*This template is for a* ***Retrospective cohort study design*** *(some type of chart review where your research question only addresses previously accumulated data).* *Use this template if you intend on comparing groups by treatments and determining if outcomes are different between the groups. The IRB will use this protocol to make their exempt determination. Please reference sections in this document to complete the application.*

**Title**

(Descriptive title; keep it tight, no 100 word titles)

**Investigators:**

**Version Date** (e.g., the date the protocol was created)

**Significance/Background:** Using the literature, establish any previous work related to your research question. This section should describe the gaping hole in the literature and how your specific aims will attempt to address it. **Make sure to cite your references in this section!**

***Example:***

*The controversy surrounding motorcyclist helmet use has been a long-standing dispute between government, motorcyclists, and medical providers. Since 1966, the year Congress initially enacted helmet use legislation, intense lobbying efforts by motorcyclist activists have overturned legislation stating mandatory helmet laws encroach on personal freedoms of riders. By 1975, only 50% of the United States still had a universal helmet law (1). There has been growing evidence to support mandatory helmet laws to increase helmet use compliance among motorcyclists, and lack of such laws decreases helmet usage. Costs incurred from unhelmeted motorcyclists have been shown to be substantially larger, with a difference of approximately $250 million dollars in medical costs as compared to helmeted riders nationwide (2). Despite efforts of the government and medical literature supporting mandatory use of helmets among motorcyclists, state legislatures have continued to enact partial and no helmet laws for riders (3). After 35 years of requiring riders to remain helmeted at all times, on April 13, 2012 Michigan joined many states by enacting a partial helmet law (4). This study intends to investigate the trend of motorcycle crash injuries, including the morbidity and fatality of riders among other variables in the months following Michigan’s change in helmet use legislation.*

**Objective(s):** Identify the specific aim(s) for your study.

***Example:*** *To determine the impact of the motorcycle helmet law on clinical outcomes among motorcycle crash victims in the state of Michigan.*

***Primary Outcome Variable(s):***Describe any primary outcome variables for the study.

***Example:*** *Mortality, length of stay*

***Secondary Outcome Variable(s), if applicable:***Describe any secondary outcome variables for the study.

***Example:*** *Injury severity score, length of ICU stay, time on ventilator, cost, payer, alcohol and/or drug use, and disposition*

***Setting/Resources for the Study:*** Describe where the research will take place. This includes both the setting for the research, as well as the location of any of the patient records to be obtained.

***Example:*** *The setting for this research is General Hospital. The electronic medical record will be accessed by the investigators to obtain the necessary information.*

***Study Design:*** Describe the study design.

***Example:*** *Retrospective cohort study*

***Study Subjects:*** Describe where you will obtain your subjects, over what time period and the specific inclusion and exclusion criteria used.

***Example:*** *All patients admitted to the trauma service at General Hospital involved in a motorcycle crash as the driver or passenger between 04/11/11 and 11/15/11 (prior to no helmet law) and between 04/11/12 and 11/15/12 (five months following no helmet law). Patients with no documentation of helmet use will be excluded from the study.*

***Study Procedures:*** This section basically describes methods for obtaining your data and descriptions/definitions of your variables. If you plan to request a report from the hospital, you may consider contacting the clinical informatics department to explore feasibility. Depending on the complexity of the report, the turnaround times can be lengthy.

***Example:*** *Patients will be divided into two groups based upon their admission date. Those admitted between 04/11/11 and 11/15/11 (before the helmet law change) and those admitted between 04/11/12 and 11/15/12 (after the helmet law change).*

*Data to be collected from a retrospective chart review will include circumstances of the accident, comorbid conditions, exam findings, injury severity score, admission GCS, demographic data including age, sex, helmet and protective gear status, length of hospital stay, length of ICU stay, labs, blood product use, need for intervention (e.g. operative), cost and disposition.*

***Statistical Plan* *(please don’t struggle with this section, contact Biostatistician at 269-337-6466)***

***Sample Size Determination:*** Describe the statistical methods for determining the sample size for the study (reason for choice of sample size).

