**Study Title**: *Insert Study Title*

**Principal Investigator**: *Insert PI name and contact information*

University of Arkansas for Medical Sciences

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Little Rock, AR 72205

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**Sub-Investigator (s)**: *Insert name and contact information*

( or Faculty Advisor for University of Arkansas for Medical Sciences

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Little Rock, AR 72205

Telephone: *123.456.7890*

Email: *john.doe@researchclinic.org*

**Study location**: *Insert Study Site and Address*

Template instructions are in *italics* in the text below. Please review the entire document and delete instructions or non-applicable template language before submitting. Investigators should revise any template language as appropriate to their research.

Delete all superfluous template text before finalizing the protocol, including this box.

**Background and Rationale**

*This section should establish the significance of the topic to be researched and provide the conceptual framework for addressing the study hypothesis. Provide background information on the disease or intervention being studied and summarize previous research or information available in the literature.*

**Hypothesis** *and/or* **Specific Aims***or* **Objectives**

*This section must clearly state the hypothesis(es) to be tested or the specific aims for the study. Every research study must have a focused, clearly-defined objective.*

**Study Design and Procedures (sometimes called “Methods”)**

*This section should begin with a description of the study design (e.g. retrospective and/or prospective chart review, observational, randomized intervention, etc.) and must include an in-depth narrative describing the study methodology. Flow charts or study calendars may be used to describe the schedule for procedures and tests (if a study is complex enough to warrant a calendar to aid understanding). For medical records review studies, specify the data elements to be recorded from the medical record or refer to a data collection form listing the data elements (which should then be uploaded as a separate document), and describe the time period of interest. All study procedures should be well described so that the reader can easily figure out what will happen to the subjects and/or their data/specimens.*

**Study Population**

*Include the subjects’ age range and the total number of subjects to be enrolled. List all inclusion and exclusion criteria for study participants (see below). If the study is a chart review only, the source of the data must be listed. If more than one population is involved (such as active and control or parent and child), there may be more than one set of inclusion/exclusion descriptions.*

Inclusion Criteria

Exclusion Criteria

Recruitment *Provide a complete description of how you will find potential subjects. Examples of recruitment methods include, but are not limited to:*

* *reviewing clinic schedules and medical records to identify potential subjects and then approaching them in clinic*
* *asking AR-CDR for a list of subjects meeting eligibility criteria and then reviewing medical records for a retrospective chart review*
* *finding prospective subjects via AR-CDR or medical records review and then contacting them about the study*
* *using the* [*AR Research Registry available via TRI*](https://tri.uams.edu/resources-and-services/tri-resources/arresearch-registry/)
* *posting fliers or brochures (say where), etc.*
* *Advertising in print or electronic media, including social media*

*Please include a full description of how, exactly, potential subjects will be approached for participation. Examples: If they will be approached in clinic, specify whether they will be there for routine clinical visits, whether the study team will also be the treating team, whether the study team will review daily schedules to assess for possibly eligible subjects and then ask the clinical team to allow access to the patient to the discuss the study, etc. If people will respond to advertisements, describe the process for initial contact with the study team. For retrospective chart reviews, describe the process for searching charts to find subjects, e.g. will you search specific procedure or diagnosis codes. You do not need to list each specific code; instead, you can say, “We will search diagnosis (or procedure) codes related to (whatever it is you’re studying).” If you are doing a retrospective chart review, also consider using the AR-CDR in your recruitment process. The IRB may ask you for a rationale for NOT using AR-CDR for chart review studies, if you will not use that resource.*

**Risks and Benefits**

*Describe the expected risks and benefits of the study procedures and the procedures taken to minimize those risks. \*\*Note: only include risks of research-related procedures, not those of normal clinical activities that will occur regardless of study participation. Be sure to include loss of confidentiality as a potential risk. If there is no benefit to the participant, this should be noted. See examples below; edit as needed:*

A risk to study participants is the potential for loss of confidentiality of study data.

Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

Potential benefits include…..

*Note access to medical care, free or otherwise, and compensation may not be listed as potential benefits.*

There will be no direct benefits to the study participants; however, knowledge gained from the study could potentially benefit patients in the future.

