University of Wisconsin-Madison

IRB Review Determination for Exemption or Not Human Subjects Research

Health Sciences IRB ▪ Health Sciences Minimal Risk IRB

Project/Protocol Number: 2015-0376
Project Lead/Principal Investigator: Deepak Gopal
Project/Protocol Title: A Retrospective Review of Outcomes in Colonic Stenting for Malignant and Benign Indications - revised
Staff Reviewer & Contact Information: Sherry Holcomb; ssholcomb@medicine.wisc.edu
Date Exemption Granted*:* 4/6/15

The IRB has reviewed the study indicated above for exemption and its determination is indicated below. Please review this determination and any additional guidance provided by the IRB. If you have any questions regarding this determination, please contact the staff reviewer listed above. For additional details regarding the submitted exemption application, you must log in to your ARROW account at www.arrow.wisc.edu.

☐ 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)
- ☐ involve human subjects as defined under 45 CFR 46.102(f)

Additional Information**:**

Please note: If this application falls under VA purview, no activities should begin until VA R&D approval is received.

☒ Your study qualifies for exemption under category: 45 CFR 46.101(b)(4). Although your study is exempt from federal regulations, UW Human Research Protection Program policy requires that all human subjects research be conducted in accordance with the highest ethical standards/Belmont Report. **Please contact the staff reviewer listed above if you plan to make a significant change to your research that affects the exempt status of your study (see examples below)**.

Additional Information**:** The signed Data Use Agreement with GI Associates must be submitted to the staff reviewer when available.

Please note: If this application falls under VA purview, no activities should begin until VA R&D approval is received.

☐ Your study involves the use and/or disclosure of PHI and therefore, HIPAA regulations apply. The following are approved by the IRB:
- ☐ HIPAA Authorization Form
- ☐ Application for Waiver of Authorization
- ☐ Other:

Additional Information:

Examples of changes that could affect the exempt status of a study:
45 CFR 46.101(b)(1): Changes to the setting in which the educational activity is being conducted could affect the exempt status. In addition, changes to the purpose for which an educational activity is being conducted (e.g., conducting an activity specifically for research purposes rather than a standard class requirement) could also affect the exempt status under category 1.

45 CFR 46.101(b)(2): Changes to the identifiability of survey or interview results could affect the exempt status under category 2, as well as changes to the survey or interview tools to add collection of sensitive or stigmatizing information.

45 CFR 46.101(b)(4): Changes to the date range for data collection such that not all of the data is currently in existence could affect the exempt status under category 4, as well as changes to the identifiability of the data to be collected.