



DATE: February 7, 2019  
 TO: Sarah Odell  
 FROM: Carole Harris, IRB Chair  
 SUBJECT: IRB Determination – Exempt  
 PROJECT #: 121772.0.019.00.000  
 PROJECT NAME: Evaluation of Technical Assistance and Training Approaches to Accelerate Comprehensive Cancer Control Outcomes

ICF's IRB has reviewed the description and supporting materials submitted for the project reference above and determined that the activities qualify for the Exemption identified below. Note that changes to your project activities may alter the Exempt determination. Contact the IRB prior to implementing any changes to discuss whether re-review is needed.

2018 Common Rule Exemptions	
Research involving children is allowed in categories 1, 4, 5, 6, 7, & 8. Limitations/exclusions of children apply in categories 2, 3. Research involving prisoners is allowed under all categories <u>only</u> when prisoners are incidentally included. To qualify for exemption, the research must align with the following categories and involve only minimal-risk <sup>1</sup> to subjects.	
Category	Exemption
<input type="checkbox"/> 1. 45 CFR 46.104.1	<b>Research involving education practices.</b> Research involving normal education practices and instructional techniques used in classroom management; conducted in established education settings.
<input checked="" type="checkbox"/> 2. 45 CFR 46.104.2	<b>Research involving <u>only</u> educational tests, surveys, interviews, observation of public behavior.</b> (1, 2, or 3 must apply)  <input type="checkbox"/> 1. Recorded information cannot readily identify the subject (directly or indirectly/linked)  <input checked="" type="checkbox"/> 2. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)  <input type="checkbox"/> 3. Recorded information includes identifiers (and may be sensitive) but adequate privacy and confidentiality protections are in place.

<sup>1</sup> Minimal risk: defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons

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<input type="checkbox"/> <b>3.</b>  45 CFR 46.104.3	<p><b>Benign behavioral interventions.</b> Research with adults limited to verbal or written responses, data entry or audiovisual recordings where adults prospectively agree.</p> <input type="checkbox"/> 1. Recorded information cannot readily identify the subject (directly or indirectly/linked)
<input type="checkbox"/> <b>4.</b>  45 CFR 46.104.4	<p><b>Secondary research use of identifiable Information or identifiable biospecimens.</b> Data were (or will be) collected for other research. Consent for current project not required.</p> <input type="checkbox"/> 1. Biospecimens or information are publically available.
<input type="checkbox"/> <b>5.</b>  45 CFR 46.104.5	<p><b>Public benefit or service programs.</b></p> <p>Research designed to study, evaluate, improve or examine public benefit/service programs, if the research is conducted by or supported by a federal department or agency</p>
<input type="checkbox"/> <b>6.</b>  45 CFR 46.104.6	<p><b>Taste and food quality.</b> Research limited to food taste and food quality evaluation and consumer acceptance studies.</p> <input type="checkbox"/> 1. Consumption of wholesome foods without additives

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	to be safe, by the FDA, EPA, USDA.
<input type="checkbox"/> <b>7.</b>  45 CFR 46.104.7	<b>Storage or maintenance of identifiable private information or biospecimens.</b> Can only be used with:  <input type="checkbox"/> 1. Broad consent from subjects for storage, maintenance, and secondary use of their materials.
<input type="checkbox"/> <b>8.</b>  45 CFR 46.104.8	<b>Secondary research with identifiable private information or biospecimens.</b> Can only be used with:  <input type="checkbox"/> 1. Broad consent from subjects for storage, maintenance, and secondary use of their materials.  <input type="checkbox"/> 2. Documentation of consent was obtained.  <input type="checkbox"/> 3. Individual results are not returned to subjects.

<p><b>List of Reviewed Project Materials:</b></p> <ol style="list-style-type: none"> <li>1. IRB Project Information Form</li> <li>2. Case Study Interview Guide for Program Directors and Managers</li> <li>3. Case Study Interview Guide for Evaluators</li> <li>4. Case Study Interview Guide for Partners</li> <li>5. Case Study Introductory Letter</li> <li>6. Case Study Follow Up Email</li> <li>7. Case Study Interviewee Identification Worksheet</li> <li>8. Case Study Interview Informed Consent Statement</li> <li>9. Web Survey Primer Email</li> <li>10. Web Survey Invitation Email with Survey Link</li> <li>11. Web Survey</li> <li>12. Web Survey Reminder Emails 1 and 2</li> <li>13. Web Survey Completion Thank You Email</li> </ol>
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If you have any questions regarding this finding, please email [IRB@icf.com](mailto:IRB@icf.com).

(Revised 02/2019)