

Innercare Research Interest Form Guidelines

How to Use These Guidelines

These guidelines correspond to the numbered sections of the Innercare Research Interest Form. They are intended to help prospective research partners provide sufficient information for Innercare to evaluate feasibility, privacy, regulatory, operational, contractual, and resource requirements. Submission of a Research Interest Form does not constitute project approval or a commitment of Innercare personnel, data, facilities, or other resources.

1. Request Details

- **Request Submission Date:** Provide the date the Research Interest Form is submitted to Innercare.
- **Requested Start Date:** Provide the anticipated project start month and year (MM/YYYY). If the timing is not yet known, enter "TBD."
- **Project Title:** Provide a brief title for the project. This may be a preliminary title and may be modified during project development.
- **External Partner Organization(s):** Identify each external institution, sponsor, academic partner, research organization, or other entity participating in or supporting the project.
- **Project Type:** Select the category that best describes the proposed activity: Research, Quality Improvement (QI), Program Evaluation, Operations, or Other. If Other is selected, specify the proposed classification.

The applicant's selection is preliminary. Innercare and, when appropriate, the reviewing IRB will determine the final classification. A project described as QI, operations, or program evaluation may still require privacy review, contractual protections, patient authorization, or IRB consultation.

2. Contact Information

- **Primary Contact Person:** Identify the individual who will serve as the project liaison during the development phase. This person may or may not be the lead academic researcher (e.g., Principal Investigator/Project Leader).
- **Secondary Contact Person (if applicable):** Identify a designee for the primary contact person, or the lead academic researcher if a project coordinator/manager or another investigator is named as the primary contact.

3. Proposed Project Overview

- **Project Abstract (limit 500 words):** Provide a clear and concise description of the project, including Aims, Methods, Potential Impact, and Future Directions.
 - Include a clear rationale for the project, achievement goals, potential impact 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 project start and end dates (MM/YYYY-MM/YYYY) and the dates the proposed project will be funded (MM/YYYY-MM/YYYY).
- **Proposed Investigators:** Provide the names, degrees, affiliations, and roles of all known investigators, including the lead academic researcher(s) (PI/MPIs) and co-investigators.
 - The CV for the lead academic researcher should be submitted with the Research Interest 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 you would like to work with within Innercare (see Innercare Organizational Chart).
 - If collaboration is ongoing or communication has been established with Innercare collaborators, indicate the extent of the commitment to collaboration.

Note: Identification of an Inncare employee or department does not constitute a commitment of Inncare personnel or resources.

4. IRB, Consent, and Regulatory Status

- Human Subjects Research: Indicate whether the project involves human subjects research by selecting Yes, No, or Unsure — consultation needed.
- IRB Status: Select the current status: Not applicable; Planned — not yet submitted; Pending; or Approved — attach approval letter.
- Reviewing IRB's Name: Identify the IRB responsible for review, when applicable.
- IRB Protocol Number: Provide the protocol or study number assigned by the reviewing IRB, when applicable.
- Principal Investigator Named on the Approval: Provide the name of the PI shown on the IRB approval or determination.
- Approval and Continuing-Review Dates: Provide the approval date and the expiration or continuing-review date, when applicable.
- Inncare as a Site or Data Source: Indicate Yes, No, Not applicable, or Unsure as to whether Inncare is listed in the IRB materials as a study site or data source.
- IRB Reliance Agreement: Indicate Yes, No, Not applicable, or Unsure as to whether an IRB reliance agreement is anticipated.
- Approval of Participant-Facing and Authorization Materials: Indicate whether recruitment materials, authorization language, consent documents, and waivers, as applicable, have been approved. Select Yes, No, Not applicable, or Pending / partially approved.
- Amendments Involving Inncare: Indicate whether amendments must be submitted before changes involving Inncare. Select Yes, No, or Unsure / TBD.
- Exemption Determination: Indicate whether the project has received an exemption determination by selecting Yes, No, Pending, or Not applicable. If Yes, identify who made the exemption determination.

