



March 31, 2020

Richard Schilsky, MD  
American Society of Clinical Oncology  
2318 Mill Road  
Suite 800  
Alexandria, Virginia 22314

Dear Dr. Schilsky:

**SUBJECT: IRB EXEMPTION—NOT HUMAN SUBJECT RESEARCH**  
Investigator: Richard Schilsky, MD  
Protocol Title: ASCO Survey on COVID-19 in Oncology (ASCO) Registry

This letter is in response to your request for an opinion as to whether the above referenced research would constitute human subject research requiring IRB review.

This opinion is based on federal regulation 45 CFR 46 and associated guidance.

We determined this study is exempt from IRB review because it does not meet the definition of *human subject* as defined in 45 CFR 46.102. Specifically this study will de-identified data in the form of limited data sets from the participating clinics and institutions and you will enter into Data Use Agreements, and you will not otherwise interact with the patients.

This determination can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make such determinations. WIRB cannot provide a determination that overrides the jurisdiction of a local IRB or other institutional mechanism for making such determinations. You are responsible for ensuring that each site to which this determination applies can and will accept WIRB's determination.

Please note that any future changes to the project may affect its status as research that does not involve human subjects, and you may want to contact WIRB about the effect these changes may have on the status before implementing them. WIRB does not impose an expiration date on its determinations of research that does not involve human subjects.

**Western Institutional Review Board®**

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If you have any questions, or if we can be of further assistance, please contact R. Bert Wilkins, J.D., M.H.A., C.I.P., at 360-252-2852, or e-mail [RegulatoryAffairs@wirb.com](mailto:RegulatoryAffairs@wirb.com).

RBW:tb

NHS-Exemption-Schlisky (03-31-2020)

cc: Suanna Bruinooge, American Society of Clinical Oncology

Patricia Hurley, American Society of Clinical Oncology

WIRB Accounting

WIRB Work Order # 1-1288274-1