**GEMINI Project Proposal Form**

***INSTRUCTIONS: There are two parts to this form. Part A is to be completed and submitted for review by the GEMINI Project and Publications Committee. Part B is to be completed once your project proposal has been approved AND if your project requires GEMINI Data Analyst support.***

***Part A: PROJECT DESCRIPTION***

*Please provide a brief (1-2 pages) description of your proposed project. Provide just enough detail for the GEMINI Project and Publications Committee (non-specialist investigators) to determine whether the study is feasible.*

|  |
| --- |
| **Project Title** |
|  |

|  |
| --- |
| **Project Investigator(s) and GEMINI Leads** |
|  |

|  |
| --- |
| **Study Question/Objective** |
|  |
| **Please select the GEMINI research objective(s) that applies to your proposal:** | [ ] Develop methods to deidentify, standardize, assess and improve the quality of data for research across multiple hospitals[ ] Characterize populations of hospitalized patients, examine variations and associations related to sociodemographic data, clinical characteristics and conditions, processes of care, resource use, and clinical outcomes for COVID and non-COVID illnesses[ ] Predict and model clinical outcomes and resource use for patients with COVID and non-COVID illness[ ] Study the effects of the COVID-19 pandemic and corresponding changes made to health systems on the demographic and clinical characteristics, processes of care, resource use, and clinical outcomes of patients with non-COVID illness in hospital[ ] Quantify the association between organizational aspects of hospital care (e.g. staff scheduling, ward organization, infection control practices, etc.) and resource use and clinical outcomes for patients with COVID and non-COVID illness[ ] None of the above |
|  |
| **Background/Rationale** |
|  |
|  |
| **Proposed Study Design** |
|  |
|  |
| **Expected Findings and Deliverables** |
|  |
| **What is the timeline for this project? Are there any upcoming deadlines?** |  |

|  |  |
| --- | --- |
| **Will you require GEMINI data analyst support for this project?** | [ ] Yes [ ] No [ ] TBD |
|  |
| **Anticipated Challenges/Limitations** |
|  |
|  |
| **Clinical, Scientific, or Policy Implications** |
|  |

|  |
| --- |
| **Prior to Submission** |
| Has a GEMINI Investigator reviewed your project proposal? If not, please contact a GEMINI Investigator to review before submitting your project proposal to GEMINI.research@unityhealth.to [ ] Yes [ ] NoName of Investigator who reviewed project proposal: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Reviewer Feedback/Comments**

***The GEMINI Projects and Publications Committee will complete this section.***

|  |  |  |
| --- | --- | --- |
| **Reviewers** | **Reviewer Comments** | **Approved?****Y/N** |
| **Reviewer 1:** | [ ] Project aligns with GEMINI core research objectives[ ] Project does not duplicate an existing project that is underway[ ] Project is feasible[ ] Project has a clear objective, study plan and deliverablesComments *(optional if proposal approved, mandatory if proposal rejected):* |  |
| **Reviewer 2:** | [ ] Project aligns with GEMINI core research objectives[ ] Project does not duplicate an existing project that is underway[ ] Project is feasible[ ] Project has a clear objective, study plan and deliverablesComments *(optional if proposal approved, mandatory if proposal rejected):* |  |
| **Reviewer 3:** | [ ] Project aligns with GEMINI core research objectives[ ] Project does not duplicate an existing project that is underway[ ] Project is feasible[ ] Project has a clear objective, study plan and deliverablesComments *(optional if proposal approved, mandatory if proposal rejected):* |  |

***Please complete Part B if your project requires GEMINI data analyst support and AFTER your proposal (Part A) has been approved by the GEMINI Projects and Publications Committee.***

***Part B: DETAILED STUDY PROTOCOL***

*Before conducting a full study, we need to ensure that we have adequate sample size and access to the necessary data elements. Think about what analysis needs to be done to check the rough sample size of your cohort and ensure that we can capture the key exposures and outcomes you are interested in. Please complete this study protocol to assist our analyst in completing your project.*

1. **Study Cohort**

| Project Cohort |
| --- |
| **Study Design** | [ ]  Cohort study [ ]  Matched cohort study [ ]  Case-control study[ ]  Cross-sectional study [ ]  Other (specify):  |
| **Patient Population** |  |
| **Inclusions (in order)**Add more rows if needed | *Step* | Description |
| 1 |  |
|  2 |  |
|  3 |  |
| **Exclusions (in order)**Add more rows if needed | *Step* | Description |
| 1 |  |
| 2 |  |
| 3 |  |

1. **Data Sources**

Which GEMINI sites will be included (if not all sites, please specify sites): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Which GEMINI Data Sources will be used:

 **CIHI DAD and NACRS:**

[ ]  IP Administrative

[ ]  ER Administrative

[ ]  Diagnosis

[ ]  Intervention

[ ]  IP SCU

**Admission-Discharge-Transfer (ADT):**

[ ]  Room transfers

**Clinical:**

[ ]  Blood Transfusion

[ ]  Imaging

[ ]  Lab

[ ]  Pharmacy

**GEMINI-Derived:**

[ ]  Derived scores

1. **Exposure and Outcome Definitions**

| Variable Definitions (add additional rows as needed) |  | Data Source\*For analyst to complete\* |
| --- | --- | --- |
| **Main Exposure or Risk Factor** |  |  |
| **Comparator** |  |  |
| **Primary Outcome Definition** |  |  |
| **Timing of Outcome** |  |  |
| **Secondary Outcome Definition(s)** |  |  |

1. **Covariates Definitions**

|  | Variable Definitions (add additional rows as needed) | Data Source\*For analyst to complete\* |
| --- | --- | --- |
| **Covariates** |  |  |

1. **Statistical Analysis**

|  |  |
| --- | --- |
| **Type of model** |  |
| **Additional comments about statistical analysis:** |  |

1. **Tables and Figures Layout**

*Please describe layout of tables/figures with all rows and column headers defined so our analyst can populate the data for you, e.g.:*

*Figure 1. Cohort creation diagram by hospital (based on Study Cohort listed above)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Step* | *MSH* | *SBK* | *SMH* | *THPC* | *THPM* | *UHNTG* | *UHNTW* | *ALL* |
| *Inclusion 1* |  |  |  |  |  |  |  |  |
| *Exclusion 1* |  |  |  |  |  |  |  |  |

*Table 1. Baseline characteristics of patient population*

*Table 2. Outcomes according to exposure variables (results from primary analyses)*

*Table 3. Covariates according to outcomes*

**Add new tables/figures as needed here:**