Request for Exempt Research Determination

Instructions: To request a written determination that an activity is exempt from the federal regulations which govern human subjects research, please submit this form to the WellStar Research Institute (WRI) via the WRI Inbox (research@wellstar.org). If you have any questions about whether an activity is exempt, please contact the WRI for guidance. All exempt and non-human subjects research may proceed pending any other relevant institutional approvals without IRB review once the determination is made by the WRI. However, if the activity is not exempt and deemed to be human subjects research, it must be reviewed by the IRB prior to initiation.

Principal Investigator _______________________________ Department ____________________
E-mail ______________________________ Phone ___________________
Co-PI(s) _______________________________ E-mail ______________________________
Sub-Investigator ________________________ E-mail _____________________________

1. Protocol/Project Information

Note – if you request an exempt determination and the research does not qualify for an exempt determination, this may delay the review of your research.

Sponsor (if applicable)

Protocol Title

Anticipated Start Date
Anticipated End Date
Student Project (Yes/No)
If Yes, Type of Research
(Thesis, Dissertation, Capstone, other)
2. Project Details
   
a. State the purpose of the research and research questions:

b. Will your research involve the analysis of existing data? (Yes/No)

   **If yes, answer i, ii, iii, and iv**
   **If no, proceed to question c.**

   i. Briefly describe the types(s) of data that will be analyzed. *If data was collected from surveys, please provide the instrument.*

   ii. Where is the data currently stored and who is the custodian of the data?

   iii. Was data collected for research purposes? (Yes/No) *If yes, provide IRB approval letter, exempt determination, or non-human subjects determination.*

   iv. How many records will be included in the analysis?

   c. Describe your study population (e.g. adults, medical staff employees, etc.) and include any inclusion/exclusion criteria for subjects

3. Minimal Risk

*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (21 CFR 56.102 A (i))

**Explain how the research activity presents no more than minimal risk (including risks of breaches of confidentiality of protected health information) to human subjects**
3. **Category for Exempt Determination**

Please indicate which of the categories below applies to the proposed research. Check all that apply. At least one category must be selected.

<table>
<thead>
<tr>
<th>Category 1: Research conducted in commonly accepted educational settings involving normal education practices</th>
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<tbody>
<tr>
<td>a) Research on regular and special education instructional strategies</td>
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<td>b) Research on effectiveness of or comparison among instructional techniques, curricula, or classroom management methods</td>
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<th>Category 2: Research involving only the use of: educational tests, (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior UNLESS.</th>
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<tr>
<td>information is obtained in a way that subjects can be identified, directly or through identifiers linked to the subjects; AND</td>
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<tr>
<td>any disclosure of responses outside of the research could place the subject at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.</td>
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To be eligible for this exemption,
- the information must be recorded anonymously with or without placing the subject at risk... **OR**
- the information may be recorded with identifiers AND not place the subject at risk....

**Note: this exemption can only be used with children if it involves observations of public behavior where researcher is not participating; surveys and interviews are not eligible**

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<th>Category 3: Research using educational tests if subjects are elected or appointed officials or any federal statute requires confidentiality of personally identifiable data throughout the research and after.</th>
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<tr>
<th>Category 4: Research involving collection or study of existing data, documents, records or specimens if the sources are publicly available or if data are recorded in a way that subjects can’t be identified.</th>
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**Note: to qualify for this exemption the data must have been collected before this research was proposed**
Category 5: Research on public benefit or service programs

Category 6: Taste and food quality evaluation and consumer acceptance studies

Please attach the following documents to complete your submission:

1. Full research proposal or protocol
2. Informed consent document, if applicable
3. HIPAA Authorization, if applicable
4. All collection tools which will be shared with potential human subjects (e.g. fliers, script used to ask to collect samples, surveys, focus group questions)

Principal Investigator Assurance and Acknowledgement

I certify that the information provided in this application and supporting documentation is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protections of the rights and welfare of human subjects, and strict adherence to any situations designated by the WellStar Research Institute (WRI). I accept and will conform to all federal, state, institutional, and WRI provisions concerning the protection of human subjects in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project and in the protection of human subjects. I recognize that this study may not begin until it has been determined that the project does not meet the definition of human subjects or determined to be exempt from federal regulations. If neither of these determinations can be made, I will need to submit the project to an IRB and obtain IRB approval as indicated by an IRB approval letter. I will submit any proposed changes for review and approval before they are implemented and notify the IRB of any unanticipated problems that may occur during the study.

_______________________________   _________________________  _______________
Principal Investigator/PI (PRINT)                             Signature                             Date

If PI is a student researcher:

_______________________________   __________________________ ______________
Preceptor/Committee Chair (PRINT)                             Signature                             Date