Innercare Research Interest Form Approval Considerations

Please consider the following when reviewing submitted Innercare Research Interest Forms:

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

Innercare 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 Innercare 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 Innercare.

Types of research Innercare does not support:
● Research that only uses Innercare as a recruitment site.
● Research with no tangible short-term or long-term benefits to patients at Innercare.
● 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.*

Review Criteria: Research interest forms will be reviewed according to the following criteria:
• Relevance to and impact on the clinical priorities of Innercare.
• Relevance to and impact on the training priorities of Innercare.
• 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 Innercare.

- Project Title: Provide a brief title for the project. This can be a preliminary title and may be modified during project development.
- Date of Submission: Provide date Research Interest Form was submitted to Innercare.
- Primary Contact Person: Individual who will serve as the liaison for the project during the development phase. Individual may or may not be the lead academic researcher (I.e., Principal Investigator/Project Leader).
    - 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.

Proposed Research Project Information

- Project Abstract (limit 500 words): Provide a clear and concise description of the project, including the sections: Aims, Methods, Potential Impact, and Future Directions.
    - Abstract should include clear rationale for the project, achievement goals, potential impact of the project on factors relevant to Innercare, and future directions for this line of research with Innercare. Information provided will be used to assess initial feasibility.
- Project Timeline/Funding Dates: Provide the proposed start date and end date of project (MM/YYYY-MM/YYYY) and dates proposed project will be funded (MM/YYYY-MM/YYYY).

- Funding Information (IF KNOWN): Funding Information: Provide all funding information relevant to proposed project.
    - If project has not been funded and funding will be pursued, provide any information available on which funding mechanism the team intends to use to support the project.
    - If the project has been funded, provide funding details.
- Proposed Investigators: 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 Form.
- Possible Innercare Collaborators: Indicate the areas of expertise you seek in Innercare collaborators to support the proposed project.
    - Identify clinical departments and/or individual collaborators that you like to work with within Innercare (see Innercare Organizational Chart).
    - If collaboration is ongoing or communication has been established with collaborators from Innercare, indicate the extent of the commitment to collaboration.

Additional Information

- Letter of Intent: Indicate whether a Letter of Intent is needed.
    - If a Letter of Intent is required, indicate date LOI is needed.

- <u>Human Subject Research</u>: Indicate if project will involve human subjects for research.

- <u>EHR Analysis Only</u>: Describe patient population of interest in terms of what patient records will be accessed.

- <u>Subjects</u>: Describe who will be included as subjects in proposed project. Indicate number of intended subjects and address applicable participation considerations listed below.
  - Extent to which Innercare patients, families of patients, providers, clinic managers, and/or other staff members will be involved as subjects.
  - General subject inclusion and exclusion criteria.
  - Participation involvement: Nature and length of involvement.
  - Plan for numeration of participants.

- <u>Recruitment</u>: Indicate what methods will be used to recruit subjects from Innercare.
  - EHR analysis only: Identify how subjects will be identified in EHR.
  - Indicate anticipated sample size for each subject group.
  - Consider whether random sampling patient is required.
  - 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.
- <u>Innercare Staff & Volunteer Involvement</u>: Indicate involvement and training of Project staff, on–boarded and trained as Innercare volunteers, to screen and recruit participants. If this approach is selected, be prepared to discuss the following:
  - Will project staff need specific training at Innercare?
  - Will project staff need access to patient data, clinic space, computer access, phone access to integrate research activities with existing clinical activity?
  - How Innercare staff will be involved in the project, their anticipated activities, and if IRB training (CITI) certification will be required.
  - Innercare staff who are typically involved in recruitment include Clinicians, Medical Support Staff, Referral Center Staff, and Community Health Care Workers (Promotoras/es).
  - Innercare staff who assist with recruitment will need to be included in the project budget.
  - Indicate whether Innercare staff will be considered key personnel and if biographical sketches will be required.
- <u>MRC/CAC Member Involvement</u>:
  - Indicate whether Innercare and staff will be asked to participate in reporting and/or involvement with advisory groups, panels, or activities.
  - Innercare staff who are typically involved in advisory groups include a Clinical Champion, Clinical Research Coordinator, Chief Development Officer, Chief of Government & Community Relations, and Health Information Technology Staff.

