RESEARCH COLLABORATION GUIDELINES

El Centro Regional Medical Center (ECRMC) welcomes establishing research collaborations with both academic and clinical researchers. ECRMC is interested in collaborating on research projects that are consistent with the mission and research interests of ECRMC that will have a positive impact on the patients and the community we serve. We prioritize research collaborations that have the potential to result in a long-term research partnership with ECRMC.

Any researchers interested in establishing a research collaboration with ECRMC should follow these guidelines prior to submitting a Research Proposal Form via the El Centro Regional Medical Center Website (insert website address).

ECRMC Mission

Promote health and wellness through the delivery of innovative, high-quality patient care.

ECRMC Priority Research Areas

1. Current Health Disparities present in Imperial Valley
    - Diabetes and related chronic illnesses
    - Health Literacy
    - COVID-19 (short and long term)
2. Substance Use Disorder/ Medication Assisted Treatment
3. Access to Care Solutions
    - Telemedicine
    - Wearables
4. Patient Experience
5. Institutional Needs

Types of research ECRMC supports

- Programmatic research that improves access to and/or quality of care.
- Research that supports expansion of clinical services.
- Research that brings new resources to ECRMC and the community.
- Research based on disparities +/or health needs identified in the EMR data

Types of research ECRMC does not support

- Research that only uses ECRMC as a recruitment site without express benefit to community or target population.
- Research with no tangible short-term or long-term benefits to patients at ECRMC or the community.
- Proposed projects without funding to support administration costs will be evaluated on a case by case basis.

Eligibility

The submitted Research Interest Form must be led by an academic researcher or research team with demonstrated expertise and/or potential to successfully conduct the proposed research project. The PI should have expertise and publications related to the research project being proposed, and will be asked to *submit his/her/their CV with the Research Interest* Form *(Stage 1).*

Review Criteria

Research interest forms will be reviewed according to the following criteria:

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- Relevance to and impact on the research priorities of ECRMC.
- Relevance to and impact on the clinical priorities at ECRMC.
- Feasibility of carrying out the research project given the staff needs.
- The extent to which the research project has the potential to help develop a program of research or new clinical services and/or outreach programs at ECRMC.

Guidelines for Preparing Research Interest Forms and Grant Application

Research Interest Form - *Stage 1*

1. **Primary Contact Person.** This is the person who will serve as the liaison for the project during the development phase. This person may or may not be the lead academic researcher (i.e., Principal Investigator/Project Leader).
2. **Secondary Contact Person** *(if applicable).* This is a designee for the primary contact person, or may be the lead academic researcher if a project coordinator/manager or another investigator is named as the primary contact person.
3. **Project Title.** Please provide a brief title for the project. This can be a preliminary title and may be modified during project development.
4. **Project Abstract.** *(limit 500 words)* Please provide a clear and concise description of the project, including the following sections: *Aims, Methods, Potential Impact, and Future Directions.* Your abstract should include a clear rationale for the project, what you hope to achieve and how potential impact of the project is relevant to ECRMC research and clinical priorities. and future directions for this line of research with ECRMC. Please be as clear as possible when describing your methods as this information will be used to assess initial feasibility.
5. **Project timeline.** Please provide the proposed start date and end date of the project ***(MMIYYYY- MMIYYYY).***
6. **Proposed Investigators.** Please provide the names, degrees, and affiliations of all known investigators, including the lead academic researcher(s) (PI/MPIs) and co-investigators. The CV for the lead academic researcher must be submitted with the Stage 1 Research Interest Form.
7. **Possible ECRMC Collaborators.** Please use this space to indicate the areas of expertise you seek in ECRMC collaborators to support the proposed project. Please identify clinical departments and/or individual collaborators that you would like to work with at ECRMC (*see ECRMC Clinical Organizational Chart).* If this is an ongoing collaboration or you have been in communication with collaborators from ECRMC, please indicate the extent to which they have committed to working with you.
8. **Funding Information.** If the project is not already funded and the team intends to pursue funding, please provide any information available on what funding mechanism the team intends to use to support this project. If the project is already funded, please provide the funding details. If no funding is being sought to support this project, provide detailed justification for how project expenses will be addressed, including those of the project staff and any involved ECRMC staff.

Your justification should also include letters of support from key organizational personnel supporting the study outlining all contributions (ie. in-kind time, resources etc.)

