|  |  |
| --- | --- |
| **Protocol Title:** |  |
| **Principal Investigator:** |  |
| **Co-Investigators:** | List all collaborators |
| **Study Coordinator:** | If a coordinator / research nurse / research assistant has been identified |
| **Population:** | Include sample size, gender, age, general health status, geographic location |
| **Number of Sites:** | Single site / UA COMPHX is lead site of multi-site study / Participating in multi-center study / Data coordinating center |
| **Study Duration:** | State duration of study |
| **Subject Duration:** | State duration per subject (“As per medical records” for retrospective studies) |

**General Information**

* A brief description of the research project. (One or two sentences)

**Background Information**

* Include study hypothesis, summary of findings from studies that have potential significance to proposed study and a discussion of important literature and data that are relevant to the study and that provide background for the study.
* Applicable clinical, epidemiological or public health background or context of the study.
* A common approach is to undertake a multi-step analysis:
  + Describe the magnitude and impact of the condition being studied
  + Describe the current state of knowledge/literature on the topic
    - i.e List the existing solutions (if appropriate)
  + Describe the lacunae in knowledge or motivators for undertaking this study
  + Describe the intervention/procedure/factor that is being studied
  + Describe the study aims briefly and how the study addresses the lacunae described earlier in this section.
* References to be placed at the end of the document

**Objectives**

* Primary and secondary objectives/outcome measures.
* Include statement of purpose e.g., to assess, to determine, to compare, to evaluate and method of assessing how the objective is met, i.e., the study outcome measure.

**Study Design**

* A description of the design of the study to be conducted (e.g. randomized controlled double blind, chart review, case cohort, non-interventional etc.).
* Inclusion/Exclusion Criteria
* Site(s)
* Duration of study

**Study Population**

* The study population and inclusion/exclusion criteria should be clearly and unambiguously defined in this section of the protocol.
* Clearly mention if this includes
  + Both genders
  + Adults/Children
  + Specific/ all Ethnicities/Races (especially Native Americans or International Indigenous Population)
  + Vulnerable/special consideration populations: Pregnant women, prisoners, Neonates, students.
* This section should include a discussion of selection of the study population and inclusion/exclusion criteria.

**Study Procedures**

* Specify the type of information the PI will gather, along with the means for collecting and recording it.
* Specify how data will be obtained.
* Specify how the list of eligible patients will be obtained/created.
* Specify whether Educational and/or Employment records will be sought/obtained/included in the study\
* Specify whether Mental Health/HIV/Other Confidential information will be collected.
* Specify if any third party/publicly available databases will be utilized / linked to PHI. (Research on publicly available datasets does not require IRB approval, but if efforts to link them to patient data not available in the public domain has to go through the IRB process)
  + Reference : <https://rgw.arizona.edu/sites/researchgateway/files/access_to_records_v2015-05.pdf>
* All study procedures will be undertaken in accordance with Arizona State Law.
  + References :-
    - [www.azleg.gov/arizonarevisedstatutes.asp](http://www.azleg.gov/arizonarevisedstatutes.asp).
    - <https://rgw.arizona.edu/sites/researchgateway/files/arizona_state_law_v2015-06.pdf>
* All protocol/ procedure amendments will be submitted it UA IRB prior to implementation.
  + Reference: <https://rgw.arizona.edu/sites/researchgateway/files/amending_approved_research_v2017-02.pdf>
* State if a certificate of confidentiality will be obtained prior to initiation of study
  + Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator
  + and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.
  + Reference: <https://rgw.arizona.edu/sites/researchgateway/files/certificates_of_confidentiality_v2016-03.pdf>

**Consent**

* If consent is being sought,
  + Written permission to access PHI will be obtained from the owner of the record before access to the record is permitted.
  + Attach consent form in separate document.

or

* A waiver of consent is being sought
  + A waiver or alteration of PHI will be obtained from the University of Arizona IRB or a designated Privacy Board or IRB

**Data and Safety Monitoring**

* State if adverse events are expected, if yes, describe how these events will be identified, assessed and graded.
* Describe plans for reporting unanticipated problems (including adverse events, protocol deviations, other problems).

**Statistics**

* A description of the statistical methods to be employed, including timing of any planned interim analysis.
* The number of subjects planned to be enrolled. In multicenter trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
* The level of significance to be used.
* The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects, patients with complete records in EHR).

