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14 Research Institutional Review Board

FWA00035273, IRB 00005850, IORG0004908

**Institutional Review Board Screening Form**

Date:

To: 14 Research Screening Committee at IRB@14-research.com

From:

Research Study:

**Section A. The importance of human subject protections**

\*\*Instructions: Read Section A carefully and initial and date\*\*

The principal investigator and/or the governing person of record on the aforementioned research study, as well as others who participate in designing, conducting or reporting on said research study have, with respect to human subjects, ethical responsibilities that require adherence to the following principles:

* Participants are informed about the research and how their information will be used.
* Consent must be obtained or explicitly waived (if risks to participants are minimal).
* Adequate provision is made to protect the privacy of human subjects and to maintain confidentiality of data, where promised and as appropriate.
* Risks to subjects are minimized to the extent possible in research designs and implementation.
* Risks to subjects are reasonable compared with the anticipated research benefits.
* The selection of human subjects in research is equitable and the burdens and benefits of participation in research are fairly distributed among all human subjects.
* Staffers must consider all risks and aspects of conducting research on vulnerable populations and protected health information.

***I acknowledge and understand the contents of Section A:***

**Section B. Institutional Review Board (IRB) screening form submission**

As the principal investigator and/or the governing person of record on the aforementioned research study, I submit this IRB screening form to 14 Research with a recommended type, if any, of IRB review for the research study.

**Section C. Research study description**

\*\*Instructions: In Section C, summarize the research study and explicitly discuss facts, problems, and remedies, as applicable, to the participation of human subjects in the study. Attach the research study’s protocol and other documentation. If you have questions completing this section or any section of this screening form, then contact the screening coordinator promptly at 404.668.3728.\*\*

**Section D. IRB screening criteria**

\*\*Instructions: read Section D carefully and check the appropriate boxes\*\*

I supply answers below in accordance with the 45 CFR Part 46, Subpart D Federal Regulations, which provides for necessary protections for human subjects in research studies.

1. Will this research study obtain or use any type of primary or secondary data, other than public use data,[[1]](#endnote-1) about or from living persons?
   * See definitions at [https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html%2346.102)

 No – I determine and recommend that no IRB review is needed.

*Proceed to Section E of this screening form, check the box indicating “No IRB review” and read the requests and stipulations. Sign, date, and submit this screening form to IRB@14-research.com.*

 Yes.

*Continue to question 2.*

1. Does this research study meet one or more of the exemption criteria provided in [45 CFR Part 46, Subpart A § 46.104 Exempt Research](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)?

 No.

*Continue to question 3.*

 Yes – I determine that this research study meets one or more of the exemption

criteria provided in 45 CFR Part 46, Subpart A § 46.104 Exempt Research and,

therefore, I recommend one of the following (Note, the following exemption categories will need a limited IRB review: 45 CFR 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii)):

 An exemption review is needed.

 A limited IRB review is needed.

*In the space below, please carefully and thoroughly identify and justify all exemption criteria that apply to this research study. If the exemption that you recommend requires a limited IRB review for the purposes of the exemption, then please explain further. Attach additional pages to this form as needed.*

*Once completed, proceed to Section E of this screening form, check either “Exemption review” or “Limited IRB review,” as appropriate, read the requests and stipulations, and sign, date, and submit this screening form to IRB@14-research.com with the study documents.*

1. Will this research study principally involve data about subjects likely to be vulnerable to coercion or undue influence (such as children,  prisoners,  pregnant women, people with disabilities,  economically or educationally disadvantaged persons, or ­­­­­­ data containing *protected health information*[[2]](#endnote-2)?

 No.

*Continue to question 4.*

 Yes.

