**Research Project Outline**

The Research and Innovation Council of the University of Wisconsin-Eau Claire and Mayo Clinic Health System – Northwest Wisconsin.

|  |
| --- |
| **PROJECT TITLE** |
|  |
| **PRINCIPAL INVESTIGATOR** | **CO-PRINCIPAL INVESTIGATOR** |
| Name (s) |  |  |
| Title (s) |  |  |
| Primary Institution | ⎕ Mayo Clinic Health System⎕ UW-Eau Claire⎕ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | ⎕ Mayo Clinic Health System⎕ UW-Eau Claire⎕ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Phone Number  |  |  |
| E-mail Address  |  |  |

|  |  |
| --- | --- |
|  **RESEARCH FUNDS REQUESTED**  **(*COMPLETE BUDGET TEMPLATE*)** | **PROPOSED PROJECT DURATION** |
| Total: $ | Start Date: |
|  |  | End Date: |

|  |  |
| --- | --- |
| **INTELLECTUAL PROPERTY** |  |
| Please indicate if you have any intellectual property (“IP”) disclosures or background IP that will be used in or associated with this project.Please note: * WiSys handle matters of IP protection for UWEC.
* Mayo Clinic Ventures will be engaged for any intellectual property disclosures or background IP identified by Mayo.
 | UWEC:  No ⎕ Yes ⎕ Mayo:  No ⎕ Yes ⎕ For each response, please identify and define the IP being utilized or shared for this project. Please include the WiSys Reference Number and Mayo Case Number (below):  |
| Please provide detail for each disclosure above: |
| PLEASE NOTE THAT ANY IP GENERATED FROM THIS PROJECT WILL BE JOINTLY OWNED BY BOTH PARTIES UNDER THE MASTER COLLABORATION AGREEMENT BETWEEN MAYO AND UWEC.  |

1. **QUESTIONS** to be answered in order of scientific priority:

**Significance** and overall innovation. (*What problems face healthcare providers and address the unmet needs of our patients? What problems can students help solve? Address why someone should invest in this project and how it will help achieve the aims and objectives.*)

**Hypothesis**currently being examined. (*Use the* ***PICO****format. Outline the* ***P****atient/****P****roblem,* ***I****ntervention,* ***C****omparison,* ***O****utcome*).

**Background** and summary information justifying the current hypothesis. *(Include 5-10 references in AMA format that support the hypothesis, if needed, please use a separate page).*

**Human Subjects**. If human subjects are being used, complete Appendix A. If no, state N/A.

**Data and Specimens**. Are Data or Specimens (patient samples) being transferred or accessed for this research: Yes ⎕ No ⎕

If your project involves Data, please answer the following questions:

1. Which institution is providing Data? UWEC ⎕ Mayo ⎕
2. Please identify how the Data will be accessed/transferred to the receiving party.
3. Please define the Data being provided.
4. If you already have the appropriate IRB approval to share the data, please provide the approval. \*\*\*

If your project involves the transfer of or access to Specimens, please answer the following questions:

1. Which institution is providing the Specimens? UWEC ⎕ Mayo ⎕
2. Please identify how the Specimens will be accessed/transferred to the receiving party.
3. Please define the Specimens being provided.
4. If you have the appropriate IRB approval to share the Specimens, please provide the approval. \*\*\*

\*\*\***Please note that Mayo Clinic requires IRB approval for any external data transfer or specimen transfer.**

**Vertebrate Animals**. If animals are being used, complete Appendix B. If no, please state N/A.

**Milestones and timeline**. Identify short-term achievable milestones that would aid in supporting or refuting the hypothesis. Plot the resources necessary in the table below (tangible and sequential achievements). You can also use this table to begin estimating costs. More detailed costs should be compiled in Appendix C.

NOTE:  Please include time at the beginning of your project initiation to allow for the RPO and budget review, IRB approval, and statement of work completion.

|  |  |  |  |
| --- | --- | --- | --- |
| Milestone | Resource Needs | Initiation Date | Completion Date |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Impact**. Outline evidence of anticipated short-term and long-term benefits for our patients and students as a result of this study.

1. **METHODS** to test the hypothesis *(address the feasibility and robustness of technical expertise to be successful)*:

**Study Design – Clinical Trial, retrospective data review, prospective data collection, or Quality Improvement Project**

**Sample Population and Size Needed (include Sample Size/Power calculations as applicable)**

**Recruitment and Consent Plan (as applicable)**

**Study Procedure**

**Confidentiality of Data (explain if data will be exchanged and, if so, how it will be secured)**

**Laboratory Test(s)**

**Statistical Analysis Plan (complete Appendix D as needed)**

1. **STUDENT ENGAGEMENT** as part of advancing the research collaboration is encouraged.Outline opportunities to utilize [Blugold Biomedical Innovator](https://www.uwec.edu/academics/explore-opportunities/research/blugold-biomedical-innovator-program/) students or a [Blugold Fellow](https://www.uwec.edu/blugold-fellows/) in the project. Examples include project development, implementation, and evaluation.

