

*Title:
*PI:
*Sponsor:

CHART REVIEW TEMPLATE

***ELEMENTS REQUIRED BY UAMS IRB POLICY 10.3**

***TITLE:**

***PRINCIPAL INVESTIGATOR:** Name
Department
1 Children's Way
Little Rock, AR 72202
Phone:
Email:

CO-INVESTIGATOR: Name
Department
1 Children's Way
Little Rock, AR 72202
Phone:
Email:

LOCATION: Arkansas Children's Hospital (ACH)

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***BACKGROUND AND SIGNIFICANCE**

***HYPOTHESIS/ SPECIFIC AIMS**

***STUDY DESIGN AND PROCEDURE(S)**

The intent for this study is to do a chart review of _____ subjects operated in the ACH department of _____ from _____ to _____ for _____.

***STUDY POPULATION/DATA SOURCE:**

A chart review a series of _____ consecutive cases with an age range of _____ to _____.

The source of the data is _____.

The data elements to be collected are _____.

***Subject Inclusion Criteria**

***Subject Exclusion Criteria**

***ETHICAL CONSIDERATIONS**

This should include a description of the informed consent process or justification for waiver as appropriate.

***RISKS & BENEFITS**

This should provide the expected risks and benefits of the study procedures and the procedures taken to minimize those risks. Provisions to protect subject privacy and the confidentiality of the data should also be addressed.

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***STATISTICAL PLAN:**

Statistical analysis will be performed to discern the following:

Describe your statistical plan. Contact the biostatistics department at achbiostat@uams.edu for help in developing this area.

***DATA HANDLING AND RECORDKEEPING.**

Provides information on the method(s) for data collection and specifies data collection tools. Should also address confidentiality, deidentification of data, data storage, and security measures.

***STUDY REGISTRATION AND PUBLICATION**

Provides information on the planned dissemination of data, including plans for publications, presentations, and website registration (i.e. www.clinicaltrials.gov)

***REFERENCES**

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