Research Collaboration Guidelines
Clínicas de Salud del Pueblo, Inc.

Clínicas de Salud del Pueblo, Inc. (CDSDP) welcomes establishing research collaborations with academic researchers. CDSDP is interested in collaborating on research projects that are consistent with the CDSDP mission and research areas of interest, that have a positive impact on patients and the organization, and have the potential to result in a long-term research partnership with CDSDP.

Researchers interested in establishing a research collaboration with CDSDP should read and follow these guidelines, and submit a Research Interest Form via SDSU HealthLINK Center.

CDSDP Mission

To improve the health and well-being of the communities we serve through providing access to excellent care, available to all.

CDSDP Priority Research Areas

1. Quality of care improvements
2. Innovations in clinical care
3. Clinical system interventions
4. Management of chronic diseases
5. Dissemination and implementation of evidence-based practices
6. EHR analyses to improve clinical practices and patient care
7. Behavioral health stigma
8. Health promotion outreach

Types of research CDSDP 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 CDSDP.

Types of research CDSDP does not support

- Research that only uses CDSDP as a recruitment site.
- Research with no tangible short-term or long-term benefits to patients at CDSDP.
- Grant applications with subcontract budgets that are not adequate to support the costs to administer and carry out the terms of the subcontract.

Eligibility

The submitted Research Interest Form must be led by an academic researcher or research team with 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)*.

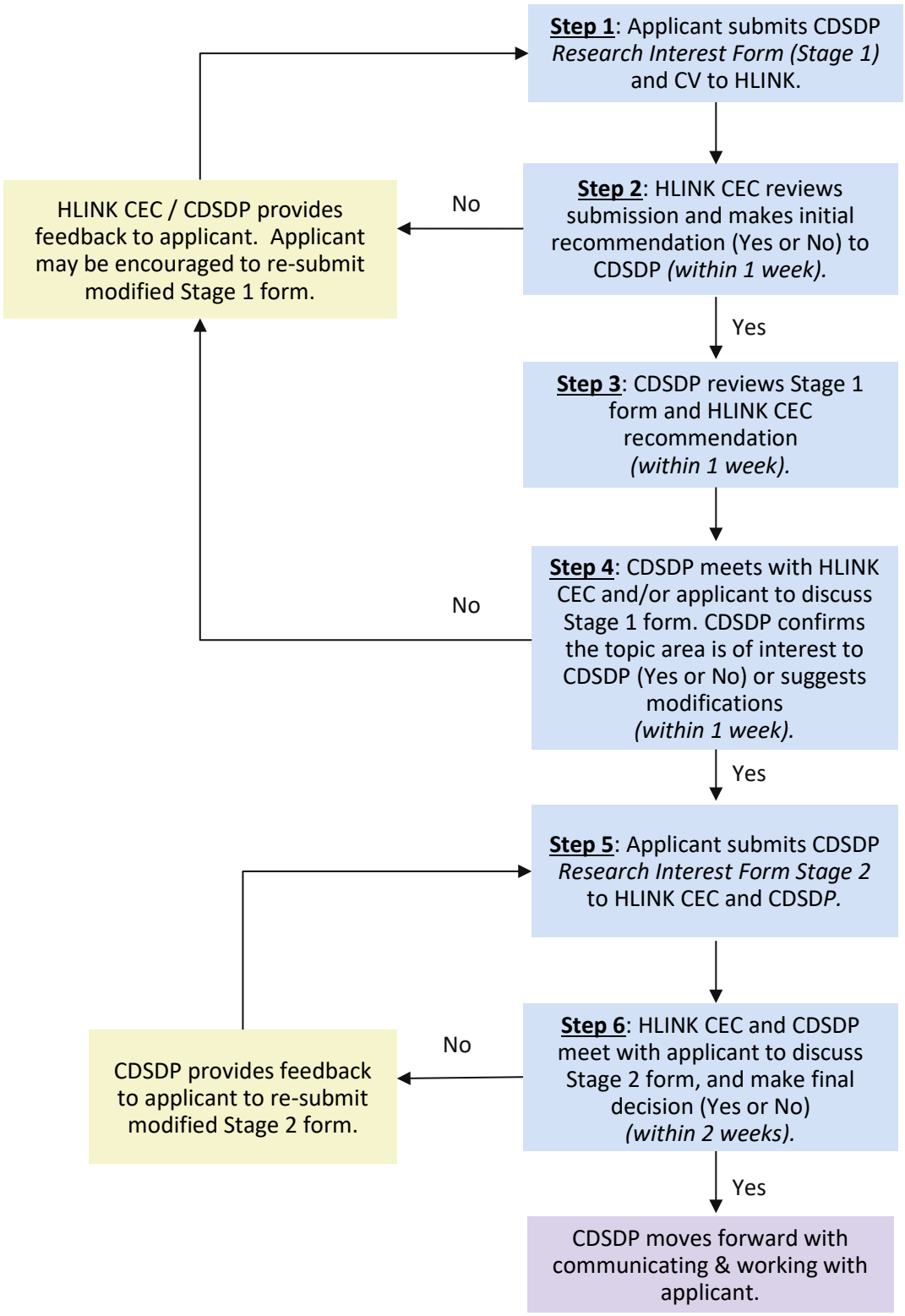
Review Criteria

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

- Relevance to and impact on the clinical priorities of CDSDP.
- Relevance to and impact on the training priorities at CDSDP.
- 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 CDSDP.

Submission Workflow Process

See Research Interest Forms (Stage 1 and Stage 2).



Reviewers of Research Interest Forms

1. **HLINK CEC**: SDSU HealthLINK Center Community Engagement Core Co-Lead, Co-Investigator and/or Coordinator.
2. **CDSDP**: CDSDP Chief Medical Officer, Chief Development Officer and Research Coordinator.

