**Note**: This document is intended to assist all AAH investigators in preparing a researchprotocol for submission and reviewto the Advocate/Aurora IRB for locally initiated studies and submitted for IRB review along with the appropriate submission application. This protocol template may be used for the following studies: specimen/data collection; banking/future research; retrospective chart reviews; survey studies; prospective cohort studies with and without an intervention. This list is not exhaustive, call the RSPP office (414.219.7744) if you have questions**.** Completion of all fields below is required. Insert all responses in the box directly below relevant headers. Do not delete or renumber any items; use N/A if a field is not applicable to your study. If this document is not completed in its entirety, it will be returned for completion. Information in sections below are intended to guide comprehensive completion of this document and should be replaced with details relevant to your study.

# ADVOCATE Aurora Health

**Protocol Title:**

**Protocol Version dATE and number:**

**lEAD Principal Investigator:**

[First Name] [Last Name] [Credentials]

[Position]

[Site]

[Address]

[Phone:]

[Fax:]

[Email:]

**LOCAL PIs (for multi-site studies)**

**Sponsor (if applicable): [Name]**

**IND/IDE Number (IF APPLICABLE):**

1. **STUDY SUMMARY**

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| *In a few sentences, describe the purpose and goal of this study.* |

1. **BACKGROUND SIGNIFICANCE/LITERATURE REVIEW**

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| *This section should contain the following information:*   * *Background and history* * *State the gap in research or care and provide justification and rationale for proposed research, including references to pertinent studies* * Explain the public health impact - how will this study impact the subject, this patient population, and/or society?   *This section should summarize all available non-clinical and clinical data (published or available unpublished data) that could have clinical significance and have relevance to the protocol under development. Provide concise narrative review of the literature or previous studies that support the scientific aims of the research and basis for this study. This should be a relatively detailed overview of past scientific investigations, but the language should be understandable to the non-scientific IRB members. If the study involves an unapproved device that does not have an IDE, include the rationale for a Non-significant Risk determination.* |

1. **STUDY OBJECTIVES**

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| Describe the overall objectives   * Primary objective(s) * Secondary objective(s) * Tertiary objective(s)   State any hypothesis(ses) to be tested by the study |

1. **SUMMARY OF METHODS**
   1. **Study Design**

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| *Include a brief description of the study design. State whether your study is prospective or retrospective, multi-site study, etc. Most common study designs include:*   * *Experimental*   + *RCT* * *Observational*   + *Cohort*   + *Case-Control*   + *Cross-sectional*   *If experimental, state whether the study will be randomized, placebo-controlled, blinded, Phase I, II, or III.* |

* 1. **Setting**

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| *List the hospital and department or clinic site where this study will be conducted or data will be collected (actively or passively).* |

* 1. **Study Population**

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| *Describe the group of people to which this study will apply or generalize.* |

* 1. **Sample Size**

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| *List the proposed maximum number of subjects to be included in this study, including the individual number of subjects expected in each group or across each site. If study is descriptive/will not utilize inferential statistics, a sample size calculation is not required. Explain the rationale for the proposed number of subjects. Describe all formal sample size calculations that were performed supporting the proposed sample size. Enough information should be given to determine that the sample size and statistical power associated with the sample size is adequate. Please note this information does not need to be included for FDA regulated studies that have an IND/IDE or are Phase IV)* |

* 1. **Recruitment**

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| *This section applies to all studies. Describe, how, when and by whom participants will be both identified and approached for recruitment. Describe whether the recruitment and screening process will be active (patients identified in a clinic) or passive (patients identified via a database or medical record review). Provide detail on the step-by-step process of screening patients for inclusion.*   * *If prospective:*   + *Explain all methods to be used for recruitment (e.g. traditional paper or internet advertisements, database queries, newsletters, recruitment by sending letters, physician referrals, medical record reviews, etc.), including how they will be used. For example, if flyers and posters will be used, explain where they will be posted or how they will be distributed.*   + *Describe the plan in action to respect patient’s privacy, including how the patient will be first notified of the potential to be included in a research study, who will first notify the patient, how the research team will be introduced to the patient and how that patient’s medical information will be protected.*   + *Explain who will approach the potential subjects, when and where they will be contacted and the amount of time provided for potential subjects to consider participation.*   + *REMINDER: The recruitment process must promote voluntary participation and must not be coercive in any way.* * *If retrospective:*   + *Explain how you will identify patients of interest. Be specific on required resources to identify potential patients (e.g. administrative records, Data Analytics team, EPIC search) and confirm eligible patients if applicable (e.g. manual chart review).*   *NOTE: All active recruitment materials and practices must be reviewed and approved by the IRB.* |

