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| **GENERAL INFORMATION** |
| 1. **Name:** |
| 1. **E-mail:** |
| 1. **Phone:** |
| 1. **Supervisor information:** *(if trainee)* |
| 1. **Project title:** |
| 1. **IRB approval obtained?** *(send file as attachment)* |
| 1. **Study timeline:** *(provide approximate dates; these will be used to communicate progress with Chair and Supervisor)*   **-**Introduction:  **-**Results:  **-**Discussion:  **-**Complete Manuscript:  **-**Manuscript Submission:  **-**Any Strict Deadlines (e.g. conference, special editions, etc.): |
| 1. **Primary and secondary choice of journal for manuscript** *(provide journal names and impact factor)* |
| **DESCRIPTION OF RESEARCH** |
| 1. **Background and rationale for study:** *(explain in max. 200 words the background and specific rationale for your study; what is currently lacking and what is your study going to add to the current literature; use max 5 references)* |
| 1. **Specific Aims:** *(what are your study’s specific aims; try to be as specific as possible and make a distinction between primary and secondary aims)* |
| 1. **Hypotheses:** *(add separate hypotheses for each of your specific aims; if it is not clear from your background text then add here too why you hypothesize a specific outcome)* |
| 1. **Population:** *(specify your target population and be as specific as possible in regards to, e.g. ICD-9 procedure or diagnosis codes, age range, etc.; if possible provide references for any specific ICD-9/10 codes used;* ***clearly state inclusion and exclusion criteria****)* |
| 1. **Timeframe:** *(specify the time frame of the study and any justifications if necessary)* |
| 1. **Intervention:** *(specify the intervention or main effect of interest and how it is* ***categorized*** *and how it is* ***defined****; also state if there are any secondary effects of interest)* |
| 1. **Comparison:** *(specify the comparison group)* |
| 1. **Outcome(s):** *(specify primary and secondary outcomes and how they are defined; if necessary add references)* |
| 1. **Covariates of interest:** *(list* ***ALL*** *other variables of interest that may be available in your data source and provide a rationale for each variable and how it will be categorized; add references if necessary)* |
| **DATA / ANALYSIS** |
| 1. **Database to be used:** *(provide codebook with field definitions if providing own data)* |
| 1. **Sample size:** *(provide any justifications for the sample size needed; do you expect a strong effect? Is the outcome of interest common? etc.)* |
| 1. **Analyses requested:** *(provide* ***empty tables and figures in an Excel file*** *as you envision them in your manuscript, this will clarify the analyses needed; be as specific as possible in this section and try to describe the analyses needed based on each table/figure you think you need)*   *Some options*  ***-****Univariable (t-test, chi2, non-parametric tests, comparing >2 groups, etc.)*  *-Multivariable (regression, propensity score analysis, instrumental variable analysis, survival analysis, etc.; clearly state what variables need to be adjusted for and why)*  *-Trend tests*  *-Correlation*  *-Pre-Post*  *-Interactions*  *-Clustering analyses* |
| 1. **Describe any potentials for the introduction of bias:** *(be very specific about why you think bias may occur and provide references if necessary; this section is extremely important as it may help in defining sensitivity analyses)* |
| 1. **Sensitivity analyses:** *(describe any sensitivity analyses that will strengthen validity of your study results; these are very important to ensure robustness of your results, think of subgroup analysis, other ways of analyzing data, using alternative definitions of outcomes or other variables, etc.)* |
| 1. **Limitations of study:** *(specify any known limitations of the proposed study)* |