*[-Consider your areas of expertise and specific areas of interest*

*-Is there a problem that you notice in practice, based on your work experience?*

*-Examine the scientific literature, particularly discussion sections of journal articles as well as review articles and meta-analyses on your topic area to determine gaps in research and need for future work.*

[*https://rushu.libguides.com/libraryhomepage*](https://rushu.libguides.com/libraryhomepage)

*-What are the implications of the research findings that you summarize?*

*-Frame the project in an understandable, precise, and concise manner.]*

<Name>

<Department>

<Study/ Research Project Title>

**Abstract/Objectives:**

The goal of this project is to <…> at Rush (Rush University Medical Center and/ or Rush Oak Park) as collected in the Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) Common Data Model version <#> of database. The project has the following aims:

**Aims:**

Primary Aim:

Secondary Aims:

Exploratory Aim:

*[-Aims operationalize the research question. What do you want to achieve through conducting this research project?*

*- Aims should succinctly describe the purpose of the research and what you will be measuring and accomplishing.*

*-Indicate population of focus, type of program/ intervention, what you are measuring, how and when?*

*-Average number of aims: 2-4*

*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3140151/*

*https://www.niaid.nih.gov/grants-contracts/draft-specific-aims*

*https://www.pcori.org/get-involved/suggest-patient-centered-research-question/how-write-practical-useful-research-question*

*https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm*

*https://www.ncbi.nlm.nih.gov/pubmed/26200582*

*http://bjsm.bmj.com/content/34/1/59]*

**Significance:**

<...>

*[-What is the impact of the problem? – Review websites such as WHO, CDC, Health Departments*

*-Why is this research important? Support by synthesizing the literature.]*

**Innovation:**

<...>

*[-What makes this research unique?*

*-How does it contribute to the field? Support by synthesizing the literature.]*

**Analytic Approach:**

***Hypotheses:*** Data retrieved from the CAPriCORN data set will be used to answer the following questions or test the following hypotheses <…>

***Study Cohort:*** The cohort of interest in this study is the set of <…> at Rush during the period of data collection available in the CAPriCORN database, January 1, 2011 through <…>.

Inclusion Criteria:

<...>

Exclusion Criteria:

<...>

***Consent:*** As the study is retrospective and involves a large sample cohort in order to produce valid de-identified and aggregate data, we are requesting a waiver of consent. The data set evaluated will be limited based on the inclusion and exclusion criteria evaluated above, with Race, Ethnicity, Gender, and Preferred Language as the only types of individual patient information besides CPT codes.

***Study Variables:*** The independent variable in this study is <…>. The dependent variable is <…>.

*Definition of Independent Variable(s)*:

<…>.

*Definition of Dependent Variable(s)*:

<…>.

*Covariates:*

<…>

*[Analytic Approach should align with what is being requested in data request form. Review variable tables to determine variables extracted. Data extraction conducted using SQL.]*

***Methodology:***

*Data Source:* The Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) is a collection of patient and treatment information from 11 Chicago-area healthcare institutions, including RUMC. The project, funded by the Patient Centered Outcomes Research Institute (PCORI), was established in an attempt to standardize electronic health record collection across Chicago. Each institution de-identifies its patient information using a hashing algorithm embedded with a secret key. This pseudo-identifier is termed the patient’s HashID. This method of patient de-identification is HIPAA-compliant. This study will only evaluate data collected from RUMC and Rush Oak Park. Core patient and patient care data at RUMC and Rush Oak Park is held in an electronic medical record (EMR). This information is tabulated in Rush’s Enterprise Data Warehouse, designed to make data retrieval easier. Rush has created a data mart that matches that of the CAPriCORN common data model so as to extract data from the Rush portions of the CAPriCORN database. This Rush data mart will be used to extract the data variables of interest to this study.

***Confidentiality of Data***: The requested data will be pulled from the CAPriCORN database by data analysts in the Biostatistics/Bioinformatics Core other than those involved in this investigation. This data, which will be presented in aggregate, will be completely de-identified, and we will not have any access to information that might identify a specific patient. This study is subject to IRB non-human subjects determination and, if determined to be human subjects’ research, IRB expedited approval. The Rush data mart that conforms to the CAPriCORN common data model data is protected by a firewall and normal RUMC security protections.

The data will be delivered from researchers working with the CAPriCORN database in the form of a spreadsheet containing patient Race/Ethnicity, Age, Gender, Preferred Language and <...>. We will analyze this data to look for <...>.