- <u>Electronic Health Records (EHR) Use and Information Technology (IT) Needs</u>: Describe project needs for EHR data.

- o Consider all aspects of the research project, including to understand the patient population prior to recruitment, intervention and/or evaluation purposes.
- o Consider the type of EHR data that is needed:
    - ▪ Identifiable vs. De-Identified data
    - ▪ Individual vs. Aggregate
- o Consider what data will be accessed and who will be accessing it.
- o Indicate which IT systems will be accessed.
    - ▪ EHR (NextGen)
    - ▪ SharePoint for secure File Sharing, access to Recruitment Reports (SQL)
    - ▪ Virtual Private Network (VPN)
- o If Innercare EHR data is being used, a Data Use Agreement (DUA) may need to be established for the project (see Innercare DUA Template).
- o Innercare staff who are typically budgeted for in projects involving use of EHR data include Health Information Technology Staff.

- • Expected Outcomes:
  - o The research team should demonstrate the potential to have an impact on patient care and services at Innercare.
  - o Research projects and activities should have the potential to result in a change in relevant metrics or development of new clinical services.
    - ▪ Objective measures of clinical outcomes
    - ▪ Patient-reported outcomes
    - ▪ Number of referrals consistent with guideline-concordant care
    - ▪ Utilization rate for targeted services
    - ▪ Cure rates among patient population
    - ▪ Disease control rates among patient population

- • Potential Benefits:
  - o Potential benefits for Innercare, patient care and/or services.
- • Proposed Research Study Co-Author:
  - o Will Innercare be listed as co-authors at the conclusion of the study?
- • Presentation of Study Findings:
  - o Will Innercare staff be able to present at Public Health, CPCA (California Primary Care Association) or NACHC (National Association of Community Health Care Center) conferences?
- • Clinic Sites and Space:
  - o If you do not need involve sites or require the use of clinic space, write "Not Applicable". Indicate which Innercare site(s) that will be involved in the project? (see Innercare Clinic Hours of Operation and Services).
  - o Provide details on what clinic sites are needed and what space is needed for recruitment, evaluation activities, and/or intervention delivery.
  - o Indicate anticipated timeframe and schedule for use of Innercare space (frequency and duration)?

- Additional Innercare Space Needed:
  - Please indicate any additional Innercare space needed such as:
    - Interview Room
    - Exam Room
    - Other
- Additional Information Needed:
  - Please indicate any additional information needed from Innercare staff in order to submit grant application:
    - Support with writing portions of the grant application
    - Feedback and guidance on the development of project activities
    - Electronic health record (HER) data to characterize the patient population
    - Other

- Projected Days Research Staff will be onsite:
  - Please indicate which days research staff will be onsite.
  - Information requested in order to coordinate schedules with IT Department and/or to gain EMR access.
- Additional Questions for Innercare Staff:
  - List additional questions for Innercare staff to be discussed.
- Additional Budget Information to Consider: Budget development will vary depending on what is required by the funder and staff requirements at Innercare.
  - Number of required staff for each project.
  - Staff budget line items that must be included in any project conducted in collaboration with Innercare:
    - Medical Director and/or Clinical Champion: Listed as the Subcontract Principal Investigator per Innercare preferences – Recommend at 5% FTE base.
    - Clinical Research Coordinator: % FTE will depend on project activities.
    - Health Information Technology Staff - % FTE will depend on project activities.
    - Innercare 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, and intervention delivery.
      - Referral Center Staff – FTE will depend on project activities. Assists with recruitment of participants who are referred for clinical services.
      - Other Innercare Staff – Consider other staff who will be needed to complete anticipated project activities.

- o Other important budget considerations:
  - Innercare requires a 10% minimum indirect rate. Other indirect rates will be considered on a case-by-case basis for each project.
  - The Innercare fiscal year follows the calendar year (January 1 – December 31).
  - After Innercare staff are named and the contract is set up, automatic billing will begin.
  - A budget template is available upon request *(see Innercare Budget Template)*.
- Required Subcontract Documents: Documents should be prepared in collaboration with Innercare for applications.
  - o The required subcontract documents may vary for each project, but typically involve the following:
    - Scope of work
    - Support with subcontract budget estimates
    - Subcontract budget justification
    - A signed letter of support
    - Biographical sketch for Innercare site PI and any other key personnel