



DATE: December 20, 2019
 TO: Kristen Cincotta; Bhuvana Sukumar
 FROM: Carole Harris, IRB Chair
 SUBJECT: 152691.0.008.01.30
 PROJECT NAME: Get Ahead of Sepsis Consumer and Healthcare Professional (HCP) Assessment

ICF's IRB has reviewed the description and supporting materials submitted for the project referenced above and determined that the activities qualify for the Exemption identified below.

Please note that this Exempt determination eliminates the Continuing Review requirement. However, the following communications with the IRB are still required:

- Submit a Protocol Modification form to the IRB prior to implementing any changes to your study as changes may alter your Exempt status.
- Submit an Adverse Event/Unanticipated Problem/Protocol Deviation form to the IRB within 2 business days of an event.

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 ¹ to subjects.	
Category	Exemption
<input type="checkbox"/> 1. 45 CFR 46.104.1	Research involving education practices. 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	Research involving <u>only</u> educational tests, surveys, interviews, observation of public behavior. (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)

¹ 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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Category	Exemption
	<input checked="" type="checkbox"/> 3. Recorded information includes identifiers (and may be sensitive) but adequate privacy and confidentiality protections are in place.
<input type="checkbox"/> 3. 45 CFR 46.104.3	<p>Benign behavioral interventions. 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"/> 2. Any disclosure of responses outside 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 in place.
<input type="checkbox"/> 4. 45 CFR 46.104.4	<p>Secondary research use of identifiable Information or identifiable biospecimens. 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"/> 2. Recorded information/biospecimens cannot readily identify the subject (directly or indirectly/linked)
	<input type="checkbox"/> 3. Use of data is regulated under HIPAA as healthcare operations, research, or public health research
	<input type="checkbox"/> 4. Research is conducted by/on behalf of federal agency using data collected for non-research purposes
<input type="checkbox"/> 5. 45 CFR 46.104.5	<p>Public benefit or service programs.</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
<input type="checkbox"/> 6.	<p>Taste and food quality. Research limited to food taste and food quality evaluation and consumer acceptance studies.</p>

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Category	Exemption
45 CFR 46.104.6	<input type="checkbox"/> 1. Consumption of wholesome foods without additives <input type="checkbox"/> 2. Food contains food ingredient(s) at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, EPA, USDA.
<input type="checkbox"/> 7. 45 CFR 46.104.7	Storage or maintenance of identifiable private information or biospecimens. 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"/> 8. 45 CFR 46.104.8	Secondary research with identifiable private information or biospecimens. 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>List of Reviewed Project Materials:</p> <ol style="list-style-type: none"> 1. IRB Project Information Form 2. Attachment D_GAOS Informed Consent_Consumer Pilot Assessment v3 2019.12.20 revised 3. Attachment D_GAOS Informed Consent_HCP Pilot Assessment v3 2019.12.20 revised 4. Attachment B_GAOS Consumer Assessment Research Questions - Updated 12.15.2019 5. Attachment B_GAOS HCP Assessment Research Questions - Updated 12.15.2019 6. Attachment A_GAOS Pilot Assessment Overview_Consumers 7. Attachment C_GAOS Consumer Recruitment Invitation 8. Attachment E_GAOS Consumer Survey_11.22.2019 9. Attachment A_GAOS Pilot Assessment Overview_HCPs 10. Attachment C_GAOS HCP Recruitment Invitation 11. Attachment E_GAOS HCP Survey_11.22.2019
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If you have any questions regarding this finding, please email IRB@icf.com.

