**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.*

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| **Project Title** |
|  |
| **Project Acronym/Nickname/Short Title** |
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| --- | --- |
| **Project Members and Institution**  ***Name, Institution*** | |
| **Lead Investigator:** |  |
| **GEMINI Lead Investigator:** |  |
| **Team Members:** |  |
| **Main contact and email: (for kickoff meeting and communication)** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Question/Objective** | | | | |
|  | | | | |
| **Please select the GEMINI research objective(s) that apply to your proposal:** | Develop methods to de-identify, 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**  **Provide background, rationale and how the selected GEMINI research objective(s) apply to the proposal** | | | | |
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|  | | | | |
| **Study Overview** | | | | |
| **Study Design**  (E.g. cohort, case-control, etc.) | |  | | |
| **Patient Population** | |  | | |
| **GEMINI data date range**  (E.g. Apr 2015-Mar 2020) | |  | | |
| **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 |  | |
| \*Please be specific with your inclusion and exclusion criteria. These will be treated as step-by-step instructions when creating your GEMINI data cut. For instance, if your GEMINI cohort is based on ICD codes, please provide the specific ICD codes and CIHI diagnosis types that define your cohort. | | | | |
| **Include details on primary outcome, explanatory variables, and high-level description of analyses:** | | | | |
|  | | | | |
|  | | | | |
| **Requested Data Elements** | | | | |
| Which **GEMINI Hospital sites** will be **excluded** (if all sites included, leave blank):  Click or tap here to enter text.  What **Data Tables** will be used in the analysis (check all that apply):  GEMINI Data Dictionary can be downloaded [here](https://www.geminimedicine.ca/access-data)  [In this order please]  IP Administrative  ED Administrative  IP Diagnosis  ED Diagnosis  IP Intervention  ED Intervention  IP Special Care Unit  Room Transfer  Radiology Test Occurrence (date/time of whether tests occurred)  Radiologist Reports (narrative text) - If requested, please justify for this:  Laboratory  Blood Transfusion  Pharmacy  Derived Variables  Locality Variables  Other: | | | | |
| Please note that data available for research is subject to change. For the most up-to-date details, please review the latest GEMINI Data Repository Dictionary available on <https://www.geminimedicine.ca/access-data>. | | | | |
|  | | | | |
| **What is the timeline for this project?** | | | |  |
| **Are there any upcoming deadlines?** | | | |  |

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| --- | --- |
| **Will a GEMINI data analyst conduct the analytic component of this project?** | Yes No |
| **If No, list the researcher(s) who require access to HPC4Health to conduct the analytic component of this project (name and email)** |  |
| **Please check the box below to confirm that the researcher(s) accessing HPC4Health and conducting the analytic component of this project are:**   * Comfortable with basic Unix commands * Familiar with R and/or Python   Please note: the following tools are available: RStudio Workbench, GitLab and slurm. There is no internet access or use of Microsoft software on HPC4Health.  **I confirm** | |

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| **Grants/Funding** |
| Is this proposal related to a grant submission [pre-award stage]? Yes No  Has the grant been successfully funded? Yes No  If yes, please list the name of the grant competition and the main aims:  If not, please inform the GEMINI team when the grant has been successfully funded. |
| **Conflict of Interest** |
| Is this project industry-sponsored, have any industry ties or commercial component? Yes No  If yes, please describe:  Do you have any perceived or actual conflicts of interest and/or industry ties, which the Projects and Publications Committee should be aware of? Yes No  If yes, please describe:  As per GEMINI's data Governance Policy, the use of GEMINI Data is strictly restricted to the purpose of conducting REB-approved scientific research. GEMINI Data or the output of analyses using GEMINI Data is not be used for commercial purposes or interest, nor to be shared with any third parties for such purposes. |
|  |
| **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](mailto:GEMINI.research@unityhealth.to)  Yes No  Name of Investigator who reviewed project proposal: Click or tap here to enter text.  Is your project related to any of the following specialty areas?  Specialized methods (e.g., AI/machine learning)  Specialized patient population (e.g., paediatrics)  Specialized dataset (e.g. cancer/ONCO) |
|  |

**Reviewer Feedback/Comments**

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| --- | --- | --- |
| **To be completed by the GEMINI Projects and Publications Committee** | | |
| **Reviewer #1**  Name:  Date of Decision: | 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 deliverables  Comments *(optional if proposal approved, mandatory if proposal rejected):* | |
| **Reviewer #1 Decision:** | **Approved** | **Denied** |
| **Reviewer #2**  Name:  Date of Decision: | 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 deliverables  Comments *(optional if proposal approved, mandatory if proposal rejected):* | |
| **Reviewer #2 Decision:** | **Approved** | **Denied** |

***Please complete Part B if a GEMINI data analyst is conducting the analytical component of your project 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. **Exposure and Outcome Variable Definitions**

| Variable Definitions (add additional rows as needed) | |  | Data Source \*For analyst to complete\* |
| --- | --- | --- | --- |
| **Main Exposure** |  | |  |
| **Primary Outcome Definition**  Detail timing of outcome if relevant |  | |  |
| **Secondary Outcome Definition(s)** |  | |  |

1. **Covariates and Subgroups of Interest**

|  | | Variable Definitions (add additional rows as needed) | | Data Source \*For analyst to complete\* |
| --- | --- | --- | --- | --- |
| **Covariates**  Please see Table 1 below for commonly used variables you may wish to include | |  |  |
| **Subgroups of Interest** | |  |  |

1. **Statistical Analysis**

|  |  |
| --- | --- |
| **Type of model** |  |
| **High-level description of modeling approach** |  |
| **Modeling considerations**  (e.g. a-priori covariates, interactions, functional forms, etc.) |  |
| **How will model estimates and results be presented?** |  |
| **Additional comments about 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* |  |  |  |  |  |  |  |  |
| *Inclusion 2* |  |  |  |  |  |  |  |  |
| *Exclusion 1* |  |  |  |  |  |  |  |  |
| *Exclusion 2* |  |  |  |  |  |  |  |  |

Table 1 below must be completed. Please add or remove pre-populated covariates at your discretion.

Tables 2-5 should be completed if they are relevant to your proposal.

*Table 1. Baseline characteristics of patient population*

*Table 2. Descriptive table of outcome measures*

*Table 3. Results of primary analyses (e.g. multivariable regression table)*

*Table 4. Results of secondary analyses*

*Table 5. Results of subgroup analyses*

*Table 1. Baseline characteristics of patient population*

|  |  |  |
| --- | --- | --- |
|  | Exposure 1  (n = ) | Exposure 2  (n = ) |
| Number of unique patients |  |  |
| Median Age (25th-75th) – years |  |  |
| Female sex - (%) |  |  |
| Neighborhood income quintile (%)   * Lowest quintile * Highest quintile |  |  |
| Charlson Comorbidity Index score (%)   * 0 * 1 * 2 * 3+ |  |  |
| Median Laboratory Acute Physiology Score (25th-75th) |  |  |
| Weekend admission (%) |  |  |
| Most common principal discharge diagnosis (%)   * 1 * 2 * 3 * 4 * 5 * 6 * 7 * 8 |  |  |
| Most common comorbidities (%)   * 1 * 2 * 3 * 4 * 5 * 6 * 7 * 8 |  |  |
| Admitted through emergency department (%) |  |  |
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|  |  |  |

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