



September 13, 2018

Jeffrey R. Alwang, PhD
Virginia Tech
Hutcheson Hall 215-I
250 Drillfield Drive
Blacksburg, VA 24060

Dear Dr. Alwang:

SUBJECT: REGULATORY OPINION—IRB EXEMPTION
Protocol Title: Impact Assessment of Seed Producer Groups in Nepal
Investigator: Dr. Jeffrey Alwang, PhD

This letter is in response to your request to Western Institutional Review Board (WIRB) for an exemption determination for the above-referenced research project. WIRB's IRB Affairs Department reviewed the exemption criteria under 45 CFR §46.101(b)(2):

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

We believe that the research fits the above exemption criteria. The data will be collected in a way so that the subjects can be identified, directly or through identifiers linked to the participants. However, any disclosure of the human subjects' responses outside the research will not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. You have also confirmed that the results of this study will not be submitted to the Food and Drug Administration (FDA) for marketing approval.

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 WIRB (such as an internal IRB) to make exemption determinations. WIRB 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 WIRB's exemption decision.

Western Institutional Review Board®

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Please note that any future changes to the project may affect its exempt status, and you may want to contact WIRB about the effect these changes may have on the exemption status before implementing them. WIRB 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 Sean W. Horkheimer, JD, CIP, at 360-252-2465, or e-mail RegulatoryAffairs@wirb.com.

SWH:dao

B2-Exemption-Alwang (09-13-2018)

cc: WIRB VA Tech

WIRB Accounting

WIRB Work Order #1-1113010-1