*Check appropriate group(s) above and follow these instructions:*

1. *If data will be unlinked by identifiers to human subjects, then you may request an expedited IRB review. Proceed to Section E, check the box indicating “Expedited IRB review,” and read the requests and stipulations. Sign, date, and submit this screening form to IRB@14-research.com.*

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1. *If data will be linked by identifiers to human subjects or contain protected health information, then request a mandatory full IRB review. Proceed to Section E, check the box indicating “Full IRB review,” and read the requests and stipulations. Sign, date, and submit this screening form to IRB@14-research.com.*
2. Will this research study involve the collection or storage of data of a personal, private, and/or sensitive nature[[3]](#endnote-3)? Most surveys contain some elements that meet this criterion.

 No.

*Skip to question 6.*

 Yes.

*Continue to question 5.*

1. If the data collected in this research study will be personal, private and/or sensitive, will the data also be linked by identifiers to the human subjects from whom they will be obtained (e.g. by name, address, case, number, geography, etc.)?

 No – I determine an expedited IRB review is warranted.

*Proceed to Section E, check the box indicating “Expedited IRB review” and read the requests and stipulations. Sign, date, and submit this screening form to the IRB@14-research.com.*

 Yes.

*Continue to question 6.*

1. To what extent will participation in the research study pose minimal[[4]](#endnote-4) risk to human subjects?

 There will be more than minimal risk to human subjects. I therefore determine and recommend that a full IRB review is required.

*Proceed to Section E, check the box indicating “Full IRB review” and read the requests and stipulations. Sign, date, and submit the screening form to* [*IRB@14-research.com*](mailto:IRB@14-research.com)*.*

 There will be no or only minimal risk AND personal, private, or sensitive data (for which confidentiality will be assured) will be collected. I therefore determine and recommend that an expedited IRB review is warranted.

*Proceed to Section E, check the box indicating “Expedited IRB review” and read the requests and stipulations. Sign, date, and submit the form to IRB@14-research.com.*

**Section E. Determination and recommendation of IRB review**

I determine and recommend the type of IRB review, if any, below.

 No IRB review

 Exemption review

 Limited IRB review for exemption # \_\_\_\_\_\_\_\_\_\_

 Expedited IRB review

 Full IRB review

Requests and stipulations:

* Please review this form and offer your own determination and concurrence or non-concurrence of my recommendation within one business of my submission of this form.
* I understand that if you concur with my recommendation, then I will proceed with the above determined type of IRB review, if any.
* I understand that if you do not concur with my recommendation, then you will schedule a reconciliation meeting to discuss your non-concurrence within one business day of the return of this form to me.
* I request that you assign the aforementioned research study a IRB protocol number with your concurrence or non-concurrence, unless the concurrence requires no IRB review in the event of an exempt determination.

**SIGNATURE:**

**Date:**

1. This does not include data that are available to the public without restriction or condition of use, or data about students collected in school settings by surveys, observations, interviews, or standard educational tests provided the children cannot be identified directly or through identifiers linked to the subjects. [↑](#endnote-ref-1)
2. Health information about living persons that is considered individually identifiable (i.e., contain one or more of the following identifiers: names, all geographic subdivisions smaller than a state – see special rules for zip codes, telephone numbers, fax numbers, e-mail addresses, Social Security numbers, medical record numbers, health plan beneficiary numbers, account numbers, all elements of dates - except year – relating to any individual, certificate/license numbers, vehicle identifiers, device identifiers, URLs, IP address numbers, biometric identifiers, full face photographic images, any other unique identifying numbers, characteristics, or codes). Health information about decedents requires only representations that the data is exclusively for research and that it is necessary to the research. [↑](#endnote-ref-2)
3. “Private” data include data on behaviors or on records that an individual could reasonably expect would not be observed or made public. (most personal data -- income, address, etc. -- probably are private data under this definition) “Sensitive” data include data that if made public could cause physical, mental, emotional, economic, or other harm (including to their employment standing or reputation) to an individual. [↑](#endnote-ref-3)
4. Minimal risk means that the probability and magnitude of harm or discomfort anticipated is not greater than ordinarily encountered in daily life. [↑](#endnote-ref-4)