**Research Proposal Request Form**

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| **Instructions**  Please answer the questions in this form to the best of your ability. Your proposal will be evaluated based on the following criteria:   * The data can be used to address study aims. * The methods are suitable to the question.   *(Please note that in reviewing the application, the committee is giving priority to the use of rigorous scientific methods and less emphasis to the importance of the study question. Our intent is to ensure that the results are likely to be valid).*   * The investigator has the capacity/skill to do the work. * There is no overlap with an existing study using the ICN Research Database. * Affiliated with an IRB that can provide oversight and enforce sanctions in the event of a breach of contract. * Signed Data Sharing Expectations Policy   For a complete submission package, please return the following documents to Kendra Wiegand at [Kendra.Wiegand@cchmc.org](mailto:Kendra.Wiegand@cchmc.org). Feel free to email Kendra with any questions you may have.   * Completed Research Proposal Request Form * Proposal (instructions below) * Signed Data Sharing Expectations form * Principal Investigator Bio-sketch * Mentor Letter of Support (if applicable)   Review Process:   * Upon submission of a complete package, your proposal documents will be reviewed by at least two assigned Research Committee members. * The proposal will be presented and discussed during a Research Committee Meeting. *(This meeting takes place on the 4th Tuesday of each month.)* * A determination of Approved, Provisional Approval, Table, or Decline, will be assigned during the Research Committee Meeting. * You will receive an email notification of the determination with supporting comments. |

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| **Proposed Project Title:** | | |
| **Principle Investigator** | | |
| Name: |  | |
| Position/Title: |  | |
| Institution: |  | |
| Email Address: |  | |
| Phone: |  | |
| Link to Bio-sketch: | |  |
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| **Additional Key Personnel/Co-Investigators:**  Please include Name, Degree(s), Position Title, Institution (if differs from PI’s) | | |
| **Mentor Name (if applicable)**  Please include Name, Degree(s), Position Title, Institution, qualifications and level of support | | |
| **Proposal Study Start and End Dates:** \_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Overall Study Question (and primary hypothesis to be tested):** | | |
| **Basic design category:**  Please check one.  Observational (includes retrospective and prospective)  Interventional (includes randomized trial) | | |
| **ICN Data Requested:**  Please check one.  De-Identified Dataset  Limited Dataset  No Dataset Requested | | |
| **Is this proposal related to a grant application?**  Yes If yes, list sponsor and application date: \_\_\_\_\_\_\_\_\_\_\_\_  No | | |
| **Does this proposal have existing funding?**  Yes If yes, list sponsor: \_\_\_\_\_\_\_\_\_\_\_\_  No | | |
| **Additional Expertise/Support Needed from ImproveCareNow?**  Yes  No  If yes, please describe:   |  | | --- | |  | | | |
| **Are you interested in collaborating with additional ICN investigators?**  Yes  No | | |

**Provide below a brief summary of the proposal focusing on the study question and the methods for answering that question (2 pages).**

Include the following information:

**Background and Significance (100 words):**

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**Specific Aim(s) (100 words):**

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**Methods (1-2 page summary including the detailed information below):**

* Study design
* Study population
* Estimated sample size
* Proposed inclusion/exclusion criteria
* Data sources
* Outcome variables
* Exposure/treatment/predictor variables
* Other variables of interest (e.g., potential confounders, effect modifiers, and/or mediators)
* Basic analysis plan for this stage of the study
* Pre-specified subgroup(s) of interest
* Approximate study timeline (starting from time of approval)

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**Plan for patient and parent engagement:**

Describe current or planned patient/caregiver engagement in the proposed research such as inclusion on the study team or service in an advisory role. Opportunities for parent/patient involvement include: 1) idea generation/proposal development, 2) study design, 3) study conduct or management, 4) data analysis or interpretation, 5) results dissemination. Please provide justification if patient/parent engagement is not planned.

The Research Committee and PWG Research Subcommittee are available to assist with parent/patient engagement.

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**Anticipated Impact on patient decisions and/or clinical outcomes:**

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