate a list of potential candidates based on the following criteria: [date range, other indicators, etc.] The list of records generated in that report will be de-identified before handing to the study team for analysis and will include only the data points in the data collection form (Appendix A).*

**Number of Subjects:**

* **Local number:** Indicate the total number of subjects to be accrued locally. This will be the total number you are approved by the IRB to enroll. If you need more subjects, an amendment will be required. So be sure not to underestimate. If applicable, distinguish between the number of subjects expected to be enrolled and screened and the number needed to complete research procedures (i.e. the number of subjects minus screen failures).
* **Study wide number:** If multisite, include total number of subjects to be enrolled across all sites.

**Study Procedures and Risks**:

* Describe and explain study design and procedures.
* This section must include all research procedures to be performed. Failure to include a procedure that is performed will be a protocol deviation. Be sure to accurately define those procedures that are being done for standard of care or per normal operating processes (i.e. Ask yourself, but for this study would this be done on subjects. If the answer is yes, then you can describe but clearly state that this is a standard procedure/process done that subjects will experience no matter their decision to participate in research).
* Describe the source records that will be used to collect data about subjects. Provide a copy of data collection forms.
* Describe the risks of these procedures and steps taken to minimize the risk. Note even minimal risk studies have risks – even if that risk is simply a risk to one’s privacy/confidentiality. Then describe how it is minimized, i.e. Describe steps taken to secure the data (i.e. training, authorized access, password protect, encryption, separation of identifiers and data) during storage, use and transmission.
* **NOTE: To qualify under exempt category 4 for data that is not publicly available investigators cannot contact human subjects or take any steps to re-identify human subjects. To ease the review process in qualifying for an exemption, be sure to include these two statements in your protocol.**
* *Example: Study involves review of data-only. Risks include a possibility of a breach of confidentiality. This risk is minimized by:*
	+ Data is recorded in a manner that reduces the risk of a breach of confidentiality: *<choose what applies>*
		- *Identifiers are not viewed by the research team. The providers of the data only provide the data to the researchers in a de-identified format. Investigators cannot identify the human subjects.*
		- *Data has identifiers, but identifiers are removed. Data is recorded in a de-identified manner only.*
		- *Data has identifiers, but identifiers are stored in a separate linking list stored in a different location than the data set. Therefore, in an unlikely event of a breach, the recipient will not be able to link the data to the identifiers.* ***NOTE: If identifiers are required for the research, then this study will not qualify for exempt category 4 and will go for expedited review.***
	+ Data is stored in a secure manner. Security measures include:
		- *Data limited to listed study personnel.*
		- *Data is stored on a password protected computer.*
		- *Computer or electronic devices housing data is stored in a restricted access location: <state location>.*
	+ *REQUIRED STATEMENT FOR EXEMPT CATEGORY 4:* The investigators will not contact the human subjects.
	+ *REQUIRED STATEMENT FOR EXEMPT CATEGORY 4:* Investigators have no plans and will not take any steps to re-identify the human subjects.

Consent Process: *Generally, consent is waived for retrospective data studies. Include information to justify the waiver request.*

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

* If asking for a waiver, be sure to describe:
	+ How the research involves no more than minimal risk to subjects.
	+ How the waiver or alteration of the consent process will not adversely affect rights and welfare of subjects;
	+ That the research could not practicably be carried out without the waiver being granted.
		- Mere inconvenience in contacting individuals to consent is not a justification that has been accepted by OHRP.
		- OHRP guidance finds that just because it is a retrospective chart review does not necessarily mean that consent is impracticable. Be sure to include justification why it is really hard to contact subjects and ask for consent, i.e. subjects are not available to be contacted; data is obtained in a de-identified fashion and re-identification to obtain consent would increase risk of confidentiality.

*Example:*

* *This research study is limited to a retrospective review of data. Data obtained is <describe why the risk is minimal, i.e. de-identified and therefore has little to no risk to subjects, already publicly available and therefore presents no additional risk to subject’s privacy or confidentiality, or is identifiable but identifiers are removed or maintained securely and the data being reviewed is not sensitive to pose more than minimal risk to subject privacy or confidentiality.*
* *The waiver will not adversely affect rights and welfare of subjects.*
* *This is a retrospective data review and contacting subjects to ask for consent is impracticable because: <choose what applies to your study>*
	+ *The data is obtained from the source in a de-identified fashion. To re-identify subjects to obtain consent would increase the risk to subject privacy and confidentiality.*
	+ *The data is already publicly available, and subjects have consented to its posting. To recontact subjects would increase their risk to privacy and confidentiality.*
	+ *The data was obtained in a previous research study where consent to perform future research was obtained. To recontact subjects would increase their risk to privacy and confidentiality.*
	+ *The data is identifiable, and subjects could theoretically be contacted for consent. However, <provide justification why it would be hard to do so, i.e. the number of subjects needed for this subject would make it impracticable to perform the study if consent was required; the contact information for subjects is not readily available or outdated to make re-contacting difficult if not impossible.>*

**Study Statistical Considerations:**

* Describe and explain the study’s primary and secondary endpoints.
* Describe the data analysis plan, including any statistical procedures.
* Provide a power analysis.
* Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.

**Study time-lines**:

* Describe the duration of the individual’s participation in the study. This should match the informed consent form.
* Duration of anticipated enrollment.
* Estimated date for investigators to complete this study.

**Data management:**

* Describe procedures used for quality control of collected data.
* Describe how long you will retain data after study completion. **NOTE: You must be regulation keep the data for 3 years after the study closes.**

References

* *Provide the citations for all publications and presentations referenced in the text of the protocol.*