An initial/preliminary review will be completed and any concerns or questions will be directed to the primary point of contact for the project. If the project is deemed feasible and of benefit to the organization, the primary contact person will be asked to present it to the ECRMC Multidisciplinary Research Council (MRC).

Presentation Requirements:

1. A written proposal must be provided a minimum of one week prior to the council's meeting for review. A brief overview of the proposal should be included in the project presentation.
2. The presentation should include a brief overview of the key personnel, and include all pertinent information (target population, sample size, recruitment plan, study activities, etc.).
3. The presentation should explicitly outline the benefits of the project to either ECRMC and/or the community

If the proposed project is approved through the council, a letter of support will be issued and the primary contact person will be asked to complete Stage II of the Research Interest Form for further review by the Clinical Research Department. A follow-up discussion meeting will be scheduled after receipt of the completed Research Interest Form.

Guidelines for Completing the Research Interest Form - *Stage 2*

1. **Does this project involve human subjects for research?** Please answer "yes" or "no" to indicate whether your project will involve human subjects.

2. **Subjects.** Describe who will be included as subjects in your project, how many subjects you intend to include, and address the applicable participation considerations listed below. If you are not recruiting human subjects (e.g. EHR analysis only), please describe the patient population of interest in terms of what patient records you propose to use in your project.

    a. Extent to which you propose to involve **ECRMC patients, families of patients, providers, clinic managers, and/or other staff** as subjects.

    b. General subject inclusion and exclusion criteria.

- *If applicable.* What will participation involve? What is the nature and length of their involvement?
- How will participants be remunerated for their involvement in the project?

3. **Recruitment.** Indicate what methods will be used to recruit subjects from ECRMC. If you are not recruiting human subjects (e.g. EHR analysis only), please indicate how subjects will be identified in the EHR.

    a. Include anticipated sample size for each subject group.

    b. Consider whether random sampling of patients is required.

    c. The following are potential recruitment methods for consideration:

        i. Reports of eligible patients using EHR data (*see section on EHR Data use below).*

        ii. Posting or distributing project flyers at clinic sites.

        iii. Involvement and training of **Project staff,** on-boarded and trained as ECRMC volunteers, to screen and recruit participants. If this approach is selected, please be prepared to discuss the following with ECRMC:

- Will project staff need specific training at ECRMC?

- Will project staff need access to patient data, clinic space, computer access, phone access, to integrate research activities with existing clinical activity?

    - Involvement and training of **ECRMC staff** to assist with screening and recruiting eligible participants at ECRMC or ECRMC community events/health fairs/canvassing events. If this approach is selected, please be prepared to discuss the following with ECRMC:

- How ECRMC staff will be involved in your project, their anticipated activities, and if they will need to complete IRB training (CITI) certification.

- **ECRMC staff** who are typically involved in recruitment include Clinicians, Medical Support Staff, Referral Center Staff, and Community Health Workers (or Promotoras/es). Please know that ECRMC staff who assist with recruitment will need to be included in the project budget.

4. **Electronic Health Records (EHR) Use and Information Technology UT) Needs.** Describe project needs for EHR data.

- Consider all aspects of the research project, including to understand the patient population prior to recruitment, for recruitment purposes, for intervention purposes, and/or for evaluation purposes.

- Consider the type of EHi data that is needed:

    - Identifiable vs. De-Identified data

    - Individual vs. Aggregate

- Consider what data will need to be accessed? Who will need access to the data?

- What IT systems will need to be accessed? o EHR (Soarian Clinicals & MedHost)

- SharePoint for secure File Sharing, access to Recruitment Reports (SOL)

- Please note that if ECRMC EHR data are used, a **Data Use Agreement (DUA)** may need to be established for the project *(see ECRMC DUA Template).*

6. A DUA is required any time the covered entity (i.e., ECRMC) shares with an investigator (i.e., SDSURF) a limited dataset {excludes 16 categories of direct identifiers but includes 2 categories of indirect identifiers) to be used for research purposes without individual consent (i.e., the patients have not been consented and the research will proceed using a waiver of consent). A *ECRMC DUA Template* is available, but each DUA must be developed in conjunction with and approved by Jacqueline Ramos, Compliance Manager at ECRMC. For more information about DUAs and limited dataset refer to: privacyruleandresearch.nih.gov/pr 08.asp#Bd.
7. **ECRMC staff** who are typically budgeted for in projects involving use of EHR data include Health Information Technology Staff.

