



Date: April 26, 2023

Protocol Number: 2303009812
Principal Investigator: Vivek Joshi, MD
Review Type: Exempt Determination
Exempt Category(ies): 2(i)
Sponsor: Biochemistry
Project Title: Diagnostic disparity of PCOS between OB GYN Physicians and Endocrinologists.

This submission has been evaluated by designated reviewers from the Drexel Institutional Review Board (IRB) and was determined to qualify for exemption under the above cited category(ies) per 45 CFR 46.104.

As the Principal Investigator (PI), you are responsible for following HRP-070 Investigator Obligations, and for reporting the following to the Drexel IRB office:

- Your study protocol changes in such a way that exempt status would no longer apply or the project no longer meets the criteria of the exemption category(ies) noted above.
- You add or remove any research personnel working on this study.
- You have received or have been made aware of any complaints, problems, or adverse events that are related or possibly related to participation in the research.
- Final Report/Study Closure as described in HRP-070 Investigator Obligations. Note: If the Principal Investigator is leaving Drexel, the study must either be formally closed or a modification must be submitted to approve a new Principal Investigator.

Please be aware that approval may still be required from other relevant authorities or “gatekeepers” (e.g. school principals, facility directors, custodians of records), even though the project has been determined to be exempt.

This determination applies to the activities of Drexel affiliates and does not apply to external collaborators. IRB reliance agreements are not typically executed for exempt research and external collaborators should consult their local IRB. Drexel affiliates are provided oversight for the duration of their employment or status as a student at the institution.

Please contact the IRB at (267) 359-2471 or HRPP@drexel.edu if you have any questions.