



Wellstar Research Institute

Application to Create or Contribute to a Registry or Database

Registry or Database Owner \_\_\_\_\_ Department \_\_\_\_\_

E-mail \_\_\_\_\_ Phone \_\_\_\_\_

1. Protocol/Project Information

Table with 2 columns and 4 rows: Sponsor, Protocol/Project Title, Anticipated Start Date, Anticipated End Date

2. Project Details

a. State the purpose of the registry or database:

b. Will your project involve the use or sharing of existing data? If yes, answer questions i, ii, iii, and iv before proceeding to c. If no, proceed to c.

i. Briefly describe the type(s) of data that will be used and/or disclosed. Provide specifically the data items which will be collected and analyzed and the source from which the data will be abstracted.

ii. Where will the data be stored, and who will be the custodian of the data? Please provide a brief description of protections in place to keep the data secure, including who will have access to the data.

iii. Was the data collected from another research registry or database?

iv. How many Wellstar records will be included in the registry or database?

c. Describe your population (e.g., adults, medical staff team members, etc.) and include any inclusion/exclusion criteria for subjects.

3. Please describe the plans for the data after the project has been completed.

4. Minimal Risk. Explain how this activity presents no more than minimal risk (including risks of breach of confidentiality of protected health information) to human subjects.

5. Please attach the following documents to complete your submission:

- a. Full project proposal or protocol
b. Informed consent document, if applicable
c. HIPAA authorization, if applicable

- d. Request for Waiver of Authorization, if applicable
- e. All data collection tools/spreadsheets.
- f. Any information that will be shared with potential human subjects (e.g., fliers, surveys, questionnaires).

**Registry or Database Owner Assurance and Acknowledgement:**

*I certify that the information provided in this application and supporting document is complete and accurate.*

*As the Registry or Database Owner, I have ultimate responsibility for the conduct of this project, the ethical performance of this project, the protections of the rights and welfare of human subjects, and strict adherence to any situations designated by the Wellstar Research Institute (WRI).*

*I accept and will conform to all federal, state, institutional, and WRI provisions concerning the protection of human subjects in research.*

*I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project and in the protection of human subjects.*

*I recognize that this project may not begin until it has been determined that it is exempt from federal regulations. If this determination cannot be made, I will need to submit this project to an Institutional Review Board (IRB) and obtain approval, as indicated by an IRB determination letter.*

*I will submit any proposed changes for review and approval before they are implemented and notify the IRB of any unanticipated problems that may occur during the study.*

*I am responsible for assuring that no arrangement has been entered into where the value of any ownership interests will be affected by the outcome of this project, and no arrangement has been entered into where the amount of compensation will be affected by the outcome of this project.*

\_\_\_\_\_  
Registry or Database Owner      Signature (may be typewritten)      Date      \_\_\_\_\_

If student researcher:

\_\_\_\_\_  
Preceptor/Committee Chair      Signature (may be typewritten)      Date      \_\_\_\_\_