Important: IRB approval, exemption, or a determination that an activity is not human-subjects research does not independently authorize Inncare to disclose PHI. Inncare must separately approve the privacy and data-sharing pathway.

- Informed Consent / HIPAA Authorization: Indicate whether informed consent and/or HIPAA authorization will be obtained by selecting Yes, No, Waiver requested, or Unsure. Final requirements will be determined through the applicable IRB and Inncare Compliance/Privacy review.
- Data or Specimens Shared Outside Inncare: Indicate Yes, No, or Unsure. If Yes or Unsure, briefly describe what will be shared and with whom; provide additional detail in Section 5 as applicable.

5. Data, Records, and EHR Use (Minimum Necessary)

- **Data Needed:** Indicate the types of data needed and select all applicable categories on the Research Interest Form.
- **EHR / Records Use (limit 300 words):** Describe exactly how the EHR and/or records will be used, including the requested data elements, who will access them, the source of the data (EHR, surveys, etc.), who will pull the data (Inncare staff, research staff, etc.), whether data will leave Inncare systems, and the frequency of data pulls (e.g., weekly, monthly, quarterly). Address identifiable vs. de-identified and individual vs. aggregate data as applicable.

Requested Data Classification — select all that apply:

- ☐ Aggregate data with no patient-level records
- ☐ HIPAA de-identified data — Safe Harbor
- ☐ HIPAA de-identified data — Expert Determination

- ☐ Limited data set
- ☐ Identifiable PHI
- ☐ Direct patient identifiers or contact information
- ☐ Coded data with a re-identification key
- ☐ Biological specimens
- ☐ Genetic or genomic information
- ☐ Behavioral health information
- ☐ Psychotherapy notes
- ☐ Substance use disorder records potentially subject to 42 CFR Part 2
- ☐ Minor-consent or other specially protected information
- ☐ Photographs, audio, video, or voice recordings
- ☐ Social Security, financial, or government identification information

A limited data set is still identifiable health information, although specified direct identifiers are removed, and it requires a Data Use Agreement for disclosure.

- **Behavioral Health / Specially Protected Information (limit 300 words):** If BH and/or specially protected information is involved, describe how information will be accessed, who will access it, where it will be stored, and how privacy and minimum necessary will be maintained.

Attach a Data Elements and Disclosure Matrix listing:

- Each requested field or variable
- The reason each field is necessary
- Source system
- Date range
- Patient population
- Identifiability level
- Person or organization receiving it
- Frequency of disclosure
- Method of transmission
- Retention period

Approval of the project does not constitute approval of every requested data element. Innercare may reduce or modify the requested data set to meet the minimum-necessary standard.

Research Recruitment and Initial Contact: Innercare workforce members may identify and initially contact potentially eligible patients when permitted under an approved protocol and applicable HIPAA requirements. An external researcher may not receive a patient recruitment list or directly contact an Innercare patient based solely on verbal permission. Disclosure of patient names, contact information, or other PHI to an external research team requires an approved HIPAA pathway, such as the patient's valid written authorization or documentation of an applicable IRB or Privacy Board waiver or alteration.

Innercare must approve the recruitment workflow, scripts, documentation method, data fields, and personnel authorized to conduct recruitment before recruitment begins.

Innercare may still use a "permission to contact" process operationally—for example, Innercare calls the patient and asks whether the research team may contact them—but the permission and resulting disclosure should be governed by a written, Compliance-approved workflow rather than a blanket verbal-approval statement.

6. HIPAA Privacy, Security, and Data-Sharing Compliance

Depending on the project and the data involved, Innercare may require a HIPAA authorization, IRB or Privacy Board waiver documentation, Data Use Agreement, Business Associate Agreement, research agreement, subcontract,

data-transfer agreement, or another written agreement. Approval by an IRB does not, by itself, authorize Innercare to disclose PHI. Innercare Compliance/Privacy and Legal will determine the required documentation before access or disclosure occurs.

