**Not Research Determination Decision Tool**

**Health Sciences IRB - Health Sciences Minimal Risk IRB**

**Instructions:**
1. Please complete the requested project information, as this document may be used for documentation that IRB review is not required.
2. Please select the appropriate answers to each question in order as they appear on the form. If all of the questions are answered without receiving an error message, the form may be printed as certification that the project is “not research”, and does not require IRB review.

**Project Information:**

<table>
<thead>
<tr>
<th>Name of Project Lead/Investigator:</th>
<th>Dr. Example</th>
</tr>
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<tbody>
<tr>
<td><strong>Title of Project</strong></td>
<td>Provider and Clinic-level Determinants of Blood Pressure Control Among Patients with Early Stage Chronic Kidney Disease</td>
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<tr>
<td><strong>Brief Description of Project/Goals:</strong></td>
<td>The aim of the study is to assess patient, provider, and clinic-level determinants of blood pressure control among patients with early stage (stage I-III) chronic kidney disease. This project will use electronic health record information for patients with Stage I-III CKD in 2011 (baseline) and 2012 (reporting year) (n=1,270). We will look at blood pressure control (&lt;140/90 mmHg, yes/no) and if there are patient, provider and clinic-level determinants of BP control. To do so, we will look at patient sociodemographics (age, gender, marital status, race/ethnicity, language), insurance, health behavior (body mass index, tobacco use), comorbidities (as measured by 29 chronic condition indicators), and UW outpatient visits in the baseline year (primary care provider and specialist).</td>
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**Questions:**

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?
   - [ ] Yes
   - [ ] No

2. Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?
   - [ ] Yes
   - [ ] No

3. Is the primary intent of the project to contribute to generalizable knowledge (e.g. testing a hypothesis) AND has the project been designed in such a way that the findings will be generalizable (e.g. randomization of subjects; comparison of case vs. control)?
   - [ ] Yes
   - [ ] No

4. Will the results of the project be published, presented or disseminated outside of the institution conducting it?
   - [ ] Yes
   - [ ] No

5. Will the project occur regardless of whether individuals conducting it may benefit professionally from it?
   - [ ] Yes
   - [ ] No

6. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?
   - [ ] Yes
   - [ ] No

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**If no message appears above indicating the certification is not valid, IRB Review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). Please print a copy of this form to save with your files, as it serves as documentation that IRB review is not required for this project.**

**Current Date:** 11/25/13

[Print Form]