***Example:*** *The primary outcome variable for this study is the difference in hospital length of stay between the two groups. If we assume that a difference of five days is clinically important, with a standard deviation of 14 days, with α=0.05 and β=0.20, we will be able to detect a statistically significant difference with 125 subjects in each group, using the unpaired t-test. If we assume that 10% of the records will be unusable we will need a total of 275 subjects for this study.*

***Statistical Methods:*** Use this section to provide a thorough description of the statistical tests that will be used in the analysis of your data.

***Example:*** *Summary statistics will be calculated. Quantitative data will be expressed as the mean+SEM and nominal data will be expressed as a percentage. Comparisons between groups for quantitative variables will be performed using the t-test. Nominal variables will be evaluated using the χ2 test. Significance will be assessed at p<0.05.*

***Confidentiality and Management of Data:*** Describe the plan to protect identifiers from improper use and disclosure, provisions taken to protect the confidentiality of subjects’ information and research data, plan to destroy identifiers, and why the research could not practicably be conducted without the waiver. Describe how the data will get from place to place. If it transferred electronically, discuss the software being used and who controls access. If paper documents are to be transported, discuss how that will occur. If you plan to keep the link to identifiers, explain.

*Example: Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A full waiver of HIPAA authorization will be sought. Patient data will be entered into electronic spreadsheets. One spreadsheet (the correlation tool) will contain the patient name, medical record number, and patient study number. The second spreadsheet will contain the patient study number, as well as all of the variables required by the study. The two spreadsheets will be stored as separate files, protected by unique passwords. Only the investigators will have access to the files and their passwords. De-identified data will be sent in password protected files to the WMed Epidemiology and Biostatistics Department for data analysis. Any paper records will be stored in hard copy in a locked filing cabinet in the investigator’s office for a minimum of five years. At this time the information will be destroyed at in accordance with the General Hospital documentation destruction policy.*

*Boilerplate Language for* ***REDCap***

*Data for this study will be stored electronically in the WMed REDCap platform. The platform is managed by the WMed Information Technology Department. Only Research study members will be granted access to the system. Access to data collection forms for this study will be the responsibility of the Principal Investigator and will be limited to those named in this application. The REDCap system is housed within the WMed Oakland Drive data center. Daily full backups are stored locally and copied to the WMed long term storage system.*

*A request to maintain identifiable information is being made for the following reasons:*

*1) When a manuscript is submitted for review, it is not unusual for the reviewers to request additional information; if the data have been de-identified, the only way to add the new information would be to go through all of the charts to gather the original information as well.*

*2) It is not unusual for investigators to amend protocols to request additional information; if the data have been de-identified, the only way to add the new information would be to go through all of the charts to gather the original information as well.*

*3) During data analysis, there are occasions when certain data appear to have been miscoded (e.g., age of 150 years). If the study were exempt, you would not be able to use patient identifiers to go back into the charts to determine the correct information.*

**The next two sections should be left as is**

***Risks to Subjects:*** This study is based on retrospective data, the only possible risk would be loss of confidentiality.

***Potential Benefits to Subjects:*** This study is based on retrospective data, there will be no benefit to the study subjects.

***References:*** Use this section to provide all of the references used throughout your study. Pick a format from your favorite journal and use it consistently.

***Example:***

1. Motorcycle helmets and rider safety: A legislative crisis. Allison J Derrick, Lee D Faucher Journal of Public Health Policy 30, 226-242 (13 July 2009) doi:10.1057/jphp.2009.11 Research

2. Economic Impact of Motorcycle Helmets: From Impact to Discharge. Eastridge, Brian MD et al. The Jounral of Trauma 2006.60:978-984

3.Croce, Martin A. M.D. et al. “Impact of Motorcycle Helmets and State Laws on Society’s Burden: A National Study.” Annals of Surgery. 2009.

4.Liu B.C., Ivers R, Norton R, Boufous R, Blows S, Low S.K. “Helmets for Preventing Injury in Motorcycles: Review.” The Cochrane Collaboration. 2009.