* 1. **Informed Consent and Regulatory Requirements**

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| *This section applies to studies requiring informed consent. Describe the process of obtaining consent, including how and where you will approach potential subjects and conduct the informed consent process (if prospective) or confirm inclusion via medical record review (if retrospective). If you are requesting a waiver or alteration of consent, please indicate so in this section. AAH requires a treating relationship with the patient be in place prior to approaching potential subjects about the study.*  *Including the following information if applicable:*   * *How will subjects be identified/approached for study participation* * *Is consent going to be in-person/ virtual (zoom, phone, etc.)?* * *How will you ensure the potential subject understands what their participation entails?* * *Will an electronic consent platform be used to document the subject’s participation in the research?* * *How will the signed informed consent be stored?* * *How will the signed informed consent be loaded into the EMR?*   *Information on the informed consent and the regulatory requirements below:*  *There should be an appropriate plan to obtain and document legally effective informed consent. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.*  *Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject, and by the person who conducted the informed consent discussion.*   * *The case history for each individual shall document that informed consent/authorization was obtained prior to participation in the study. This documentation may consist of a chronological record of the events establishing that informed consent/authorization was obtained prior to a procedure required by the investigation, or that informed consent/authorization was obtained prior to the time the first study-related procedure was performed on the prospective subject. This must be done to demonstrate that the appropriate discussion took place with the prospective subject about the elements of informed consent/authorization and that the prospective subject’s questions were answered. At a minimum, compliance with this requirement may be met by completing the checklist on the last page of the Aurora IRB consent/authorization form.* |

* 1. **Inclusion criteria**

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| * *Create a list of the criteria which must be met for study enrollment. Bullet are preferred in this section.* |

* 1. **Exclusion criteria**

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| * *Create a list of criteria that would exclude a participant from study enrollment. Do not list the opposites of any inclusion criteria. Bullets are preferred in this section.* |

* 1. **Vulnerable Populations**

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| *Will vulnerable populations be included in the study design? Is the inclusion or exclusion of vulnerable populations justified? What safeguards are in place to protect the rights and welfare of vulnerable subjects, if any, that are expected to be recruited?*   * *Examples of vulnerable populations: women, children, employees, trainees, economically disadvantaged, prisoners, terminally ill, individuals with intellectual disabilities, individuals with mental disorders* |

* 1. **Study Endpoints**

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| *Define or specify the endpoint(s) – differentiated as primary, secondary, tertiary – that will be used to evaluate success or failure of the exposure of interest (e.g. investigational agent, intervention) in this research study. Primary endpoint should be clearly stated and defined to address study objectives listed in section 3. Endpoints should also be used for sample size calculation(s). Examples include survival, mortality, ICU admission, length of stay, remission, onset of disease, etc. Bullets are preferred in this section.* |

* 1. ***Prospective* Study Procedures (for retrospective studies see next section)**

