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| **Advocate Aurora Health (AAH)**  **Research Subject Protection Program (RSPP)**  Human Subject Research Determination | RSPP Tracking Number:  Received Date:  For IRB Office Use Only |
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Sometimes it is difficult to discern whether a proposed activity constitutes research or human subject research. When uncertainty exists, the AAH RSPP will make a determination whether the activity is Human Subject Research. The information provided will be reviewed to determine whether the proposed activity would require review and approval by an IRB. See the AAH System Policy: *Research Involving Humans or their Identifiable Data or Biospecimens*.

**Instructions:**

* **Submit completed form along with any other supporting documents (surveys/questionnaires, etc.) to the AAH RSPP office: In WI via e-mail to** [**IRBOffice@aah.org**](mailto:IRBOffice@aah.org)**; in IL via IRBNet.**
* **Please allow a minimum of 2 weeks for RSPP review and determination.**

# SECTION I: General Information

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| Project Title: | | | | | | | | | | |
| Requestor (including degrees): | | |  | | | | Department/Organization: | |  | |
| If the requestor is not employed by AAH, include name of AAH contact: | | | | | | | | |  | |
| Mailing Address: | |  | | | | | | | | |
| Telephone: |  | | | E-mail: | |  | | | | |
| Sponsor or funding source (Identify all source(s) of funding for the project): | | | | |  | | | Is this project federally funded? | |  |

# SECTION II: Study Information

1. Is the project designed to contribute to **generalizable knowledge,** which means the results of the activity are expected to:
   1. supplement an established body of knowledge or inform a field of study
   2. be distributed in order to influence behavior, practice, theory or future research design be
   3. be applied beyond the subject population or site of data collection to other settings
   4. be replicated in other settings
   5. inform public policy
2. Describe the reasons for conducting the proposed project:

1. Provide a brief synopsis of the project, including objective(s) (include details about if the project is testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research):

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?
2. Will the project involve testing a new tool or survey that has not been previously validated?
3. List all sites where it is expected for this project to be conducted:

1. Will AAH medical records of living individuals be accessed during this project?
2. Describe the subject population/type of data/specimens to be studied. Indicate whether the data/specimens will be identifiable, entirely de‑identified or whether the data/specimens will be linked by any code or identifiers (e.g., name, medical record number, date of birth, zip code, etc.):

# SECTION III: Advocate Aurora RSPP Determinations

FOR RSPP USE ONLY

1. **YES /**  **NO Is the activity RESEARCH as defined by DHHS Regulations?**
2. **YES /**  **NO Does the activity include Human Subjects under DHHS Regulations?**
3. **YES /**  **NO Will identifiable protected health information (PHI) be used and/or disclosed as part of this project?**
4. **YES /**  **NO Is the activity Human Research under FDA Regulations?**

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| The proposed activity, as described**, DOES NOT** constitute Human Subjects Research. Submission of an IRB research application is not required.  The proposed activity, as described, **DOES** constitute Human Subjects Research.  Submission of an IRB research application **IS REQUIRED**. Review and approval or exempt determination from an IRB must be obtained before the investigator begins their research.  Advocate Aurora Health is **NOT ENGAGED** in the research. Research team must send project to RAP for consideration. No additional AAH IRB/RSPP review is needed for research where Advocate Aurora Health is not engaged.              \_\_  Advocate Aurora Health IRB Chair or designee Date |