*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.*

***Management of Data:*** Research involves increasingly complex arrangements for the storage and transmission of research data. **Robust data privacy and security planning is necessary to protect the privacy of research subjects and to secure sensitive, personally identifiable information.** When crafting a data management plan, consider:

* Any contracts or agreements that may be needed
* Documentation
* Storage and back-up
* Sharing and re-use
* Retention and disposal

Some data require special management considerations. For example, Protected Health Information (PHI) is subject to several restrictions. Describe:

* How any data sharing will be tracked or documented
* Where the data will be stored (In the cloud? Accessed from a secure server?)
* How the data will be stored and protected (On a secure, password protected, server behind a firewall (e.g., on a G: drive, not a C: drive)? How protected? Password or encryption? How many people get the password? Who may access?)
* If using mobile computing device (laptop, PDA, iPod) or removable media (flash drive, CD/DVD) for any part of your study, determine how the data containing PHI will be stored.
* Estimated size of datasets that will be collected and produced, and whether the amount and/or formats of data will change over time; The IT departments may need to be informed of anticipated large data sets in order to support back-up.

Talk to EPI/BIO to create a secure research computing environment especially if your research involves sharing data or electronic data transfers from Borgess and/or Bronson.

Consider what data should be retained. EPI/BIO data managers and IT may assist in planning or establishing processes for archiving data, including aiding in the selection of formats and media. Familiarize yourself with publication requirements and institutional guidelines for data retention.

**Identifiable data should be held for the minimum amount of time necessary to conduct the research** (and meet any access requirements). For example, data that is collected in a corporate sponsored clinical trial might have contractual obligations regarding how long the data must be retained. Data collected in federal or state funded projects or when using large health care data sets, may require public access to data and therefore may have specific requirements regarding retention, disposal and archiving. It is essential to understand such requirements and proactively plan so that, at the end of a project, data is properly retained, disposed of, shared, or securely archived.

**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.