DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date August 15, 2022

From NIOSH Institutional Review Board

Subject IRB Approval of Amendment to NIOSH Protocol 20-NIOSH-07, "Heat-related changes in cognitive performance" (Convened)

To Kristin M. Yeoman, MD, MPH
Project Officer, NIOSH/SMRD

The NIOSH IRB reviewed the amended protocol for protocol 20-NIOSH-07, "Heat-related changes in cognitive performance" at the June 14, 2022, NIOSH IRB meeting and the June 30, 2022, NIOSH IRB Ad Hoc meeting and approved the protocol. The IRB determined the study poses greater than minimal risk to subjects.

The changes include:

I. Updated COVID mitigation plan and table.
II. Updated consent forms.

COLLABORATOR SITE RESTRICTION: NIOSH study activities may not begin with the following collaborator/site until documentation indicating current IRB approval or IRB Authorization Agreement has been received by the NIOSH Human Research Protection Program (HRPP) and the PI has been notified by the HRPP this restriction has been lifted and study activities may begin:

University of Arizona

Due to the funding and collection of identifiable, sensitive information the project is determined to be covered by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act.

This study is a clinical trial. Please post the consent form on Regulations.gov after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. 45 C.F.R. 46.116(h)

Reminder: IRB approval of protocol 20-NIOSH-07 will still expire on June 8, 2023.

Any problems of a serious nature must be brought to the immediate attention of the NIOSH IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

If you have any questions, please contact the NIOSH Human Research Protection Program (513)533-8591 or e-mail: NIOSH IRB Mailbox.

Request for Subsequent Action of IRB-Approved Protocol

Use this form to submit a protocol for continuing review or amendment by a CDC IRB or a non-CDC IRB. [See 45 CFR 46.109(e).] See *HRPO Guide: Non-Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 20-NIOSH-07 Protocol version number 7 Version date 07/14/2022

Heat-related changes in cognitive performance

Protocol title:

☐ Continuing Review
☒ Review of changes

☐ *Requesting transition to the 2018 Common Rule *(*Optional)*

Note: This may require changes to the study, including informed consent documents, to comply with the 2018 Common Rule

2 Key CDC personnel

☒ **No change** in key CDC personnel. If no changes, please list only the primary contact and principal investigator.

	Name and degrees (First Name, Last Name, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/Division
Primary contact (required)	Kristin Yeoman, MD, MPH	vij6	11/04/2023	NIOSH/SMRD
Principal investigator (required)	Kristin Yeoman, MD, MPH	vij6	11/04/2023	NIOSH/SMRD
Co-Investigator	Brianna Eiter, PhD	viy3	09/27/2024	NIOSH/SMRD
Co-Investigator	Gerald Poplin, PhD	ert8	01/23/2023	NIOSH/SMRD
Co-Investigator	Seth Finley	ytw3	12/07/2023	NIOSH/SMRD
Co-Investigator	Tashina Robinson, MS	ngg9	03/03/2025	NIOSH/SMRD

Notice: *Re-Verify if required CITI training is expired or found expired for any personnel listed on this protocol. Lapse in current training can result in removal from the study or suspension of the study until requirements are met.*

List all other CDC investigators or staff engaged in the conduct of the research, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/division):

Tim Bauerle, PhD, wjo6, 2/15/2025, NIOSH/SMRD; Zoe Dugdale, MPH, nxl4, 12/7/2023, NIOSH/SMRD; Alyssa Weakley, PhD, UC Davis and Synergy contractor, CITI 10/21/2023; Eryn Murphy, MS, Synergy contractor, CITI 6/8/2024; Kimberly Honn, PhD, Washington State University, CITI 6/24/2023; Tim McMurry, PhD, Timothy McMurry LLC (independent contractor), CITI 10/28/2023
Addition of the following from NIOSH: Yongli Zhao, PhD, qso3, 11/24/2023, NIOSH/SMRD; Carol Nixon, PhD, qlp1, 8/28/2023, NIOSH/SMRD; Alex Johnson, MPH, mqz6, 11/23/2023, NIOSH/SMRD; Nilo Tayag, ynd1, 6/11/2024, NIOSH/SMRD; Laura Hernandez, ogy1, 12/2/2024, NIOSH/SMRD; Brent Baker, PhD, bwb3, 3/10/2025, NIOSH/HELD

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 intervening or interacting with subjects.
☒y ☐n CDC employees or agents will obtain or use identifiable (including coded) private data or biospecimens.
☐y ☒n CDC employees or agents will obtain or use anonymous or unlinked data or biospecimens.
☒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 Study Subjects

Have any subjects been enrolled in the last 12 months? ☐ yes ☒ no

Total number of subjects needed for study: 89

Total number of subjects enrolled to date: 0

Comments on sample size:

4.1 Contact status

Check one of the following.

☐ Study is not designed to involve research-related contact with subjects (e.g., research using existing records); study activities involve only access to or analysis of data or biological specimens and writing reports.

☒ Study is designed to involve contact with subjects. Check one of the following:

- ☒ Contact with subjects has not yet begun.
- ☐ Contact with subjects has begun and continues; this may include follow-up for debriefing or notification of results.
- ☐ Contact with subjects is completed; study activities involve only data analysis or report writing.

4.2 Consent status

"Consent" includes adult consent, child assent, and parental permission. Check one of the following.

☐ The IRB previously waived all requirements to obtain consent in this study.

☐ Although not waived, there is no further need to obtain or document consent (e.g., enrollment is complete).

☒ *Subjects will be asked to provide consent (with or without documentation).