**Appendix A:  Human Subjects and Human Subject Research Information**

Are human subjects involved?    Yes ⎕ No ⎕

**If yes, please note that you will be required to fill out an IRB form after the Research and Innovation Scientific Sub-Council has approved your study.**

**IRB Notes:**

* The Mayo IRB process must be used if patient records or information needs to be accessed or collected. If Mayo is the IRB of Record, a Mayo faculty/staff member must serve as the PI on the Mayo IRB application. Please note that this does NOT mean that the Mayo faculty/staff member must also serve as the overall project leader. Overall, project leadership is separate and is determined by mutual agreement between the collaborators.
* UWEC IRB <https://www.uwec.edu/orsp/faculty-academic-staff/research-using-human-subjects/> must also be consulted when planning collaborative projects. Please work with Jose Rico to engage the UWEC IRB chair for additional information.

Are any data/imaging/specimens collected under a separate IRB application used for this project? Yes ⎕ No ⎕

If yes, please provide that IRB number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**appendix B: Invertebrate Animal Form**

Are animals involved? Yes ⎕  No ⎕

What type of species will be requested?

Where will animals be housed?

Personnel to be involved in the project?

What is the IACUC number for this project? \_\_\_\_\_\_\_\_\_\_\_\_

Is a previously approved IACUC study be utilized under this project? Yes ⎕  No ⎕

**Appendix C: Budget Estimate**

Projects are funded and awarded on a calendar year basis. Though projects may be initiated at any time, cost calculations should align with the calendar year for budget planning purposes. For instance, a 12-month project that begins on April 1 would include costs associated with the first nine months of activity in Year 1 and expenses related to the final three months of activity in Year 2.

Subsequent year funding or additional funding requests require review and approval by the Research and Innovation Council. This can be requested during the biannual review process.

* Please note expenses not to be included in the budget:
	+ Effort for Mayo Clinic physicians
	+ Travel expenses for Mayo Clinic physicians who have a CME budget for support
	+ Manuscript publication charges

**Please refer to Jose Rico and Heather Johnson Schmitz for the budget template and to secure their guidance in its completion.**

Mayo Clinic – Jose Rico: RICO.JOSE@MAYO.EDU

The University of Wisconsin - Eau Claire – Heather Johnson Schmitz: SCHMITZH@UWEC.EDU

**Appendix D: Statistical Analysis Plan**

last updated: Date

Lead Statistician:

# Data

Registry/Data set(s):

Important deadlines:

Population:

 Starting Population:

 Exclusion Criteria:

Handling of missing data:

# Primary Objectives/Aims

1. Space Holder: These are the hypotheses from the investigator and may be taken directly from the proposal. Example: We think diabetic patients have worse ICU outcomes following cardiac surgery.
2. Space Holder

# Specific Objectives

Objective 1: space holder; Early objectives (e.g., Objective 1 and Objective 2) may be simple descriptions of the sample. For Example: Describe the patient sample by diabetic status at admission. Later objectives will translate the Primary Objectives above into a testable hypothesis. Ex: Evaluate the relationship between diabetic status and ICU length of stay

Analysis strategy: space holder; Describe statistical methods. Linear regression will evaluate the length of stay as the outcome and diabetic status as the exposure/predictor. Unadjusted and adjusted estimates will be reported for diabetic status; adjustment variables include age, sex, hypertension, … . Regression assumptions will be assessed by … . <may include evaluation and possible transformations of LOS / describe methods here>. The functional form of continuous adjustment variables will be evaluated by …, and modifications applied when necessary. ETC –details outlining the study

Results and Potential Conclusions: The relationship between diabetic status and length of stay will be reported as the regression coefficient with a 95% confidence interval. The regression coefficient represents the expected difference in mean length of stay (after adjusting for other variables).

Objective 2: space holder

Analysis strategy: space holder

Results and Potential Conclusions: space holder

Objective 3: space holder

Analysis strategy: space holder

Results and Potential Conclusions: space holder

# APPENDICES: On a separate page, please add appendices below as needed

## New variable definitions:

## Summary of missing data:

## Example table shells:

**Submit the completed RPO to** **EURESEARCH@MAYO.EDU** **and carbon copy Jose Rico:** **RICO.JOSE@MAYO.EDU** **and Heather Johnson Schmitz:** **SCHMITZH@UWEC.EDU****. Be sure to complete Appendices A, B, C, and D as applicable.**

**Research and Innovation Council approval:** The Research Project Outline requires full approval from the Research and Innovation Council (RIC) to continue. You will be welcome to attend a portion of the RIC meeting to provide an overview of the project and answer any questions. A RIC assistant will be in contact with you regarding the meeting timeline. After the meeting, you will receive a minute excerpt highlighting any questions that need to be addressed.