**Instructions: the instructions for how to create a complete protocol are in red. Once you have completed a section with substantive protocol details, delete the instructions.**

**Title:** *Title of Research Proposal should be the first section of your proposal. Be consistent about the title used throughout the study.*

**Version Date:** *Give the version and the date of the protocol (e.g., Version 1.0, 1-1-2016). You will be making several revisions over the duration of the research and it is a good idea to keep track of which version you are working on from.*

**Principal Investigator (PI) and Contact information:** *Name of primary investigator of the study (one person only). Provide contact information here.*

**Site(s):** *List all Legacy sites, including the PI’s office.*

**Sub-Investigators:** *Names of other investigators (if applicable). These should be people directly involved in design or creation of the protocol.*

**Sponsor/Funder:** *This is the organization or person that is sponsoring or paying for the research. The PI and sponsor, if the same person, are conflated and the research is then considered “PI-Sponsored” or “PI-initiated research”. If you do not have a sponsor, delete this section or indicate “N/A”.*

**Table of Contents:** *Use only if needed for a long protocol.*

**Abstract:** *The abstract should be a concise overview of your protocol in lay language or at least simplified language. Max 200 words. If in plain English and and clear enough, this language can be used to describe the research to subjects in the consent form.*

**Background/Reference Literature:** *This section should include the historical and scientific significance of the project and should include a review of the existing literature. If you have completed previous research on this topic include it here.*

**Objectives:** *Indicate the “primary objective” or describe* *the main purpose of the study. This should be focused on the research question. Describe if applicable. Objectives should be simple, specific, and stated in advance. After statement of the primary objective, secondary objectives may be mentioned.*

**Hypothesis:** *One sentence should be stated describing the research question.*

**Study Design:** *Describe the overall approach of the study, e.g. prospective, interventional, observational, retrospective, etc. If your study includes more than one group, arm, or subject population, describe that here (for example, a study of both subjects and their caregivers, or a study with both a prospective interventional arm and a retrospective chart review arm). The study design of all protocols must meet the criteria of “sound research design” to be approved as ethical research under federal law. That is, the protocol study design must be scientifically sound. Therefore, the study design is the key section that provides the scientific background and rationale for the hypothesis to be tested, interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done, etc.*

**Methods, Interventions and Procedures:***This section provides the details of the study plan, or “protocol”.**Methods might describe the manner in which data is gained e.g., via numerous subject study visits and interventions.**Interventions should be described in detail, including a description of the intervention being tested. For example, surveys, requesting demographic information, questionnaires, interviews, etc. Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the realm of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.). Be mindful that methods, interventions, and procedures also need to be described in detail in the consent form so subjects know exactly what is expected of them during the study. All procedures and interventions that subjects will undergo must be set out in the protocol and subjects advised in the consent form. If a procedure or intervention is not in the protocol, it cannot be simply added to the consent form.*

*If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined.

Instruments which are to be used to collect information (questionnaires, data collection tools, observation forms etc.) must also be described here in detail and submitted as separate documents.*

**Data/Statistical Analysis:** *This section provides details of the statistical analysis plan and the validity of the statistical plan. There should be a description and justification of the sample size to be obtained. Prior to writing the protocol, it is advised to refine your research question and discuss your proposed project with a statistician. In developing a research project, you will need to conduct a power analysis to determine needed sample size. If the study is a “pilot study” to gather basic data, describe why a “pilot study” is statistically valid and may lead to further useful research.*

**Estimated Duration of Project:** *Estimate the length of time subjects will be in the study and how long it will take to complete the data collection and data analysis of the study.*

**Study Population:** *Describe who you are wanting to study, e.g., adults with the admitting diagnosis of sepsis who experience a rapid response within the first six hours of admission. If vulnerable populations (children, cognitively impaired, prisoners, pregnant women/fetuses) are to be included in the research, provide a rationale for their inclusion. Legally, children, pregnant women and fetuses and prisoners are “vulnerable populations” under the law (regulations) and special protections are required.*

*Be mindful of newer ideas regarding gender identity and LGBTQIA inclusion and exclusion. “Male and female” as the only population to be studied may improperly exclude subjects that can/should be included in the research or may benefit from the research.*

*State the number (or approximate number, if appropriate) of subjects you plan to include at Legacy.*

**Eligibility Criteria:** *Provide a clear description of who is eligible to be enrolled into the study. The best way to ensure that you have done that well is to describe both**Inclusion Criteria – the criteria for enrollment, and Exclusion Criteria – the criteria that excludes persons from the study.*

Inclusion/Exclusion Criteria: *Describe how individuals will be screened for*

*eligibility and the criteria that define who will be included or excluded in your*