- **Expected Outcomes**
    - The research team should demonstrate the potential to have an *impact* on patient care and services at ECRMC.
    - Research projects and activities should have the potential to result in a change in relevant metrics or development of new clinical services.
    - Examples of Metrics. Below are examples, but not an exhaustive list, of the types of metrics relevant to ECRMC:

- Objective measures of clinical outcomes
- Patient-reported outcomes
- Number of referrals consistent with guideline-concordant care
- Utilization rate for a targeted service
    - Cure rates among a patient population
    - Disease control rates among a patient population

5. **Clinic Sites and Space.** If you do not need to involve sites or require use of clinic space, please write *"Not Applicable".*

- Which ECRMC site{s) do you hope to involve in the project? (see *ECRMC Clinic Hours of Operation and Services).*
- Please provide details on what clinic sites are needed and what space is needed for recruitment, evaluation activities, and/or intervention delivery.
- What is the anticipated time frame and schedule for use of ECRMC space (frequency and duration)?
- If space is required as part of the research project please be sure to include it in the proposed research budget.

6. **ECRMC Staff Involvement**

   - For any **ECRMC staff** who may be involved in any aspect of the project, please consider how **ECRMC** staff will be involved and their anticipated activities. See all sections for suggestions on who to consider including for your project given project needs.
   - Based on their level of involvement, what IRB training (CITI) certification will staff need to complete?
   - Will ECRMC staff be considered key personnel and need to provide biosketches for the grant application submission phase?
   - **Advisory Group Involvement**
     - Indicate whether ECRMC and staff will be asked to participate in reporting and/or involvement with advisory groups, panels, or activities.
     - **ECRMC staff** who are typically involved in advisory groups include a Clinical Champion, Clinical Research Coordinator, Directors of each of the clinical departments affected by/utilized in the study. Chief Nursing Officer, Chief Clinical Research Officer, Chief Executive Officer, Chief Medical Officer, Information Services Director.

7. **Budget.** Budget development will vary depending on what is required by the funder and staff requirements at ECRMC. *Please note, budget information is not required on the Stage 2 Research Interest Form.* However, please consider the following when drafting your budget.

Required Staff for All Projects. Below are staff budget line items that must be included in any project conducted in collaboration with ECRMC:

8. **Medical Director and/or Clinical Champion** {one will be listed as the Subcontract Principal Investigator per ECRMC preferences)- Recommend at 5% FTE base
9. **Research Coordinator** - % FTE will depend on project activities. Responsible for recruitment of participants referred for clinical services.
10. Study Data Associate - % FTE will vary depending on project activities.
11. **Health Information Technology Staff** - % FTE will depend on project activities as well as direct cost incurred from the IT developer.

- **Community Health Worker/Promotor(a)** - % FTE will depend on project activities - Trained collecting data, to intervention delivery.
- **Referral Center Staff** - % FTE will depend on project activities - Assists with recruitment of participants who are referred for clinical services.
- Other ECRMC staff - consider other staff who will be needed to complete anticipated project activities.
- community health worker who engages in various project activities from recruitment, to

Other important budget considerations:

- ECRMC requires a 10% minimum indirect rate. Other indirect rates will be considered on a case-by-case basis for each project.
- The ECRMC fiscal year occurs from July 1 through June 30 of the following year. .
- Following completion of the Coverage Analysis, a plan will be set up to initiate billing for research services. gin.
- A budget template is available upon request {see *ECRMC Budget Template).*

Required Subcontract Documents. Documents should be prepared in collaboration with ECRMC for applications. The required subcontract documents may vary for each project, but typically include the following:

8. Scope of Work
9. Support with subcontract budget estimates
10. Subcontract budget justification
11. A signed letter of support
12. Biosketch for ECRMC site PI and any other key personnel

Contact Information

Inquiries about the submission process

Dr. Shiloh Williams
Research Director
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Additional Relevant Documents

ECRMC Research Interest Forms (Stage 1, Stage 2) ECRMC Organizational Chart

ECRMC Clinical Organizational Chart

ECRMC Clinic Hours of Operation and Services ECRMC Budget Template (to be added)

ECRMC Data Use Agreement Template (to be added) ECRMC Project Vignettes (to be added)