DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date March 9, 2018

From Angela M. Morley
Chair, NIOSH Institutional Review Board

Subject IRB Exemption Determination for NIOSH Protocol 18-HELD-02XM, "Understanding How Discounting Affects Decision Making and Adoption of Prevention Through Design Solutions"

To Jonathan E. Friedel
Project Officer, NIOSH/HELD

On behalf of the NIOSH Human Research Protection Program (HRPP), I reviewed the request to exempt 18-HELD-02XM, and find this research activity is exempt under 45 CFR 46.101(b)(2). This determination is valid for a period of three years through March 9, 2021**.** However, we strongly encourage investigators to close out exempt protocols as soon as NIOSH staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Please be aware changes to this protocol may not be implemented until they are reviewed by the NIOSH HRPP and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact the HRPP at cin-hsrb@cdc.gov, or by telephone at (513) 533-8591.

Signature Page for Human Research Review

Protocols and Related Documentation

Anniversary Date: 03/09/2021

Use this signature page when submitting HRPO forms to your center-level Human Subjects Contact. When submitting materials with these forms, please consecutively number all pages, beginning with the protocol title page and followed by consent form(s) and ancillary documents. See *HRPO Guide: Overview* for further details.

1 Protocol Identifiers

CAN#: 893909P0___ (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: 18-HELD-02XM Protocol Version Number: 1 Version Date: _____

Protocol Title:

Understanding How Discounting Affects Decision Making and Adoption of Prevention Through Design Solutions

Amendment Number (if applicable): _____

2 Key CDC Personnel

	Name and Degrees (First Name Last Name, Degrees)	User ID	CDC SEV #	CDC NC/Division
Primary Contact	Jonathan Friedel, PhD	ndy8	232	NIOSH/ HELD
Phone Number (required)	304-285-6106			
Principal Investigator	Jonathan Friedel, PhD	ndy8	232	NIOSH/ HELD
Phone Number (required)	304-285-6106			

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/Division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Forms Submitted with this Signature Page

Check all that apply in the appropriate column.

IRB-Reviewed Protocols

- ☐ 0.1250: Initial Review by IRB
- ☐ 0.1251: Continuing Review of Approved Protocol
- ☐ 0.1252: Review of Changes to Approved Protocol
- ☐ 0.1254: Incident Report
- ☐ 0.1254S: Supplemental Adverse Event Report
- ☐ 0.1253: End of Human Research Review
- ☐ 0.1370: CDC's Research Partners
- ☐ 0.1371: CDC Rely on a Non-CDC IRB
- ☐ 0.1372: Outside Institution Rely on a CDC IRB
- ☐ 0.1373: CDC Cover an Individual Investigator

Exempted Protocols

- ☒ 0.1250X: Initial Review for Exemption
- ☐ 0.1251X: Continuing Review of Exempted Protocol
- ☐ 0.1252X: Review of Changes to Exempted Protocol
- ☐ 0.1253: End of Human Research Review
- ☐ 0.1370: CDC's Research Partners

4 Signatures

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date Signed	Remarks
Principal CDC Investigator: Jonathan E. Friedel -S Digitally signed by Jonathan E. Friedel -S Date: 2018.02.26 15:38:49 -05'00'	03/06/2018	

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date Signed	Remarks
Team Lead: Oliver Wirth -S Digitally signed by Oliver Wirth -S Date: 2018.03.07 08:43:31 -05'00'	03/07/2018	☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): Michael E. Andrew -S Digitally signed by Michael E. Andrew -S Date: 2018.03.07 15:58:51 -05'00'	03/07/2018	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Paul D. Siegel -S9 Digitally signed by Paul D. Siegel -S9 Date: 2018.03.08 11:06:03 -05'00'	03/08/2018	☐ PI is Division Official

I concur that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants* and with other applicable CDC and national center policies.

Signature For Angela Morley	Date Signed	Remarks
/Chair NIOSH IRB: Diane C. Morris -S Digitally signed by Diane C. Morris -S Date: 2018.03.09 11:51:11 -05'00'	03/09/2018	
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

5 Additional Comments

6 Reminder Regarding Other Regulatory Clearance Processes

The principal investigator is responsible for obtaining other regulatory reviews as needed, which may include OMB clearance under the Paperwork Reduction Act (PRA) for federally sponsored information collections. Approval by or exemption from the IRB is unrelated to OMB clearance requirements under the PRA. For more information on whether your study requires clearance under PRA or other regulations, please consult the appropriate officials within your national center.

Request for Exemption from Human Subjects Regulations

Use this form to submit a protocol for exemption from human subjects regulations. See *HRPO Guide: Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 18-HELD-02XM Protocol version number 1 version date _____

Protocol title: _____

Understanding How Discounting Affects Decision Making and Adoption of Prevention Through Design Solutions

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Jonathan Friedel, PhD	ndy8	232	NIOSH/ HELD
Principal investigator (required)	Jonathan Friedel, PhD	ndy8	232	NIOSH/ HELD
Investigator 2	Anne Foreman, PhD	vpc3	11111	NIOSH/ HELD
Investigator 3	Oliver Wirth, PhD	oaw5	16875	NIOSH/ HELD
Investigator 4				NIOSH/
Investigator 5				NIOSH/

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center (or equivalent) and division (or equivalent), or coordinating center or office if submitted at that level.