*Describe steps to be taken to ensure the risk/benefit ratio remains as expected throughout the study. Will someone review data periodically to ensure it is appropriate to continue the study as is? A data safety and monitoring plan is required for all greater-than-minimal-risk protocols.*

**Data Handling and Recordkeeping**

*This section should also address measures to protect data confidentiality, de-identification of data, data storage, and security measures.*

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study.

*Specifically describe how the data will be labeled and stored. Indicate whether the data will include direct identifiers, be coded with the key to the code kept separately, or be completely anonymized with no way to relink it to individual participants after initial data collection. Indicate what medium will be used for storage (e.g. paper records, portable electronic devices, UAMS-maintained servers, third-party-maintained database, etc.) and who will have access to the collected data. If you are using portable electronic devices, state the rationale for using one of these instead of storing data on a UAMS-maintained computer or server, and confirm that you will store the minimum amount of data necessary on the portable device for as little time as possible. If data will be coded, indicate if/when the key linking identifiers to the code will be destroyed. If data will be transferred between sites/institutions, indicate how the transfer will be made.*

At the conclusion of the study, the data will *be [permanently deidentified, permanently stored in a repository for future use, retained and later destroyed in accordance with institutional policy? There should be some plan for what you will do with the data/tissues when you are finished with the project.]*

*Note: The UAMS Admin Guide requires that research data, reports and analyses be retained for seven years after final reporting or publication of a project, or longer if required by a sponsor or regulation. If only some subjects’ data will be retained for future use and that of subjects who opt out will not be kept for future use, clarify the different handling for each data subset.*

**Specimen Handling and Storage** *(Delete if no specimens will be collected)*

*If you will collect any specimens as part of the research, describe the specimen handling and storage, Describe how the specimens will be transported from the place of collection to the place where it will be used/stored (e.g. will the study team pick it up from the place of collection? Will it be obtained from pathology?). Indicate how it will be labeled, where and how long it will be stored, and who will have access to the stored specimens. Describe what will happen to the specimens and any associated identifiers, including codes, at study conclusion.*

*Note that if either data or specimens will be retained for future research, the anticipated future use should be described, including specifying if what type of future research might be done is unknown, and whether the stored samples will include identifiers, be coded, or be completely anonymized.*

**Multisite Research**

*If the study will be carried out at multiple sites, each with its own local PI and not routinely subject to UAMS IRB oversight, please add language pertaining to multisite research. This language should address issues such as whether each site will undergo separate IRB review or use a single IRB; how the sites will communicate with each other; how data and specimens may be shared between sites; reporting requirements for each site; interactions between the sites and the reviewing IRB, when applicable; whether any particular site(s) will serve as the central site, etc.*

**Data Analysis**

*Provide details of planned data analyses and statistical considerations. In addition to proposed statistical analyses, when appropriate, this section should include a justification of the sample size and a statement regarding power based on one or more of the primary outcome measures.*

**Ethical Considerations**

*This section must include a description of the informed consent process or justification for waiver as appropriate. See examples below and modify as needed. If minors or others not able to provide their own consent are involved, see wording for obtaining assent.*

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures.  This protocol and any amendments will be submitted and approved by the the IRB as required.

*Describe any plans to compensate subjects either here, or in a separate “Subject Compensation” section.*

The informed consent of each subject, using IRB-approved consent materials, will be obtained before that subject begins any study procedures.  The person obtaining consent (*Describe who that is, e.g. study coordinator, PI, research nurse, focus group leader)* will thoroughly explain what the subjects need to know about the study, including study requirements, study risks and benefits, and *(only if applicable)* possible alternative treatment(s).  The consent process will take place *[describe where and/or how, e.g. by phone, videoconference, during their clinic visit in the exam room or in a clinic office, in the pre-op area, as a group before a focus group meeting, etc. Note that additional information may be appropriate if the consent process occurs in certain areas, such as pre-op (will consent be done before any pre-op meds are administered? Or an exam room (will the participant be in a gown or in street clothes during the discussion?]* The consent discussion will occur *(how far in advance of study participation?)*.

