|  |  |
| --- | --- |
| **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) |

**Sponsor:** For externally funded projects, list Sponsor

**Clinical Trials.gov Information**

Identify if the study is or will require registration on clinicaltrials.gov and who is responsible for registering (e.g. sponsor, contractor, grantee, or awardee).

* ClinicalTrials.gov "NCT" number for this trial (provide):
* Registration pending?
* Clinical trial does not require registration (explain):

**General Information** / Lay Summary

* A brief description of the research project.

**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.

**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

**Recruitment Methods and Consenting Process**

**Recruitment Process**: Describe how potential subjects will be identified, where recruitment will take place, when recruitment will occur, and the methods that will be used to recruit.

Provide copies of any materials used to recruit subjects directly (e.g. recruitment scripts, emails, print/audio/visual advertisements, or online notices).

**Informed Consent**: Describe the consent process, setting, time to discuss and ask questions, and who will be involved. Describe how subjects will be notified of updates throughout the Human Research. Include oral and written processes for people who do not speak and/or read English. Copies of translated documents are required.

Include how consent will be documented (e.g. written, oral, online, or waived). Describe procedures that minimize the potential for coercion or undue influence. When children are subjects or where subjects are unable to consent, include procedures to protect these populations (e.g. parental permission or Legally Authorized Representative).

Complete and attach the relevant Appendix Waiver if the consent signature will be waived (e.g. online surveys), consent will be waived entirely (e.g retrospective reviews), or if a waiver or alteration to PHI is requested (e.g. prescreening of subjects from the medical record) to address the relevant regulatory criteria.

**Resources available to conduct the Human Research**

Describe the resources (personnel, facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data. This includes access and use of UA core facilities, resources from other organizations (e.g. hospital), or from other laboratories. Remember that the IRB may not be familiar with the facility in which you are conducting research.

Describe your process to ensure that all persons assisting with the study (e.g., school teachers or floor nurses) will receive appropriate training for their study-related duties and functions.

**Study Procedures**

*This section should explain the research in lay language. Include how long subject participation is expected to last. Discuss all research procedures involved in the Human Research for each subject population participating in the study. Research procedures may be direct interactions or interventions, like surveys, questionnaires, recordings, photographs, blood draws, or medical exams. Procedures may also include indirect interactions, such as records review and data analysis. NOTE: Procedures the subject would complete regardless of the research should not be included.*

*For projects investigating drugs/devices/ or treatment plans describe the tests and procedures that will be done to accomplish this. If applicable discuss the randomization ratio, the dosages of drugs being used, and the investigational treatment plan. Also, if any specimens (blood, urine, tissue, etc.) are being collected for research be sure to state the how much will be obtained and what the specimen will be used for. Finally, be sure to explicitly list which procedures are standard of care and which are being done specific for research.*

*Describe what information will be collected, including screening and long-term follow-up. Include a description of information collected by study staff and attach documentation as appropriate. If records will be accessed to collect information about subjects, discuss to whom the records belong and how the records will be made accessible to the researcher.*

* 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>

**Schedule of Events**

SAMPLE:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Visit 1 | Visit 2 | Visit 3 |
| Informed Consent | x |  |  |
| Subject questionnaire | x | x | x |
| Blood Collection | x | x | x |
| Data collection from medical records   * + Demographics   + Physical exam   + vitals | x | x | x |

**Cost to subjects**

Describe any costs, monetary and non-monetary, that subjects may incur. Include how much time it takes participants to complete research activities. The information in this section should match what appears in the consent documents.

**Risks to subjects**

Risks may be physical, psychological, social, legal, and or economic. Risks should be 'reasonably foreseeable risks of the research.' If known, discuss their probability, magnitude and expected duration. If applicable, discuss what steps have been taken to minimize risk to subjects.

Medical research: When evaluating two or more standards of care the risks of each standard of care may be different, and therefore the risks of the standard of care are the risks of the research and must be addressed. If studies have procedures that may present risk to an embryo or fetus and involve a population that are or could become pregnant, these risks should be included.

NOTE: Risks the subject may experience regardless of the research should not be included.

**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**

*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. NOTE: Compensation to subjects is not a benefit and may not be listed in this section.*

* 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 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.

**Protection of subject privacy:**

*Describe steps, if any, to protect the privacy of the subjects throughout their participation in the Human Research (e.g. during the recruitment process, consent process, and/or research procedures).*

**Protection of data confidentiality:**

*Describe steps, if any, to protect information obtained from subjects. Discuss the process for storing, securing access (including who may have access to the information), what security measures are in place (such as file encryption), and how long the information will be stored. Describe if the data will be coded, who maintains the code, and if the code will be destroyed.*

*If using video or audio recording, discuss when the recording will be transcribed and if the originals will be destroyed, shared, or kept for future research*

**Data handling and record keeping**

*Access to medical records (HIPAA): Describe what information will be accessed, who will access the information, and how the information will be recorded and stored. Written authorization is required unless waived. Provide a description of the data elements that will be reviewed or abstracted from the medical record.*

*Access to educational records (FERPA): Describe what records will be accessed, who will access the information, and how the information will be recorded and stored. Written authorization is required in most instances.*

*Access to employee records: Access to information from an employee record requires the written permission of the employee and is protected under Arizona Board of Regents policy (e.g. medical residents, staff or faculty).*

* 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.

**Subject compensation**

Discuss the amount and timing of any compensation (monetary and/or non-monetary). Describe if compensation will be prorated. NOTE: If raffles will be used, please refer to State of Arizona specific laws governing raffles.

**Medical care and compensation for injury**

If the research involves more than minimal risk to subjects, describe the provisions for medical care and available compensation in the event of research related injury. If the Human Research has a clinical trial agreement, this language should reflect what is stated in the agreement. The information in this section should be reflected in the consenting instruments. However, due to the technical nature of the agreement, the actual wording in the consent form may be different.

**Monitoring for subject safety**

If the Human Research involves more than minimal risk to subjects, provide a brief lay discussion of the plan to monitor for subject safety. Describe how the data will be evaluated, include a timeline of when the review(s) will occur, who will review the information, and what information will be reviewed.

**Withdrawal of subjects**

Discuss how, when and why subjects may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they are not put at increased risk.

Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.

**Sharing of results with subjects**

If appropriate, discuss how immediate and/or long term study results will be shared with subjects, families, and/or the institution.

If subjects or their insurance company will be billed for research procedures, discuss when and how procedure and billing information will be made available to the subject.

**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.

**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**

**Appendices**

* Include copies of your proposed data collection sheet and/or data collection tools (i.e. questionnaires.
* Draft study Schedule of Events table. *(This document provides you with an example of what a SOE table should look like. A SOE table is required for all prospective protocols.)*