List all other CDC investigators, if any. Include name and degrees, user ID, SEV #, CDC NC/division:

_____

3 CDC's role in project

Check yes or no for each of the following.

☒y ☐n CDC employees or agents will obtain data by interacting with participants.

☐y ☒n CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

☒y ☐n CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens.

☒y ☐n CDC employees will provide substantial technical assistance or oversight.

☒y ☐n CDC employees will participate as co-authors in presentation(s) or publication(s).

"Agents" includes on-site contractors, fellows, and others appointed or retained to work at a CDC facility conducting activities under the auspices of CDC.

4 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners.

☐ Research partners are listed on form 0.1370, which accompanies this form.

5 Study participants—planned demographic frequencies

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: Exempt Review Cycle* for definitions.

Number of participants	100
Location of participants	
Participating at domestic sites	100
Participating at foreign sites	0
Sex/Gender of participants	
Female	
Male	
Sex/gender not available	100
Ethnicity of participants	
Hispanic or Latino	
Not Hispanic or Latino	
Ethnicity not available	100
Race of participants	
American Indian or Alaska Native	
Asian	
Black or African American	
Native Hawaiian or Other Pacific Islander	
White	
More than one race	
Race not available	100

Comments on demographics

Sample is a non-representative convenience sample.

6 Regulation and policy

6.1 Exceptions or restrictions on exemptions

Check yes or no for each of the following.

☐y ☒n Research poses greater than minimal risk to participants.
CDC does not exempt research that poses greater than minimal risk to subjects.

☐y ☒n Research involves prisoners (either intentionally or incidentally).
These exemptions do not apply to research involving prisoners.

☐y ☒n Research involves interaction with children or obtaining identifiable private information about children through surveys or interviews of others.
The exemption at category 2 is restricted when children are research subjects.

6.2 Exemption categories

Check all that apply. See *HRPO Worksheet for Exemption from Human Subjects Regulations* for details.

Educational practices

- ☐ 1 Normal educational practices in commonly accepted educational settings

Educational tests, surveys, interviews, or observation of public behavior

- ☐ 2a Adults only; data are not identifiable
- ☒ 2b Adults only; data may be identifiable but are not potentially damaging
- ☐ 2c Children; limited to use of educational tests or observations of public behavior when the investigators do not participate in the activities being observed
- ☐ 3a Public officials or candidates
- ☐ 3b Federal statute requires confidentiality during and after research

Existing data, documents, records, pathological specimens, or diagnostic specimens

- ☐ 4a Publicly available sources
- ☐ 4b Information recorded by the investigator such that participants cannot be identified, directly or through linked identifiers

Research and demonstration projects (subject to the approval of the HHS Secretary)

- ☐ 5a Public benefit or service programs
- ☐ 5b Procedures for obtaining benefits or services under those programs
- ☐ 5c Possible changes in or alternatives to those programs or procedures
- ☐ 5d Possible changes in methods or levels of payment for benefits or services under those programs

Taste and food quality evaluation and consumer acceptance

- ☐ 6a Foods that are wholesome without additives
- ☐ 6b Foods that contain an ingredient, chemical, or contaminant at a level found to be safe

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

- ☒ Complete protocol
- ☐ Documentation in support of exemption 3b, if applicable (e.g., §308(d) Assurance of Confidentiality)
- ☐ Peer reviewers' comments or division waiver (NIOSH)
- ☒ Consent, assent, and permission documents or scripts
- ☐ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts)
- ☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools)
- ☐ Certification of IRB approval or exemption for research partners

8 Additional comments

CDC's Research Partners

Use this form to report current information on CDC's research partners whenever a partner institution or individual is added or information changes. Supply individual name and SEV number only for investigators collaborating with CDC under an individual investigator agreement (IIA). See *HRPO Guide: CDC's Research Partners* and either the *HRPO Worksheet for Basic Tracking of Research Partners* or the *HRPO Worksheet for Advanced Tracking of Research Partners* for details on how to complete this form.

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 18-HELD-02XM Protocol version number 1 version date _____

Protocol title: Understanding How Discounting Affects Decision Making and Adoption of Prevention Through Design Solutions

Protocol is exempt from regulation. DCMorris

Partner 1 Qualtrics LLC	**Partner 2**
Institution name: _____ Institution location: Provo, UT Individual name (IIA only): Reporting status: Initial report Regulatory coverage: Engaged/exempt Financial support: Contract/subcontract Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: 00022951 SEV number (IIA only): _____ IRB review status: Relying on CDC IRB IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 3	**Partner 4**
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: ___ Nonfinancial support: _____ FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____

Partner 5	Partner 6
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 7	**Partner 8**
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 9	**Partner 10**
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____