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| *This section should include an in-depth explanation of all study related procedures and treatments during study visits, including identification of potential subjects, recruitment, informed consent, data collection (methods and tools), data storage/management (methods and length), external data sharing, data analyses, dissemination, destruction/deletion of data. This section should clarify if the study design is experimental/interventional or observational. Be sure to create a clear differentiation between research procedures and standard care. Please include a list (or table) of all study visits and the activities (e.g. tests, surveys, etc.) that are scheduled to take place. Any research activities involving questionnaires or surveys should describe the tool, whether it is validated, estimated time to completion and other relevant issues related to the tool. A table will be helpful to provide a layout of the study. You can attach a table as an appendix of this protocol and reference it in this section. An example of such a table can be found below.*  *For specimen/data banking studies:*   * *What types of specimen/data will be collected?* * *Where will the specimens/data be housed and who will be responsible for oversight of the bank?* * *How long will specimens/data be kept? How are the specimens going to be used?* * *How will the specimens/data be destroyed upon study completion?* * *If specimens/data will be banked for future use, what will be the process for providing investigators with access to the bank and how will this be tracked?*   *For research involving the testing of drugs/biologics describe:*   * *Drug formulation, packaging, labeling and source* * *Drug storage and stability* * *Preparation, dosage, and administration of drug(s)* * *Drug accountability procedures (if applicable; usually not required for drugs obtained through commercial venues and charged as standard of care)* * *Concomitant medications allowed/disallowed, washout periods required* * *Use of placebo and source of placebo* * *Precautionary, prohibited medications and procedures* * *Prophylactic medications and procedures* * *Rescue medications* * *Clinical or laboratory evaluations required*   *For research involving testing of devices describe:*   * *Device specifications, packaging, labeling* * *Device storage* * *Device implantation/application* * *Device accountability procedures* * *Concomitant medications allowed/disallowed, washout periods required* * *Use of sham procedures* * *Precautionary, prohibited medications and procedures* * *Prophylactic medications and procedures* * *Device removal* * *Clinical or laboratory evaluations required*   *For health services research:*   * *Description of healthcare services related intervention (i.e. HIT Epic intervention, Mobile App, clinical process change, …)* * *Description of comparison group if applicable*  1. **Screening Visit**   *List all study related procedures to be performed at the screening visit.*   1. **Visit 1**   *Indicate the timeframe for this visit (e.g. Visit 1 will occur six (6) months from the registration/baseline visit with +/- one (1) week [a window]). List all “follow-up” study procedures and activities to be performed at this visit.*   1. **Visit 2**   *Indicate the timeframe for this visit (e.g. Visit 2 will occur after six (6) months from Visit 1 with +/- one (1) week [a window]). List all “follow-up” study procedures and activities to be performed at this visit.*   1. **Visit 3**   *Indicate the timeframe for this visit (e.g. Visit 3 will occur after six (6) months from Visit 2 with +/- one (1) week [window]). List all “follow-up” study procedures and activities to be performed at this visit.*   1. **Visit 4 etc…**   *Indicate the timeframe for this visit (e.g. Visit 4 will occur after six (6) months from Visit 3 with +/- one (1) week [window]). List all “follow-up” study procedures and activities to be performed at this visit.*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Study Procedures Table** | **Screening Visit** | **VISIT 1:** | **VISIT 2:** | **VISIT 3:** | **VISIT 4:** | | *Sign Informed Consent* | ***X*** |  |  |  |  | | *Pre-Survey* | ***X*** |  |  |  |  | | *Lab tests* |  | ***X*** |  |  |  | | *Blood Draw* |  | ***X*** |  |  |  | | *Blood Pressure Measured* |  | ***X*** | ***X*** | ***X*** | ***X*** | | *Medication Administration* |  |  | ***X*** | ***X*** |  | | *Follow-up*  *Interview and Post-Survey* |  |  |  |  | ***X*** |   *NOTE: Persons collecting and analyzing protected health information are considered key personnel and should be noted appropriately in the Personnel Delegation Log.* |

* 1. ***Retrospective* Study Procedures**

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| *This section should include an in-depth, step-by-step explanation of all study related procedures, including identification of potential subjects, screening of charts, confirmation of eligible subjects, data collection (methods and tools), data storage/management (methods and length), external data sharing, data analyses, dissemination, destruction/deletion of data. Provide specific details including:*   * *How you will identify potential subjects (e.g., EPIC SlicerDicer, administrative records, department-specific system like Theradoc)* * *How you will confirm inclusion/exclusion of potential subjects (e.g., manual chart review)* * *How many people will be collecting data* * *Your plan to collect data variables* * *What program/system utilized to enter/record data* * *How you will de-identify or code data* * *Where/how you will store all data* * *How data will be used* * *How long data will be stored and when it will be deleted*   *NOTE: Persons collecting and analyzing protected health information are considered key personnel and should be noted appropriately in the Personnel Delegation Log.* |

