

Exempt Status:

This protocol meets 45 CFR 46.101(b) Exemption Category(ies)

(If this study does not meet an exemption category and/or requires additional information or revisions, please insert comments in pertinent sections of the E-IRB application and select the appropriate determination with applicable notations about your determination on the "IRB Review" task page.)

General Comments that Do Not Influence Approval:

Children/Minors (if applicable)

The IRB agreed with the PI's assessment provided in the IRB application that this protocol meets the requirements for the involvement of children/minors set forth in 45 CFR 46.404 and 45 CFR 46.408:

- a. The study meets the federal definition of minimal risk;
- b. adequate provisions have been made for soliciting the assent of the child; and
- c. adequate provisions have been made for soliciting the permission of their parents or guardians.

If one parent can give permission, please document this approval.

1. On the IRB Review task window (under "Finish" tab), select the applicable determination, and per 45 CFR 46.104(d), specify here which Exemption Category(ies) this protocol meets:

(If this study does not meet an exemption category and/or requires additional information or revisions, please insert comments in the pertinent sections of the E-IRB application and on the IRB Review task window (under "Finish" tab) select the appropriate determination with applicable notations about your determination.)

General Comments that
Do Not Influence Approval:

2. (If Applicable) Limited IRB Review Section

List Exempt Research Category/(ies) for Limited Review:

If Limited IRB Review applies, in the box below explain what adequate provisions have been made for protecting the privacy of subjects and maintaining the confidentiality of data.

To help make the "Limited IRB Review" determination, consider

- Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- Use of the information;
- Extent to which the information will be shared or transferred or otherwise disclosed or released;
- Likely retention period or life of the information;
- Security controls that are in place to protect the confidentiality and integrity of the information; and
- Potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

IRB Review*

Protocol Review

Review Details	Exempt Signature	Exempt Signature	Finish
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--> Refer to this [Criteria for IRB Approval Checklist](#) as needed.
--> Refer to this [Elements of Informed Consent Checklist](#) as needed.
--> Refer to this [Reviewer Determinations Guidance](#) document for info about what each determination means.

Select Your Determination

- Approve
- Minor Revision
- Not Exempt
- Not Human Research
- Withdrawn

Serious/Continuing Non-compliance or Suspension/Termination.

Comments / Requested Revisions

I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save	Complete Review
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