**Ethics**

* State whether IRB approval will be sought from Human Subjects Protection Program or another IRB (under applicable Reciprocity Agreement).
* If waiver of consent or waiver of documentation will be sought, describe the plan to protect privacy of subjects.

**Risk / Benefit**

* There will be no direct benefit to the patients included in this study, since this is a retrospective chart audit.
* There is risk of possible loss of confidentiality if the patient data or information is inadvertently disclosed outside of this study. However, such risks would be minimized by ensuring compliance with UA-IRB and HIPPA guidelines to protect patient privacy.
* The study will be solely retrospective and therefore will not impact standard of care treatment.
* The knowledge gained by this study may help society by improving the treatment and outcomes of patients who undergo *(fill in the blanks / rewrite)* Benefits may be educational, psychological, physical, and/or medical. If applicable, indicate the probability, magnitude, and duration of the benefit, including benefit to society at large. There may be no benefit to subjects*.*
* The patient will not be compensated for participation in the study.

**Data handling and record keeping**

* Specify personnel and methods of access to source documents.
* Procedures for maintaining subject confidentiality, any special data security requirements, and record retention per the sponsor’s requirements.
* State whether human subjects will be identifiable directly or through identifying information.
* State how the data will be linked to the subjects during the study.
* State how and where the data will be stored, and how it will be protected.
* If REDCap is being used include the following boiler plate:
  + The REDCap electronic data management (EDM) system at the University of Arizona is housed on 2 virtual servers; one supporting database services and the other web services. Hardware is located in the University Of Arizona’s Information Technology Services Center (UITS). The space is a temperature controlled and physically secured within a keyless entry area. Hardware management and support is provided by UITS. The database server is located behind a firewall and the web server is in a DMZ. REDCap software support is provided by the University Of Arizona Center for Biomedical Informatics and Biostatistics. All web-based information transmission is password protected and encrypted in transit. Administration of REDCap is managed through Virtual Servers located at the University Of Arizona College Of Medicine.
  + In REDCap, all incoming data is intentionally filtered, sanitized, and escaped. This includes all data submitted in an HTTP Post request and all query string data found in every URL while accessing REDCap, among other modes through which user-defined data is submitted in the application. Server environment variables that are vulnerable to forgery by users are also checked and sanitized. All user submitted data is properly filtered for any possibly harmful markup tags (e.g. <script>) and is then escaped before ever being displayed on a web page within the application. SQL queries sent to the database server from REDCap are all properly escaped before being sent. If any values used in an SQL query originated from user-defined values, they would have already been sanitized beforehand as well, as described above. User-defined data used within SQL queries also have their data type checked to prevent any mismatching of data types (e.g. making sure a number is really a number). These processes of sanitization, filtering, data type checking, and escaping all help to protect against methods of attack, such as Cross-Site Scripting (XSS) and SQL Injection. To specifically protect against Cross-Site Request Forgery (CSRF), which is another method of attack, REDCap utilizes a “nonce” (a secret, user-specific token) on every web form used in the application. The nonce is generated anew on each web page as the user navigates within REDCap during a session.
  + REDCap was developed specifically around HIPAA-Security guidelines and is recommended to University of Arizona researchers by both our Privacy Office and Institutional Review Board. REDCap has been disseminated for local use at more than 2300 other academic/non-profit consortium partners in over 100 countries. Vanderbilt leads the REDCap Consortium, which currently supports more than 410,000 projects and 523,000 users. More information about the consortium and system security is available at https://projectredcap.org/.

**Quality control and assurance**

* Describe steps to be taken to assure that the data collected are accurate, consistent, complete and reliable. (source data verification, audits or self – assessment)
* Describe whether there are plans to have ongoing third party monitoring.

**Future use and long-term storage of data or specimens**

* Describe if data or specimens will be kept for future research, including unspecified future research and genetics. Indicate who holds the repository and what information will be sent to the repository. Explain if the data/specimens will be shared with collaborating entities or sold/shared with pharmaceutical companies. NOTE: Include a separate section in the informed consent that reflects the future use and storage. See HSPP Guidance, Storing research data and/or specimens for future use.

**Name and address of the sponsor of the study:**

If you are not seeking funding for this study, delete this section.

**Publication Plan**

* Describe plans for publication of research results.
* State if results will be returned to research subjects. i.e Will the patient/subject be notified of any relevant findings of the study.

**References**