*final study population. It is acceptable and useful to separate inclusion from*

*exclusion criteria make it very clear who can be enrolled and who may not be enrolled, like this:*

Inclusion Criteria:

XXX

Exclusion Criteria:

XXX

**Vulnerable Populations:** *Indicate whether you will include or exclude each of the following populations:*

* *Children*
* *Pregnant women*
* *Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)*
* *Prisoners*
* *Decisionally Impaired Adults: These are subjects that cannot consent for*

*themselves and need a surrogate to consent. State whether they will be included and explain the extent of cognitive impairment (complete, fluctuating, progressive, or temporary). Justify their inclusion and explain any protections to mitigate risk (such as the involvement of a caregiver or authorized representative). The Consent and assent procedures will need to be described in the consent section.*

*Justify the inclusion of any of these populations. Describe additional safeguards to protect the rights and welfare of these subjects. The IRB must make certain findings and determinations should any of these vulnerable populations be enrolled.*

**Consent Process:** *Describe in detail the consent process for all subjects. Describe the recruitment process using advertisements (in all media), from a data base, etc. Describe the consent form and include any rationale for a request for a waiver of consent or waiver of consent form signature. A consent form is needed for most but not all research, but you should not include the submitted form within this protocol. It will be a separate document that you will prepare and submit for review.*

*If minors are involved, they will typically need to be consented, with permission (consent) provided by their parents. A separate Assent form will need to be prepared and submitted.*

**Use of PHI:** *Describe the plan to obtain a signed Privacy Rule Authorization from each subject or whether a waiver of HIPAA authorization is needed.*

**Waiver of consent for all subjects:** *For waiving consent for any or all subjects, the study must justify a request for a waiver by using the following criteria. If you are requesting a waiver of consent for any or all subjects, your protocol language will make the request with this language (or something close):*

We are requesting a waiver of consent for subjects of this research. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects because XXX;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects because XXX;

(3) the research could not practicably be carried out without the waiver or alteration because XXX; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Human Subject Ethics:** *Include a description of regulatory and ethical considerations related to the proposed research: the informed consent process and documentation, the confidentiality and privacy protections for subjects, study data protections, the plan for publication of results without identifying subjects. For example, if you plan on consenting subjects, state that:*

Study subjects will be recruited and approached for participation and will be allowed adequate time to review the written consent form, have their questions answered by the PI or study staff, and will be advised about the research in a private setting where confidentiality is maintained.

**Risks:** *Describe the expected risks of the study or related procedures that are both routine and standard care and those risks not considered standard of care; discuss how these risks are minimized by the study design. The protocol must be clear on where the research will pose risks beyond standard care or treatment, and how the research risks do not unjustifiably outweigh the risks posed to subjects or others.*

*Describe the probability, magnitude, duration, and reversibility of the risks. Consider all the risks that might be implicated in the research -- physical, psychological, social, legal, and economic risks, including the possibility of the risk of breach of confidentiality, which is common to almost all research studies. The protocol should avoid stating that the research is without any risks. The protocol should also make clear that there are or may be unknown risks.*

**Benefits:** *If there are direct benefits to the subjects, describe those benefits. If there are no benefits to subject participation, state that the only benefit is that of scientific knowledge or that there may be benefit to subjects in the future. Either kind of benefit is acceptable to research proposals, but for research greater than minimal or the ordinary risks of daily life, additional justification may be needed if no clear benefit to subjects can be considered.*

*Please notes that payments or compensation to subjects are not considered benefits of the research.*

**Adverse Event Assessment:** *Describe the risks to the subjects. Usually described as “minimal” or “none” for our purposes.**Include this statement:*

Should an adverse event occur, the event will be reported to the Legacy Institutional Review Board in accordance with their reporting guidelines.

**Costs/Budget:** *This section is where you will assess any costs to completing the research project. Many times using a published survey tool costs money and will need to be investigated and planned for in advance. Also, consider if the participant/patient will incur any costs for the planned intervention, i.e. will the intervention incur extra costs to the patient outside of normal treatment? The consent form will need to advise subjects of the possible costs they incur as a result of the research, and this section in the protocol must be consistent with the language in the consent form.*

**Sharing of Results with Subjects:** *Describe whether results (study results or individual subject results, such as results of standard or research lab tests and genetic tests) will be shared with subjects or their providers. Include the plan for sharing incidental findings with subjects.*

**Data and Specimen Banking:** *Describe the plan if collected specimens may be used for future research and whether that research may include genetic research.*

**Subject Materials:** *List intended advertisements, recruitment letters, on-line pages, and other materials that study subjects will use during the study, including surveys, questionnaires*

**Appendices:** *Describe all data collection instruments, elaboration on methods and procedures to be used, surveys, questions, etc.*

**QUESTIONS?**

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