1. **SPECIMEN MANAGEMENT PLAN**

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| *The RSPP Office will want to know if there is a link to data making the specimen identifiable, when/if the specimens are being de-identified (goes to confidentiality) and how the specimens are going to be stored/released to researchers. (Somewhere [not necessarily in this section] researchers should also say what the stored specimens are going to be used for], etc.*  *NOTE: Researchers are responsible for following the AAH Policy on Biospecimen Use in Research* |

1. **DATA MANAGEMENT PLAN**

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| *How do you plan to record, store, and protect all data? Please describe the data management plan in place for protecting patient’s confidentiality and privacy, including de-identification or coding/linking of PHI. Include the plan for multi-site studies where AAH is the coordinating center. Please include electronic data management and electronic data securities in place of any third-party tools used. Also indicate if any Data Quality Assurance procedures will be implemented during the course of the study to ensure compliance with the protocol and any differences between various site data collection techniques (for multi-site protocols). Indicate whether the data will be shared with outside institutions such as a DSMB or sponsor and identify if a data use agreement is in place.* |

1. **MONITORING PLAN**

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| *This section applies to experimental or intervention studies. Describe the data and safety monitoring plan in place for this study. Define plans for data and statistical analysis, including stopping rules and endpoints. Also include any quality assurance or external monitoring plans that will take place during the course of the study.* |

1. **STATISTICAL PLAN**

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| *Please include the plan for statistical analysis and interpretation of the data, including the department who will be responsible for completing analyses. This section should provide enough evidence to convince a reviewer that the proposed design has a reasonable chance of achieving the principal objectives of the research. Include the individual or department that will be analyzing the data and where they are located.*  *This section should detail any plans to conduct univariate/descriptive analyses, bivariate analyses, and any inferential analyses or models. Describe the software to be used to conduct analysis and specific tests to be utilized. This plan should align with your study design and what is feasible based on the proposed sample size.*  *NOTE: If the study is FDA regulated and has an IND/IDE, or is a Phase IV study, this information does not need to be included.* |

1. **BENEFITS**

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| *Create a detailed list of all anticipated benefits related to the research. Potential benefits may apply directly to the subject or to the advancement of scientific knowledge. This should be a very detailed explanation of all potential benefits and provide the basis for the IRB's determination that risks are reasonable in relationship to the anticipated benefits of the research.* |

1. **RISKS**

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| *Risk is defined as the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring.*  *Create a detailed list of any potential risks, discomforts, hazards, or inconveniences of participating in the research. This should be a very detailed explanation of all risks classifying them according to frequency. There should be consideration of possible risks of psychological or social harms (i.e., financial risks, risks from breach of confidentiality, risks to employability or insurability, criminal or civil litigation, or cause embarrassment, humiliation, discrimination, or stigmatization). Consideration should also be given to the potential for group harms.* |

1. **AVAILABLE RESOURCES**

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| *List all individuals and departments, outside your own, and their roles that are required in order to conduct the research components of this study. For example, if your research procedures involve blood draws beyond routine care, the phlebotomist and lab should be listed here. Other more general examples may include the Data Analytics team to acquire data or the Patient-Centered Outcomes Research team to perform statistical analysis.*  *NOTE: Any individuals or departments outside your own that are required in order to conduct your data should be listed on your Personnel Delegation Log.* |

1. **REFERENCES**

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| *List and link references used to justify the significance of this study. These references should link to the Background Significant/Literature Review section and any other sections where references were cites, ideally using superscripts. Bullets are preferred in this section.* |

1. **Abbreviations & ACRONYMS**

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| *Define all abbreviations and acronyms used in this document to promote clarity. Bullets are preferred in this section. For example:*   * *PCOR (Patient-Centered Outcomes Research)* |

1. **DATA COLLECTION/VARIABLE DICTIONARY**

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| * *List variables/datapoints to be collected from the EMR. Also list all names of measures/instruments you will use to gather data, including tools like surveys, questionnaires, psychometric tests, interviews, focus groups, etc. and what each tool captures. Bullets are preferred in this section.*   *Indicate whether the data will be shared with outside institutions such as a DSMB or sponsor and whether a data use agreement (DUA) is in place.*  *NOTE: All measures and instruments/tools used for direct data collection should be submitted to the IRB. Data collection sheets can also be submitted to the IRB, but are not required as they should reflect the variables listed in this section.* |