



Institutional Review Board

13-Feb-2020

Notice of Exemption from IRB Review

Principal Investigator: Ellen Scherl MD

Department: Medicine-Gastroenterology and Hepatology

Re: Protocol Number: 19-04020264-02

Protocol Title: Prevalence of Vitamin C Deficiency in Inflammatory Bowel Disease (PROVIDE-IBD): a retrospective chart review

This notice certifies that the research project listed above has been determined to meet exemption requirements at HHS 45 CFR 46.104(d) because it includes only the following research procedures:

Exemption Categories: 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

Documents reviewed and approved:

- Protocol Version 1.2 – 13-May-2019

Click here to access your submission package: [Submission Page](#)

Please note that if there are changes in the future to the exemption procedures, you should submit an amendment to the Office of Research Integrity. If you have any questions, please contact the Office of Research Integrity at 646-962-8200.

Sincerely,

WCM Institutional Review Board