**Dear Research Investigator:**

The Comparative Effectiveness and Clinical Outcomes Research Center (CECORC) is delighted to partner with you in your research endeavors.

Below is a description of the partnership process between CECORC and you, with a visual presentation of all steps involved in the research process and the expectations of both parties.

You will be asked to fill out a statement located at the end of the form and before the signature line, attesting that you will add the biostatistician partnering with you in your project as a co-author of any publication (poster, abstract, or full manuscript) or presentation (local, regional, national, or international) related to the research project. In addition, the Comparative Effectiveness and Clinical Outcomes Research Center (CECORC) must be listed in any presentation or publication as one of the sites where the research was performed.

**An appropriate institutional listing would be, for example:**

1. Division of XXXXXXX, Department of XXXXXXX, Riverside University Health System Medical Center
2. Comparative Effectiveness and Clinical Outcomes Research Center (CECORC) – Riverside University Health System

**Flow Chart of Research Process**

Before starting to write your proposal, please visit [**EQUATOR Guideline**](https://www.equator-network.org/reporting-guidelines/) and determine the appropriate reporting guidelines for your study by using [**EQUATOR flow chart**](https://www.equator-network.org/wp-content/uploads/2021/11/RG-decision-tree-for-Wizard-CC-BY-26-February-2016.pdf).

**IMPORTANT: Please review this page thoroughly if you intend to use RUHS data.**

**Responsibilities of Investigators**

* **RUHS Internal Review Boards (IRB) approval for accessing RUHS data**

The CECORC is a separate entity from the RUHS IRB. Therefore, we cannot be involved in your IRB application preparation and process. Should you have any questions regarding the IRB application process, please contact:

 **Glen Moulton, Director of RUHS IRB:** **g.moulton@ruhealth.org** **/ 951-486-4098**

Tips:

* If you are conducting a study involving RUHS data, regardless of whether the study is prospective or retrospective, IRB approval is required.
* Regarding the timing of submitting the IRB application, please consult with your Biostatistician for more information.
* Please include your Biostatistician as a co-investigator on your IRB application as the IRB requires that all investigators be approved to access any RUHS data.
* Related websites:

RUHS IRB: <https://rivcoca.sharepoint.com/sites/ruhs/clinicalservices/irb/Pages/default.aspx>

IRB: <https://www.irbnet.org/release/home.html>

CITI Program: <https://about.citiprogram.org/>

* **Data Extraction Request to Clinical Integration Analysts, Information Services**

If you do not plan to create a dataset by chart review, you will need to request RUHS Informatics Reporting Team, Information Services Department, to extract data from EPIC for your study. The CECORC is a separate entity from the Information Services Department. If you have any questions, please contact:

 **RUHS Informatics Reporting Team:** **ruhs\_reports@ruhealth.org**

Tips:

* Submit your data request only after finalizing all variables and providing clear descriptions with your Biostatisticians to prevent unexpected delays.
* Please include your Biostatistician in the email correspondence and the meetings with RUHS Informatics Reporting Team since the data must be designed and constructed appropriately for intended data analysis.

 **CECORC Research Proposal Form** [v.3]

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigators:**   |  | **Email:**   |  |
| **Institution/Department:**   |  |
| **Co-investigator(s):** |  |

**Date**: Click here to enter a date.

**Title of Proposal:**

**Type of Study**: (typically, retrospective or prospective)

**BACKGROUND** (Literature review that includes the results of previous studies and clearly defines the gap in knowledge that your study will address.)

**STUDY AIM / HYPOTHESIS**

**Primary Aim:**

**Secondary Aim(s):**

**Hypothesis**: (The hypothesis[es] should be concise but detailed, clearly articulating the comparison groups and outcomes in a comprehensive manner. The hypothesis[es] must be aligned with the aims of the study.)

**DATA AND ANALYSIS**

* **PROPOSED STUDY POPULATION**

**Inclusion Criteria:**

**Exclusion Criteria:**

* **DATA**

**Primary Outcome:**

**Secondary Outcome(s):**

**Predictors:**

**Time Frame of the Data:**

**Source of Data:**

**Patient Recruitment Goal:** (This is typically applicable for prospective studies.)

**Power Analysis needed?**

[ ]  **No,** as this is retrospective study

[ ]  **Yes** (Prospective studies must include power analysis to determine the appropriate sample size needed. Provide your Biostatistician with a relevant study from which key parameters for power analysis can be identified.)

* **STATISTICAL ANALYSIS PLANS**

This part will be determined by your Biostatistician after the data, outcomes, and predictors have all been clearly identified.)

**RESULTS / VALUE OF THE RESURCH**

**Expected/Anticipated Results:** (related to the aims and hypothesis(es) stated above)

**Define how findings from this study will serve as the foundation for future studies or future funded research:**

**OTHER INFORMATION**

**Does study require informed consent, describe rationale?** (This is typically applicable for prospective studies.)

**KEY REFERENCES** (5-10 sources, ideally published within 10 years)

**I,** Click here to enter text., **agree and will comply with the requirement to add a biostatistician involved in this research project as a co-author of any publication or presentation of this work and to list the Comparative Effectiveness and Clinical Outcomes Research Center (CECORC) – Riverside University Health System, in any presentation or publication as one of the sites where the research was performed.**

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**Signature Date**

**Principal Investigator (Attending)**

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**Signature Date**

**Co-investigator (Resident/Student)**

v.3-2025 (Last edited 5/7/2025)