

Study Title: *Insert Study Title*

Principal Investigator: *Insert PI name and contact information*
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Study location: *Insert Study Site and Address*

NOTE: The way this document is formatted, the version number and date must be changed on pages 1 AND 2 in order for the changes to carry through the rest of the document.

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 are also encouraged to revise any template language as appropriate to their research.

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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 should include an in-depth narrative describing the methodology to be employed. Flow charts or study calendars may be used to describe the schedule for procedures and tests (if a study is complex enough to warrant this 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). 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

Describe how the study population will be identified (i.e. how will you find the subjects) and include a section on recruitment plans if applicable. Include the age range of the subjects 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 there is more than one population involved (such as active and control or parent and child), there may be more than one set of inclusion/exclusion descriptions.

Inclusion Criteria

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Exclusion Criteria

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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.

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

Potential benefits include..... OR

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. 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.

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

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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 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.

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 should include a description of the informed consent process or justification for waiver as appropriate. See examples below. **If minors 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 UAMS Institutional Review Board (IRB) to conduct the study.

If subjects will sign a written consent form:

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and private

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room, and subjects may take as much time as needed to make a decision about their participation. 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”**, and the person obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in the research record. *If assent is required, include a statement that assent will be obtained and that assenting minors will be consented if they reach the age of majority during the study (if applicable).*

Or

If you are requesting a waiver of the entire consent process:

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 or access to data that includes identifiers, for studies involving collection of identifiable data only..

Or

If a consent process of any sort will occur but no signatures will be obtained:

Describe the entire consent process. Then add: This is a minimal risk study and a waiver of documentation of consent is requested. 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.

Or

This study meets the criteria for exempt review and does not require formal consent of the subjects. *However, if the subjects will be informed about the study in some way (such as an information sheet) describe this. Exempt studies will often need a brief document that covers the basic elements of consent, even though it will not require all of the regulatory elements, and the waiver of consent section should be filled out in CLARA. Many exempt studies are subject to HIPAA and the appropriate HIPAA waiver or alteration should be requested.*

If any sort of consent process will occur, regardless of whether you obtain signed consent documents from participants, please add the following information, based on the requirements of [IRB Policy 15.5](#). Examples are below; edit as needed:

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Each subject's consent process will be documented in a separate note to file. **OR** Because consenting will be done in groups, the consent process for each group will be documented in a separate note to file. **OR** The consent process will not be documented in a separate note to file because (give reason; this could be something like "study participation involves survey only; the study information provided to subjects will specify that return of the completed survey will be considered documentation of consent to participate).

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.

--or--

The study results are primarily intended for will be used within the clinic/institution/other (fill in) to guide changes intended to improve patient care/educational achievement/user satisfaction/other entity (fill in). While we may disseminate the results of this projects, the primary intent is to assess an internal practice and make any practice changes that may be warranted.

The study will be listed on clinicaltrials.gov in accordance with (journal or FDA) 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.

Appendices

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. Do not attach these to the protocol document.