Anticipated HIPAA pathway, if known — select all that may apply:

- ☐ Written HIPAA authorization
- ☐ IRB/Privacy Board waiver or alteration of authorization
- ☐ Limited data set with Data Use Agreement
- ☐ De-identified information
- ☐ Preparatory-to-research review conducted within Innercare
- ☐ Business Associate arrangement
- ☐ Unsure — Innercare determination required

Final determination of the appropriate agreement and disclosure authority will be made by Innercare Compliance/Privacy and Legal.

- **Protected Health Information (PHI):** Describe how you, your staff, and any collaborating agencies will protect the confidentiality and security of PHI.
- **HIPAA Compliance Training:** Indicate whether staff and all other individuals participating in the project complete HIPAA compliance training.
- **Handling, Retention, and Disposal of PHI:** Describe procedures for handling, retaining, returning, or disposing of PHI upon completion of the program or project.

Additional security and data-management information should address:

- Exact storage system and physical location
- Whether cloud hosting or external vendors will be used
- Encryption in transit and at rest
- Multifactor authentication
- Role-based access
- User access logs and audit monitoring
- Whether data will be downloaded to laptops or portable media
- Remote-access controls
- Subcontractors and downstream recipients
- Incident and breach reporting timeframe
- Access removal when personnel leave the project
- Data backup copies
- Return or destruction process and certification
- Whether data will be transferred outside the United States
- Whether artificial intelligence, machine learning, public generative-AI tools, or external analytics platforms will receive Innercare data
- Whether the research team will link Innercare data with other datasets
- Prohibition against re-identification or contacting individuals unless expressly approved

7. Recruitment and Patient Interaction

- **Subjects:** Describe who will be included as subjects in the proposed project. Indicate the intended number of subjects and address applicable participation considerations.
 - Extent to which Innercare patients, patient family members, providers, clinic managers, and/or other staff will be involved as subjects
 - General subject inclusion and exclusion criteria
 - Nature and length of participation

- Plan for remuneration or compensation of participants
- **Recruitment:** Indicate the methods proposed to recruit subjects from Innercare.
 - EHR analysis only: Identify how subjects will be identified in the EHR
 - Describe the recruitment workflow: who will approach patients, where/when, scripts/materials, and whether Innercare staff are expected to participate
 - Indicate anticipated sample size for each subject group
 - Indicate whether random sampling of patients is required

Potential recruitment methods, subject to Innercare, IRB, Privacy, and operational approval, may include:

 - Innercare-generated reports identifying potentially eligible patients
 - Approved study flyers at designated Innercare locations
 - Other project-specific recruitment methods approved in writing
- **Research Staff On-Site (if applicable):** Indicate projected days research staff will be on-site. On-site presence may require additional approvals, training, space planning, and/or IT/EHR provisioning (limit 150 words).

8. Clinic Sites and Operational Impact

- **Clinic Sites and Space:** If you do not need clinic sites or space, write “Not Applicable.” Otherwise, identify the Innercare site(s) involved in the project.
 - Describe the clinic sites and space needed for recruitment, evaluation activities, and/or intervention delivery (e.g., conference room, exam room, interview room).
 - Indicate the anticipated timeframe and schedule for use of Innercare space, including frequency and duration.
- **Operational Impact and Workflow Changes:** Describe new forms, training, staffing impacts, space needs, EHR builds/reports, scheduling impacts, and other anticipated operational changes.

9. Innercare Resources Requested

- **Research Personnel / Innercare Workforce Involvement:** Describe any anticipated involvement of Innercare employees or external research personnel in screening, recruitment, data collection, or other project activities. If external research personnel would require Innercare onboarding, training, system access, or another formal workforce designation, identify that need here. Innercare will determine the appropriate onboarding and access requirements.
 - Will project staff need specific training at Innercare?
 - Will project staff need access to patient data, clinic space, computer access, or phone access to integrate research activities with existing clinical activity?
 - How will Innercare staff be involved in the project, what activities are anticipated, and will IRB training (CITI) certification be required?
 - Innercare staff typically involved in recruitment may include clinicians, medical support staff, Referral Center staff, and Community Health 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 whether biographical sketches will be required
- **Additional Information Needed:** Identify any additional information needed from Innercare to submit a grant application.
 - Support with writing portions of the grant application
 - Feedback and guidance on development of project activities
 - Electronic health record (EHR) data to characterize the patient population
 - Other

