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October 11, 2021

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David Dowdy, MD, PhD, ScM
615 North Wolfe St., E6531
Baltimore, Maryland 21205

Michael Barnett, MD, MS
677 Huntington Avenue, Room 407
Boston, Massachusetts 02115

Dear Dr. Alexander, Dr. Dowdy, and Dr. Barnett:

SUBJECT: IRB EXEMPTION—REGULATORY OPINION
Investigators: G. Caleb Alexander, David Dowdy, Michael Barnett
Protocol Title: Assessing Extent of Opioid Epidemic in Baltimore City: A
Retrospective Cohort Analysis

This is in response to your request for an exempt status determination for the above-referenced protocol. WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance.

We believe the study is exempt under 45 CFR § 46.104(d)(4), because the research involves the use of identifiable private information/biospecimens; and 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.

This exemption 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 WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. You are responsible for ensuring that each site to which this exemption applies can and will accept WCG IRB's exemption decision.

WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Please discuss with the local IRB authorities in the country where this activity is taking place to determine if local IRB review is required.

Please note that any future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date on its IRB exemption determinations.

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.

RBW:mr
D4-Exemption-Alexander (10-11-2021)
cc: Elena Fernandez, Monument Analytics
WCG IRB Accounting
WCG IRB Work Order #1-1482933-1