*If subjects will sign a consent form, please adapt the following text to your study. Note that consent forms may be signed on paper or electronically; be sure the text accurately describes your specific consent process.*

All subjects for this study will be provided a consent form *(how? On paper? Electronic? Etc.)* describing this study in language understandable to the study population. Consent materials will provide sufficient information for subjects to make an informed decision about their participation in this study.  *(As applicable)* Participation privacy will be maintained and questions regarding participation will be answered.  No coercion or undue influence will be used in the consent process.  This consent form must be signed by the subject or legally authorized representative (*include “or legally authorized representative only if applicable to your particular study; otherwise delete.) Describe how the consent form will be signed if the signature will be electronic*, and the person obtaining the consent.  The participant will receive a copy of the signed consent form *(specify if it will be a paper copy or emailed or otherwise provided, as applicable.* *If assent is required, include a statement that assent will be obtained (describe the assent process and if/how it will be documented) and that assenting minors will be reconsented if they reach the age of majority during the study, if applicable).*

Or

*If you are requesting a waiver of the entire consent process, use this language. Note that this language applies to both expedited and exempt status research:*

A waiver of the informed consent process is requested as this research involves no more than minimal risk to the subjects; a waiver will not adversely affect the rights and welfare of the subjects; and the research could not practicably be carried out without the waiver. *If you are requesting a waiver for a study that involves identifiable private information or identifiable specimens, describe why the study cannot be carried out without using such data/specimens in an identifiable format.*

Or

*If a consent process of any sort will occur but no signed consent materials will be obtained (i.e. you will request a waiver of consent documentation only):*

*Describe the entire consent process. Then add:* This is a minimal risk study and a waiver of documentation of consent is requested. *Indicate if subjects will receive any written information about the study.* The research involves no more than minimal risk to the subjects and either (pick one):

1. the only record linking the subject and the study would be the consent document and the principal risk is the breach of confidentiality ; or
2. the research involves no procedures for which written consent is normally required outside of the research context.

*If a consent process will occur, describe how the consent process will be documented in a record distinct from any consent form. See IRB Policy 15.5 for requirements. Suggested language (adapt as needed to your study is below.) Note that the IRB may have contingencies about your documentation plan even if you use one of the options below:*

The consent process will be documented separately via a written note in the research or medical chart for each subject.

Or

Because our consent process will occur in a group setting, we will document each group consent process in a single note in the research record.

Or

Because our research consists solely of a recorded interview, we will include the consent process on the interview recording.

Or

The survey involves only a written or electronic survey. Return of the survey will be considered as documentation of consent to participate.

*For studies involving Protected Health Information, select from the following options. Note that more than one option may be applicable to a particular study.*

Or

A signed HIPAA authorization waiver will be obtained from the participant before any protected health information is accessed.

Or

We request an alteration of the HIPAA authorization process as follows: *Describe the alteration here. If you will not obtain signed HIPAA authorizations, describe how HIPAA-related information will be provided to participants. If you would like to omit some elements of the required HIPAA disclosures, describe which will be omitted. Provide the rationale for any alteration described here.*

Or

We request a partial HIPAA waiver for recruitment purposes only. *Describe the PHI elements that will be accessed and used for recruitment, who will access them, how they will be used in the recruitment process, and how they will be protected.*

Or

We request a full HIPAA authorization waiver. The study involves protected health information (PHI) as described in this protocol. Plans to protect identifiers and to destroy identifiers as soon as practicable are described in the Data Handling and Recordkeeping section. PHI must be accessed/used to complete the research. The research cannot practicably be carried out without the HIPAA authorization waiver because *explain why not.*

**Dissemination of Data**

*Provide information on the planned dissemination of data, including plans for publications, presentations, and website registration. Also indicate whether the dataset will be made publicly available after study completion. See sample text below; revise/delete text as needed.*

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

*If applicable, include the below language; consult with the Office of Research Regulatory Affairs for assistance determining whether clinicaltrials.gov listing is required:*

The study will be listed on clinicaltrials.gov in accordance with *(journal or FDA or whoever’s)* requirements. The final, anonymized dataset will be made publicly available *(list where/how/in accordance with what, if applicable).*

**References**

*List all references cited in the protocol and/or pertinent to the study.*

***Do not add appendices to the protocol document.***

*Supplemental documents such as data collection forms, surveys, questionnaires, advertisements, and flyers should be submitted**individually to the IRB so that a change in one form does not necessitate resubmitting the rest of the documents.*