**MEDICAL DEVICE SURVEILLANCE AND ASSESSMENT RESEARCH**

**Letter of Intent (2024)**

***INSTRUCTIONS:*** *Use the template below to draft your Letter of Intent. The Part 1 of the LOI should be one page. References are not required. Please delete the instructions in red font before submitting your LOI.*

* *The LOI submission deadline is March 31 or September 30, 2024*
* *Send the LOI submission to:* Heather.Prentice@kp.org

**PART 1**

**PRINCIPAL INVESTIGATOR: [insert name, department, medical center]**

*Please list only one Principal Investigator. The PI should be willing to assume responsibility for the management of the research, while also complying with the administrative policies, and human subject protection regulations associated with the research project.*

**STUDY TITLE: [insert study title]**

***Medical Device/Implant Performance Research Focus (Select all that apply):***

[ ]  Comparative effectiveness [ ]  High risk implant

[ ]  New technology [ ]  Not applicable

***Clinical Priority Area (Select any that apply):***

[ ]  Cancer Screening and Prevention [ ]  Medication Adherence

[ ]  Cardiac Care [ ]  Mental Health

[ ]  Comparative Effectiveness for Various Agents [ ]  Telehealth and Virtual Care

[ ]  Equity, Inclusion and Diversity [ ]  Not applicable

**BACKGROUND AND SIGNIFICANCE:** *Provide a one paragraph summary of the background and significance of your research idea. The background should succinctly describe the current state of knowledge and identify the problem to be addressed. Please include any relevant references.*

**RESEARCH QUESTION:** *State the research question that will be addressed in the proposed study. Consider using the PICO format: What is the Patient, population, or problem? What is the Intervention/exposure of interest? What is the Comparison to your intervention/exposure? What is the Outcome of interest?*

**CLINICAL IMPLICATIONS / IMPACT:** *Statement of the potential clinical implications or operational impact of the proposed study. How will the findings from this project be used to change clinical practice and enhance care? Do you have the support of regional, clinical leaders to implement any changes?*

**PART 2**

**SUPPORTING DOCUMENTATION:** *Please review the categories listed below and provide the supporting documentation, if applicable.*

**Category #1: Previous Collaboration with Medical Device Surveillance and Assessment:**

[ ]  **Yes** [ ]  **No**

* *If you have participated with Medical Device Surveillance and Assessment (formerly National Implant Registries) in the past, provide a summary of your previous work (presentations / publications).*

**Category #2: Previous Research Experience:** [ ]  **Yes** [ ]  **No**

* *If you have participated in research outside of Medical Device Surveillance and Assessment (formerly National Implant Registries) in the past, provide a summary of your previous work (presentations / publications).*

**Category #3: Previous Completion of Institutional Review Board (IRB) Compliance Training:** [ ]  **Yes** [ ]  **No**

* *If you have previously completed all compliance training requirements by your region’s IRB, provide copies of certificates. If you have not completed all training, this will be required prior to the initiation of any study.*

**Category #4: Graduate Medical Education (GME) Involvement:** [ ]  **Yes** [ ]  **No**

* *If significant medical student, resident, or fellow involvement is anticipated, please indicate their role on the project.*

**Category #5: Involvement of External Parties/Investigators:** [ ]  **Yes** [ ]  **No**

* *If outside external parties are involved as collaborators (e.g., universities or other institutions), a completed Business Agreement, Data Use Agreement, Confidentiality Agreement, and/or Raptor Approval Form will need to be provided.*