**Advocate Health Care Research Department IRB Template**

Applicable for chart reviews, prospective survey studies, and non-interventional prospective studies

General recommendations:

* Delete the IRB text in italics as these are instructions to the preparer.
* Do not delete any numbered sections of the application.
* Retain the IRBs format.
* Use consistent font throughout.
* In most cases, “N/A” is not an appropriate response even though the instructions state you can use this.

**Note: IRB review and oversight is a process, not a one-time effort. Changes to your research after initial approval require IRB approval and the IRB must be closed or renewed annually.**

1. Protocol Title

Include the full protocol title as listed on the application form. Make sure your title also appears in the header and that it is consistent with all forms you submit to the IRB. This title does not have to be used in publications/presentations.

1. IRB Review History

Indicate if you have previously submitted the protocol to another, external IRB or if AHC IRB has previously reviewed this application.

If this has not been previously submitted to an IRB, state this. Examples:

* None, this study has not been submitted for review with any IRB prior to this submission.
* This is a first submission for IRB review.

1. Objectives

Make sure your objectives are clear and succinct. Avoid complex and wordy sentences as these often confuse rather than clarify the objective.

Use the PICO format to help you build you statement: Patient, Intervention, Control/Comparator group, Outcome

1. Background

Make sure you include a background with at least 2 references and include in-text citations. This does not have to be extensive but should cover relevant findings from the literature.

Note: This section can be used in a presentation/manuscript, so it is worth your time to prepare a quality background for this document.

1. Inclusion and Exclusion Criteria

Describe the criteria that define who will be included or excluded in your final study sample.

Specify the exact timeframe for which cases are eligible for inclusion.

Example: Cases meeting inclusion will be identified from medical chart X from January 1, 2015- August 15, 2015.

Exclusion

Indicate specifically that you will exclude:

* <18 years
* Adults unable to consent
* Vulnerable Population

If you do include members of the population above, they must be in your inclusion.

1. Study-Wide Number of Subjects

Indicate the total number of subjects in your study and whether it is a single or multi-site center study.

Number of cases should be stated as the maximum (up to XX of subjects/charts). Remember: you can collect fewer subjects than you state here but cannot collect one more than stated without an approved modification prior to going over the specified limit (form - HRP 213).

For multi-site studies: state the total sample to be collected at all sites. You will state the number of subjects to be enrolled at AHC in section 25.

1. Study-Wide Recruitment Methods

For single-site studies: state how your subjects will be identified. For chart reviews, cases often are identified by ICD or CPT codes and the list of potential cases is created from these codes by an administrative office such as billing or finance.

For prospective studies, state when, where and how potential subjects will be recruited.

Recruitment is a vital component of the IRB review so be as thorough as possible in this section.

For multi-site studies: state how all sites recruit using the guidelines for single-site studies. However, this text often can be generic in order to cover the process at different sites. You will explain how this process will be conducted at AHC in section 24.

1. Study Timelines

Describe the duration of your study. If the study will take longer than 12 months to complete, a continuing review will be required. Usually you will want to state “upon IRB approval, data collection or enrollment will begin”.

For retrospective studies, describe how long it will take you to complete the project.

Example: We anticipate xx months for data collection and xx months for data analysis and manuscript preparation.

For prospective survey studies, state how long the subject will be engaged in the research and your time line if data is processed at AHC.

Examples: Subjects will complete two study visits across 14 days and each visit will last approximately 20 minutes. We anticipate xx months for enrollment and data collection and xx months for data analysis and manuscript preparation.

1. Study Endpoints

For chart reviews, the endpoints are your primary (and secondary) outcomes.

For prospective studies, this includes your outcomes as well as rules for early termination of the study such as unexpected safety events.

1. Procedures Involved

Describe and explain your study design.

Describe all procedures being performed. Begin by stating whether your study is a chart review or prospective study and include where you are obtaining the data from e.g. medical chart, registry database.

For prospective studies, this needs to be a step-by-step description similar to a recipe. Clearly state in your procedures what is part of routine care and what is for research purposes. If you have extensive procedures that are routine care in your study, add this to an appendix and write everything that solely is for research purposes in your procedures. By doing this, the investigator can focus on what research procedures are being done and the IRB will then be able to differentiate between routine care and research.

If you are using a survey, describe your survey and attach it to the 503 form.

FOR ALL STUDIES: Include a complete list of variables that you will be collecting and the research definition of the variable if needed. For example, “smoker – yes/no” can be defined in many ways: are they a current smoker if they quit within X days/weeks/months; is a ‘social’ smoker defined as a smoker in your study etc. State the frequency if you are collecting data from more than one time point (e.g., SBP at baseline, 3 months and 6 months).

1. Data and Specimen Banking

This would only be filled out if you decide the data or specimen in your study will be banked for future use. Usually, this is not the case and you will answer none.

If you are creating a data registry, this form may not be the correct form for you to use – please consult with the Department of Research or the IRB to determine which form to use in this case.

1. Data Management

Your data analysis plan and sample size estimate (SSE) will be included here. The Department of Research associates can assist you with this step, usually after the objectives and procedures are clearly defined.

Also, state how you will store the data. Normally, investigators assign a number to the data ( subject 1, 2, 3….) and then keep a separate list of what MRNs correspond to these numbers which is destroyed after data collection is 100% collected and verified. This text will be repeated in subsequent sections.

Note on SSEs: To perform an SSE, a specific ‘effect’ is needed. An effect is a numeric estimation of your hypothesized results for your primary outcome. For example, I expect the mean SBP prior to residency to be 115±8.5 and to be 135±10.2 after residency begins. For proportions it would be 35% in the control group and 45% in the comparison group will be readmitted within 30 days. For prediction models, it would be OR with 95% confidence intervals for each group or β±sd for linear regression Usually this comes from the literature but can also be from clinical expertise.