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 on factors relevant to CDSDP, and future directions for this line of research with CDSDP. 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 *(MM/YYYY-MM/YYYY)*.

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 CDSDP Collaborators.** Please use this space to indicate the areas of expertise you seek in CDSDP collaborators to support the proposed project. Please identify clinical departments and/or individual collaborators that you would like to work with at CDSDP (*see CDSDP Clinical Organizational Chart*). If this is an ongoing collaboration or you have been in communication with collaborators from CDSDP, 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.

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.
   - Extent to which you propose to involve **CDSDP patients, families of patients, providers, clinic managers, and/or other staff** as subjects.
   - 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 CDSDP. If you are not recruiting human subjects (e.g. EHR analysis only), please indicate how subjects will be identified in the EHR.
   - Include anticipated sample size for each subject group.
   - Consider whether random sampling of patients is required.
   - The following are potential recruitment methods for consideration:
     - Reports of eligible patients using EHR data (*see section on EHR Data use below*).
     - Posting or distributing project flyers at clinic sites.
     - Involvement and training of **Project staff,** on-boarded and trained as CDSDP volunteers, to screen and recruit participants. If this approach is selected, please be prepared to discuss the following with CDSDP:
       - Will project staff need specific training at CDSDP?
       - 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 **CDSDP staff** to assist with screening and recruiting eligible participants at CDSDP or CDSDP community events/health fairs/canvassing events. If this approach is selected, please be prepared to discuss the following with CDSDP:
       - How CDSDP staff will be involved in your project, their anticipated activities, and if they will need to complete IRB training (CITI) certification.
       - **CDSDP 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 CDSDP staff who assist with recruitment will need to be included in the project budget.

4. **Electronic Health Records (EHR) Use and Information Technology (IT) 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 EHR 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?
     - EHR (NextGen)
     - SharePoint for secure File Sharing, access to Recruitment Reports (SQL)
     - Will Virtual Private Network (VPN) access be needed (off-site access to NextGen and SharePoint)?
   - Please note that if CDSDP EHR data are used, a **Data Use Agreement (DUA)** may need to be established for the project (*see CDSDP DUA Template*).

- A DUA is required any time the covered entity (i.e., CDSDP) 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 *CDSDP DUA Template* is available, but each DUA must be developed in conjunction with and approved by Rick Gulizia, SDSU Assistant Vice President of Research Support Services. For more information about DUAs and limited dataset, refer to: privacyruleandresearch.nih.gov/pr_08.asp#8d.
- A Business Associates Agreement (BAA) already exists between CDSDP and SDSURF.

- **CDSDP staff** who are typically budgeted for in projects involving use of EHR data include Health Information Technology Staff.

5. **Expected Outcomes**
   - The research team should demonstrate the potential to have an *impact* on patient care and services at CDSDP.
   - 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 CDSDP:
     - 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

6. **Clinic Sites and Space**. If you do not need to involve sites or require use of clinic space, please write "*Not Applicable*".
   - Which CDSDP site(s) do you hope to involve in the project? (*see CDSDP 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 timeframe and schedule for use of CDSDP space (frequency and duration)?

7. **CDSDP Staff Involvement**
   - For any **CDSDP staff** who may be involved in any aspect of the project, please consider how **CDSDP 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 CDSDP staff be considered key personnel and need to provide biosketches for the grant application submission phase?
   - **Advisory Group Involvement**
     - Indicate whether CDSDP and staff will be asked to participate in reporting and/or involvement with advisory groups, panels, or activities.
     - **CDSDP staff** who are typically involved in advisory groups include a Clinical Champion, Research Coordinator, Chief Development Officer, Chief of Government & Community Relations, and Health Information Technology Staff.

8. **Budget**. Budget development will vary depending on what is required by the funder and staff requirements at CDSDP. *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 CDSDP:

- **Medical Director and/or Clinical Champion** (one will be listed as the Subcontract Principal Investigator per CDSDP preferences) - Recommend at 5% FTE base
- **Research Coordinator** - % FTE will depend on project activities
- **Health Information Technology Staff** - % FTE will depend on project activities

Other Suggested Staff (*project-dependent*)

- CDSDP Outreach Staff
    - **Outreach Manager** - % FTE will depend on project activities - Supervises and coordinates community outreach staff and outreach activities.
    - **Outreach Administrative Lead** - % FTE will depend on project activities - Leads the hands-on and administration of community outreach activities.
    - **Community Health Worker/Promotor(a)** - % FTE will depend on project activities - Trained community health worker who engages in various project activities from recruitment, to 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 CDSDP staff – consider other staff who will be needed to complete anticipated project activities.

Other important budget considerations:

- CDSDP requires a 10% minimum indirect rate. Other indirect rates will be considered on a case-by-case basis for each project.
- The CDSDP fiscal year follows the calendar year (January 1-December 31).
- After CDSDP staff are named and the contract is set up, automatic billing will begin.
- A budget template is available upon request (*see CDSDP Budget Template*).

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

- Scope of Work
- Support with subcontract budget estimates
- Subcontract budget justification
- A signed letter of support
- Biosketch for CDSDP site PI and any other key personnel

Contact Information

Inquiries about CDSDP

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Inquiries about the submission process

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Additional Relevant Documents

CDSDP Research Interest Forms (Stage 1, Stage 2)
CDSDP Organizational Chart
CDSDP Clinical Organizational Chart
CDSDP Clinic Hours of Operation and Services
CDSDP Budget Template (to be added)
CDSDP Data Use Agreement Template (to be added)
CDSDP Project Vignettes (to be added)