

Attachment D: IRB Exemption Determination Letter



April 17, 2024

Chi Connie Park, MA, PhD
James Bell Associates, Inc.
2000 15th St N
Suite 100
Arlington, Virginia 22201

Dear Dr. Park:

SUBJECT: IRB EXEMPTION—REGULATORY OPINION
Investigator: Chi Connie Park, MA, PhD
Protocol Title: National Endowment for the Arts: ArtsHERE Equity Pilot
Evaluation

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 interview and survey portions of this study is exempt under 45 CFR § 46.104(d)(2), because the research only includes interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior; and any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

We believe the record review portion of this 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 Tara Coffin, PhD, MEd, at 360-252-2418, or e-mail RegulatoryAffairs@wgcclinical.com.

TBC:bg

D2-Exemption-Park (04-17-2024)

cc: Patricia Moore Shaffer, National Endowment for the Arts

WCG IRB Accounting

WCG IRB Work Order # 1-1757904-1