1. Provisions to Monitor the Data to Ensure the Safety of Subjects

This would only be required if your study involves more than minimal risk. Generally, these are chart reviews, survey studies and observation studies.

If your study does not involve more than minimal risks please answer “none as this is a minimal risk study.”

1. Withdrawal of Subjects

Chart Reviews: Because your study involves obtaining data from charts, no subjects can be withdrawn from studies and you would state none.

Prospective Survey or Non-Interventional Studies: Subjects must be given the choice to withdraw. Please state that they are given the choice to withdraw at any time in the study and doing so will not influence their relationship with AHC or their health care providers.

1. Risks to Subjects

Only include foreseeable risks that are related to the subjects’ participation to the research and what efforts will be made to reduce the risk as much as possible.

If your study is a chart review or has a chart review component, you would need to include the possibility of losing PHI. This text should match the data management section as well as confidentiality and privacy sections.

Example: The potential risk for accidental PHI disclosure will be minimized as described in section 12.

1. Potential Benefits to Subjects

You would only include a “direct benefit” to subjects that is already proven to be a benefit. Do not include benefits to society or future patients. Note: this always is “no direct benefit” for chart reviews and surveys.

1. Vulnerable Populations

If your research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. If you do include a vulnerable population they must be in your inclusion criteria and guidelines must be followed. Otherwise, answer none.

1. Multi-Site Research

If you include a multi-site study, include all site names and procedures on how you will communicate to the other sites. Make sure you state that approvals have all been obtained for each sites. Otherwise, it would be a single-site study.

1. Community-Based Participatory Research

Describe the involvement of the community (e.g., local churches, schools or community groups) in the design and conduct of the research. In most cases, this will be “none”.

1. Sharing of Results with Subjects

Describe whether results would be shared such as an individuals’ diagnostic tests or results pertaining to the study. Otherwise state none or individual results will not be shared with any party.

1. Setting

State all sites involved with the study and what units, location, etc will the data be collected from.

Example: All data will be collected from the MICCU, SVTU units.

1. Resources Available

Mention anyone that could be a mentor, someone in your study such as an assistant, coordinator, or others in your dept/unit that can be of great support.

Make sure to state that everyone in your study has completed CITI training.

1. Prior Approvals

Include any required approvals needed. For example, if you are adding an app to AHC computers, you might need approval from Information Services. In most cases, this will be “none”.

1. Recruitment Methods

Use the same format as described in section 7. If you have a single-site study, simply paste your response to section 7 here.

If you have a multi-site study, state how section 7 will be conducted at your AHC site.

1. Local Number of Subjects

Use the same format as described in section 6. If you have a single-site study, simply paste your response to section 6 here.

If you have a multi-site study, state how many of the total sample will be enrolled at your AHC site.

1. Confidentiality

Describe the methods to be used to ensure confidentiality of the data obtained.

For chart reviews: describe how you will protect the data. This should be similar to the data management text regarding MRNs. Also, describe who will have access to the data, especially the MRNs, names, etc

Examples:

* Data will be identified in the analysis file with a linked ID number to a separate file listing FINs, which will be destroyed after data collection is complete.
* Data will be collected and secured in a password encrypted USB only accessible to investigators listed on HRP 211. The investigators of this project will be responsible for the data.
* All information and data gathered in this study will be placed in a password protected computer with restricted access by the investigator and those listed on the 211 form.

For prospective studies: In addition to protecting the data, describe how you will protect the person’s identity on surveys or other research materials.

1. Provisions to Protect the Privacy Interests of Subjects

For chart reviews: this text will be the same as section 26.

For prospective studies: describe how you will minimize the subject’s exposure. For example, subjects will only interact with the minimal number of research staff required to conduct the study visit.

Example: Subjects will only interact with the specified research staff for data collection. Subjects will not be asked to provide sensitive or medical information in a public setting (data collection will occur in the clinic setting or by a phone number that they provide). Data collection is restricted to the minimum amount of data required to answer the research questions.

1. Compensation for Research-Related Injury

For chart reviews, prospective survey and non-interventional studies: there is no compensation so state “none as this is a minimal risk (or chart review/ survey) study.”

1. Economic Burden to Subjects

For chart reviews, prospective survey and non-interventional studies: there is no economic burden for subjects so state “none as this is a minimal risk (or chart review/ survey) study.”

1. Consent Process

For chart reviews: because it is not feasible to obtain consent from subjects found on a chart review, you will request a waiver of consent and HIPPA authorization. You will paste the Waiver or Alteration of Consent Process (case screening with use of Private Health Information (PHI) found on 30.2 of the IRB 503 form and you must answer all 9 questions. You may have already answered these questions in another section, but you also must answer them here. It is acceptable to repeat a response from another section.

For prospective studies: indicate where the consent will be processed and if done by person or through e-mail. You must include “Whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” This must be pasted onto this section. An attachment of the consent must be attached in an appendix.

1. Process to Document Consent in Writing

For chart reviews: state “We are requesting a waiver of consent and HIPAA authorization, therefore we will not be documenting consent in writing.”

For prospective studies: state how you will be obtaining consent in writing and indicate how if you will be following SOP: Informed Consent Process for Research (HRP-090. This must be pasted onto this section.

1. Drugs or Devices

For most nominal risk studies, this is “none”.

1. Glossary of acronyms

Include a comprehensive, alphabetic listing of all acronyms and the phrase they represent.