All <...> encounters at Rush will be considered. The denominator used to determine percentage of usage will be the total number <...> who were seen during the time period of CAPriCORN data collection, from January 1, 2011 through December 31, 2017.

***Data Analyses:*** *We propose to conduct the following analyses:*

*[How do your analyses address aims?]*

These analyses will be conducted using statistical analysis software: <…>

*[Examples include: SAS, R, etc.]*

**Risks and Benefits:**

***Risks:*** The major risk associated with this study is the potential breach of confidentiality while extracting data from the CAPriCORN database. To lessen this risk, only a limited dataset will be evaluated, with minimal personal identifying information. This dataset will be stored in a secure location on a password-protected computer at Rush University Medical Center. Any summary reports or manuscripts for public use will contain only aggregate data, and won’t include any individual, personal health information.

***Benefits:*** There are no direct benefits to those subjects in the CAPriCORN database whose Rush visit information is used in this study. However, <...>.

**Appendix: Examples of Tables**

**Table 1**. **Characteristics of <…> at Rush, 2011-<…>**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | All  Encounters |
| Total encounters, number (%) |  |  |  |
| Total unique IDs, number (%) |  |  |  |
| Age at Encounter |  |  |  |
| 18-24 |  |  |  |
| 25-34 |  |  |  |
| 35-44 |  |  |  |
| 45-54 |  |  |  |
| 55-64 |  |  |  |
| 65-74 |  |  |  |
| 75-84 |  |  |  |
| 85+ |  |  |  |
| Missing |  |  |  |
| Gender at Encounter |  |  |  |
| Male |  |  |  |
| Female |  |  |  |
| Missing |  |  |  |
| Ethnicity at Encounter |  |  |  |
| Hispanic |  |  |  |
| Non-Hispanic |  |  |  |
| Missing |  |  |  |
| Race at Encounter |  |  |  |
| White |  |  |  |
| Black |  |  |  |
| Asian |  |  |  |
| Other |  |  |  |
| Missing |  |  |  |
| Preferred Language |  |  |  |
| English |  |  |  |
| Non-English |  |  |  |
| Missing |  |  |  |

**Table 2. Frequency Table <…> at Rush, 2011-<…>**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Missing | Total |
|  | A (%) | B (%) | C (%) | A+B+C (%) |
|  | D (%) | E (%) | F (%) | D+E+F (%) |
| Total | A+D (%) | B+E (%) | E+F (%) | SUM(A,F) (100) |

**Table 3. Frequency Table for <…> at Rush by Race, 2011-<…>**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | White | Black | Asian | Other | Missing | Total |
|  | A (%) | B (%) | C | D (%) | E (%) | SUM (A,E) (%) |
|  | F (%) | G (%) | H | I (%) | J (%) | SUM (F,J) (%) |
| Total | A+F (%) | B+G (%) | C+H (%) | D+I (%) | E+J (%) | SUM (A,J) (100) |

**Table <…>. Percent and Total Number of Participants by Treatment Arm and by Demographic Characteristic**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Treatment Arm 1 | Treatment Arm 2 | Control Arm | Total |
| Demographic Characteristics | % (N) | % (N) | % (N) | % (N) |
| Age Range |  |  |  |  |
| Sex |  |  |  |  |
| Ethnicity |  |  |  |  |
| Race |  |  |  |  |
| Education |  |  |  |  |
| Income |  |  |  |  |

**Table <…>. Percent and Total Number of Participants with and without Outcome by Group**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Group 1 | Group 2 | Total |
| Outcome Yes | A (%) | B (%) | A+B (%) |
| Outcome No | C (%) | D (%) | C+D (%) |
| Total | A+C (%) | B+D (%) | SUM(A,D) (100) |

**Table <…>. Comparing Continuous Outcome by Group**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcome Variable | Group (N=) | Group 2 (N=) | Mean Difference (95% Confidence Interval) | t-test statistic (degrees of freedom) | p-value |
|  | Mean (Standard Deviation) | Mean (Standard Deviation) |  |  |  |

**Table <…>. Regression Analysis**

|  |  |  |  |
| --- | --- | --- | --- |
|  | β | Standard Error | p-value |
| β0 (Intercept) |  |  |  |
| β1 |  |  |  |
| β2 |  |  |  |