10. Funding (if known) and Budget

- **Funding Information (if known):** Provide all available funding information relevant to the proposed project.
 - If the project has not been funded and funding will be pursued, provide available information about the funding mechanism the team intends to use.
 - If the project has been funded, provide funding details.
 - **Additional Budget Information to Consider:** Budget development will vary based on funder requirements and Innercare staffing/resource requirements.
 - Number of required staff for each project
 - Staff budget line items potentially included in projects conducted in collaboration with Innercare:
 - Medical Director and/or Clinical Champion: May serve as a Subcontract Principal Investigator subject to project-specific approval and budget negotiations
 - 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 activities
 - Outreach Administrative Lead: % FTE will depend on project activities; leads hands-on and administrative community outreach activities
 - Community Health Worker/Promotor(a): % FTE will depend on project activities; may engage in recruitment, data collection, and intervention delivery
 - Referral Center Staff: FTE will depend on project activities; may assist with recruitment of participants referred for clinical services
 - Other Innercare Staff: Consider other staff needed to complete anticipated project activities
- Other important budget considerations:**
- Innercare requires a minimum indirect cost rate of 10%. The applicable indirect cost rate may be higher depending on the sponsor, funding mechanism, project requirements, and negotiated budget. Final indirect cost rates are subject to Innercare approval.
 - The Innercare fiscal year follows the calendar year (January 1–December 31).
 - Billing will follow the fully executed agreement, approved budget, documented effort, deliverables, and applicable invoicing terms.

11. Outcomes, Benefits, and Dissemination

- **Expected Outcomes:** The research team should demonstrate the potential to have an impact on patient care and services at Innercare. Research projects and activities should have the potential to improve relevant metrics or support 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 the patient population
 - Disease control rates among the patient population
- **Potential Benefits:** Describe potential benefits for Innercare, patient care, and/or services.
- **Innercare Authorship and Contributor Recognition:** Discuss whether and how qualifying Innercare personnel may be recognized as authors or contributors at the conclusion of the study.
 - Address whether Innercare may review manuscripts, abstracts, presentations, press releases, and public statements before submission; whether Innercare or its clinics may be named; small-cell suppression standards; whether exact clinic locations could indirectly identify patients; whether data may be used for

future or secondary research; whether data may be shared with repositories or other investigators; whether data may be commercialized; ownership of data, analytic files, inventions, and resulting materials; required notice of publications and findings; and return of study results to Innercare and participating communities.

- Indicate whether qualifying Innercare personnel will be included as co-authors when they meet applicable authorship criteria.
- **Presentation of Study Findings:** Indicate whether Innercare staff will be able to present findings at conferences such as Public Health, CPCA (California Primary Care Association), or NACHC (National Association of Community Health Centers).

12. Questions / Items to Discuss

- **Questions / Discussion Topics:** Indicate any questions or topics you would like to discuss with Innercare staff.

Innercare Internal Review and Approval Process

Depending on the project, Innercare internal review may include the following approvals and conditions:

- ☐ Compliance/Privacy approval
- ☐ Security risk review
- ☐ IT/EHR access approval
- ☐ Legal agreement fully executed
- ☐ IRB documentation verified
- ☐ Data elements approved
- ☐ Recruitment workflow approved
- ☐ Patient-facing materials approved
- ☐ Site/operations approval
- ☐ Workforce or research personnel onboarding completed
- ☐ Data-release owner identified
- ☐ Data-destruction date established
- ☐ Publication and dissemination review terms established

No PHI access, data extraction, recruitment, patient contact, on-site activity, or project launch may occur until all required approvals and agreements are documented in writing.

Application / Subcontract Documents

Required subcontract documents should be prepared in collaboration with Innercare for applications. The specific documents may vary by project, but typically include:

- Scope of work
- Support with subcontract budget estimates
- Subcontract budget justification
- Signed letter of support
- Biographical sketch for the Innercare site PI and any other key personnel