Section E. Human Subjects. Please adapt to your specific proposal

IRB Protocol Title: xxxxxx this is the title of your research project as submitted to the IRB
Site of Research: Duke University Medical Center
Investigators: PI: your name, list your mentor and other key collaborators

Introduction: The purpose of this research will be to assess xxxx. very brief state hypothesis and specific aim.

Identification of human subjects: The human subjects component of this research will be limited to subjects > 18years of age. Retrospective vs prospective, Deduce search vs pre-existing database at Duke that your mentor has access to, or other method of identifying subjects

Subjects and Recruitment: Subjects hospitalized/seen in the clinics for xxxx condition at Duke University Hospitals between xxx and xxxx dates will be recruited in this study (or have been incorporated into an existing database that this retrospective study will utilize)

Informed consent: Informed consent will be obtained from each subjects or we requested a waiver of informed consent and submitted an IRB protocol that is pending or we have already received IRB approval for this research project: Duke IRB protocol number xxxx

Risks and Discomforts: There will be minimal risk for patients included in this retrospective study (or list any potential major risks). One potential risk to the subjects will be loss of confidentiality. We will maintain the patients' names and contact information (i.e. Identifiers) and all PHI (protected health information) in an encrypted computer database or all PHI identifiers will be removed in the database during data analysis.

Data collection and storage: Patient identifiers will not be used. None of the samples will be linked to the patient' names or contact information directly. The identifiers that link to protected health information will be secured in a locked file cabinet. The computer laptops containing patient data will be encrypted. The database will be in Redcap or other data storage medium

Data analysis: State here briefly if any power analysis has been performed to determine the sample size and the basic elements of the type of statistical analysis of the data planned

Potential benefits: Patients will not receive any direct benefit from this retrospective study. We hope to learn more about the incidence and outcomes of xxxxxxxx

Compensation: There will be no monetary compensation for the subjects in this study.

Confidentiality: We will collect protected health information (the names and contact information and other identifiers of the subjects) and store and protect the information on an encrypted computer database. The database will be destroyed (or not) xxxx months after analysis of all data and completion of the project. Survey data will not be linked to the survey participant.

IRB process: The IRB proposal for this study has been submitted and we have received IRB approval or IRB submission is being prepared or IRB protocol has already been submitted and is pending at the time of grant application.