** If you check the third box, please include all current consent, assent, and parental permission materials (e.g., scripts, documents) from each study site with this submission.*

5 Study status—overall conduct *(This section can be skipped for amendments)*

[Comment 5.1] Summary of research activities to date. Briefly summarize study progress and interim findings. Include the number of potential subjects who declined enrollment and the number who withdrew from the study. If this study involves a registrable clinical trial, summarize registration status.

[Comment 5.2] Summary of study changes reviewed and approved since the last continuation. Do not include changes submitted with or before approval of this continuation but not yet approved.

[Comment 5.3] Summary of any recent literature or other information relevant to the research study (not limited to information with CDC co-authorship).

[Comment 5.4] Summary of all adverse events to date. In particular, address adverse events that were serious, unexpected (or more frequent or severe than expected), or at least possibly related to the research.

[Comment 5.5] Summary of (a) incidents that are not adverse events and (b) other substantial concerns since last continuation.

[Comment 5.6] List and include copies of progress or monitoring reports on safety or compliance (e.g., site monitor, safety review, DSM report, multi-center trial report, but not reports to PGO).

[Comment 5.7] Summary of remaining research activities, emphasizing future contact with subjects, use of identifiable private data and biological specimens, and preparation of primary reports.

6 Regulation and policy

6.1 Vulnerable populations

Check one of the following:

☐ **Change** in vulnerable populations (added or dropped).

☒ **No Change**

6.2 Free and informed consent

Check one of the following:

☒ **Change** in consent process, forms, or approved waivers.

☐ **No Change**

6.3 Other regulation and policy considerations

Check one of the following:

☐ **Change** in other regulation and policy considerations.

- Exception to PHS policy regarding notification of HIV test results
- Human genetic testing
- Inclusion of a registrable clinical trial or change in registration status
- Plans for long-term storage of identifiable biological specimens
- Involvement of drug, biologic, or device, including Investigational New Drug or Investigational Device Exemption status (See *HRPO Worksheet to Determine FDA Regulatory Coverage* for guidance on whether or not FDA regulations apply.)

☒ **No Change**

6.4 Confidentiality protections

Check one of the following:

☐ **Change** in the applicability of Certificates of Confidentiality protections.

☒ **No Change**

7 Summary of proposed changes

Describe and justify proposed modifications to the protocol. Include page numbers in reference to clean copy and marked copy. Continue summary in supplemental document if necessary.

Updated COVID mitigation plan and table per IRB comments and Nick Gipson review

Updated consent forms

8 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support and collaborators who do not receive such support. Include current information on partners added or dropped since the last review using form 0.1370. Check one of the following:

☐ No research partners have been added since the last review.

☒ Research partners have been added and are listed on form 0.1370, which accompanies this form.

☐ One or more research partners no longer collaborate for this study, and are listed as follows:

9 Material submitted with this form

Check all that apply. Describe additional material in the comments section. Required items are indicated. Optional items may be requested by HRPO or the IRB.

☒ Complete protocol (required if research poses more than minimal risk to subjects, is under IND/IDE, or has changed in the past 12 months) ***Required clean/marked copy for amendment***

☒ Consent, assent, and permission documents or scripts (required if consent will be sought in the future from prospective subjects or their representatives ***Required clean/marked copy for amendment if applicable***

☒ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts; required if consent will be sought in the future from prospective subjects or their representatives) ***Required clean/marked copy for amendment if applicable***

☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools; required if protocol has changes in the past 12 months) ***Required clean/marked copy for amendment if applicable***

☐ Certification of IRB approval or exemption for research partners (required only for partners being added or for supported/nonexempt partners) ***Required for amendments relying on a non-CDC IRB***

☐ Progress and monitoring reports (recommended when available)

10 Additional comments

11 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. I have also re-verified that the required CITI training has not expired for personnel listed on this protocol.

Signature	Date	Remarks
Principal CDC Investigator: Kristin M. Yeoman -S7 Digitally signed by Kristin M. Yeoman -S7 Date: 2022.07.26 14:25:02 -07'00'		

12 Suggested Mode of IRB Review on CDC's behalf

Location of IRB (check one):

☒ CDC IRB

☐ Non-CDC IRB through IRB authorization agreement [submit form 0.1371 if this is a new request]

Institution or organization providing IRB review:

IRB registration number:

Federal-wide assurance number:

Suggested level of risk to subjects (check one):

☐ Minimal ☒ Greater than minimal

For amendments, changes are:

☒ Minor ☐ More than minor

Suggested level of IRB review(check one):

☒ Convened-board review is suggested

Reason for convened review: Prior protocol required convened board review

☐ Expedited review is suggested, under the following categories (check all that apply):

- ☐ 1a Study of drugs not requiring Investigational New Drug exemption from FDA
- ☐ 1b Study of medical devices not requiring Investigational Device Exemption from FDA
- ☐ 2a Collection of blood from healthy, non-pregnant adults; below volume limit, minimally invasive
- ☐ 2b Collection of blood from other adults and children; below volume limit, minimally invasive
- ☐ 3 Prospective noninvasive collection of biological specimens for research purposes
- ☐ 4 Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves
- ☐ 5 Research that uses previously collected materials
- ☐ 6 Collection of data from voice, video, digital, or image recordings made for research purposes
- ☐ 7 Research that uses interview, program evaluation, human factors, or quality assurance methods

Continuing review of research previously approved by the convened IRB where

- ☐ 8a the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects
- ☐ 8b no subjects have been enrolled and no additional risks have been identified
- ☐ 8c the remaining research activities are limited to data analysis
- ☐ 9 Continuing review of research, not under IND/IDE, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified