



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 3/23/23

Title: Environmental Health and Land Reuse Certification Training PRA Reinstatement with Change Information Collection Request

Project Id: 0900f3eb8208b35b

Accession #: NCEH-CESIS-2/28/22-a3ec7

Project Contact: Laurel A Berman

Organization: NCEH/ATSDR/OCDAPS/CESIS

Status: Pending Regulatory Clearance : PRA Revision

Intended Use: Project Determination

Estimated Start Date: 06/05/2023

Estimated Completion Date: 08/04/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0923-0060

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(1)</i> Other - Training administration	3/23/23	Davis_Stephanie I. (sgd8) CIO HSC
PRA:			

PRA Applies		3/23/23	Davis_Stephanie I. (sgd8) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 8/14/19 OMB Expiration date: 8/31/22	3/7/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 04/17/2023

Determination Start Date: 01/13/23

Description:

This is a request to publish the 60-day Federal Register Notice (FRN) for "#Environmental Health and Land Reuse Certification Training" (OMB Control No. 0923-0060, discontinued 08/31/2022). ATSDR is requesting PRA clearance for a reinstatement with change information collection request (ICR). ATSDR is making administrative changes to the training administration that requires the addition of several forms and the removal of one form. ATSDR is also adjusting the time burden estimation and burden hours based on the addition of new data collection forms. The EHLR ICR was formerly covered under Project ID 0900f3eb81bf3c9d (under CDC IRB Protocol #7175). After careful thought, the NCEH/ATSDR Office of Science has determined that this training program is not research. Going forward, this new non-research project incorporates training collections, such as conference registrations, self-assessments, and evaluation of training. EHLR participants work toward certification upon successful completion of each training module.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Lab-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

ATSDR's Land Reuse Program has developed an Environmental Health and Land Reuse Certificate Training. The purpose of the EHLR Certificate is to educate environmental professionals, planners, and students in environmental/public health in basics of environmental health in relation to land reuse and redevelopment. Through a cooperative agreement, National Environmental Health Association (NEHA) is a training and training evaluation partner in this project. ATSDR is hosting a downloadable "classroom" version of the certificate for those who prefer classroom instruction or may have limited broadband that prevents full

access to course content (e.g., large PDF files). In addition, ATSDR and NEHA propose to offer additional 20-hour immersive training in three of the five EHLR training modules--community engagement, evaluation of environmental and health risks, and risk communication--as conference training sessions. NEHA is providing Certificates of Completion and continuing education credits for participants of the trainings upon verification of eligibility by the ATSDR course director.

Objective:

The overarching objective is to train the target population (primarily environmental professionals) in health-focused land reuse in its relationship to environmental health.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:

Yes

Project does not incorporate elements of health equity science:

Not Selected

Measuring Disparities:

Yes

Studying Social Determinants of Health (SDOH):

Yes

SDOH Economic Stability:

Not Selected

SDOH Education:

Not Selected

SDOH Health Care Access:

Not Selected

SDOH Neighborhood and Environment:

Yes

SDOH Social and Community Context:

Yes

SDOH Indices:

Not Selected

Other SDOH Topics:

environmental justice

Assessing Impact:

Yes

Methods to Improve Health Equity Research and Practice:

Yes

Other:

Not Selected

Activities or Tasks:

New Collection of Information, Data, or Biospecimens ; Programmatic Work

Target Populations to be Included/Represented:

General US Population

Tags/Keywords:

Education ; Health Education ; Conference registration ; Self-assessment ; Course evaluation

CDC's Role:

CDC employees will participate as co-authors in presentation(s) or publication(s)

Method Categories:

Other - Conference registration, course registration, self-assessment

Methods:

ATSDR will provide classroom and conference EHLR training with NEHA assistance. In the future ATSDR and NEHA may publish manuscripts related to environmental health education and the training.

ATSDR collects user information (name, job title, location/address, email address) from registered learners. The ATSDR Land

Collection of Info, Data or Biospecimen:

Reuse PI, Laurel Berman, securely maintains email addresses of learners who request the Classroom EHLR training. Following the CDC Records Control Schedule (RCS), the PI will delete such data after 7 years. ATSDR completed its feedback survey for the first cohort of up to 200 people within 6-12 months after the training. Under this reinstatement with change ICR, this survey will be eliminated, and ATSDR will add additional information collection related to training and its effectiveness, such as job title, voluntary self-assessments, and participant feedback.

Expected Use of Findings/Results and their impact:

ATSDR and NEHA will use the self-assessments (voluntary), and other input from Classroom and Online EHLR Basic learners to evaluate the course. We will also rely on data from the proposed immersive EHLR sessions at various conferences to determine training effectiveness and impact.

Could Individuals potentially be identified based on Information Collected? Yes

Will PII be captured (including coded data)? Yes

Does CDC have access to the identifiers (including coded data)?: Yes

Is this project covered by an Assurance of Confidentiality? No

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)? No

Is there a formal written agreement prohibiting the release of identifiers? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	National Environmental Health Association Brownfields Project (Year 4 Activity at \$75,000 and proposed Year 5 at \$85,000))	CDC-RFA-OT18- 1802	2020	5	85000.00

HSC Review

HSC Attributes

Other - Training administration

Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office

No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults

No Selection

Children capable of providing assent

No Selection

Parental permission

No Selection

Alteration of authorization under HIPPA Privacy Rule

No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults

No Selection

Children capable of providing assent

No Selection

Parental permission

No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identifiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Centers for Disease Control & Prevention	FWA00001413	07/30/26			CDC-RFA-OT18- 1802
National Environmental Health Association	FWA00030382	11/16/25	Centers for Disease Control & Prevention IRB #2 - B	10/08/24	CDC-RFA-OT18- 1802

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Gina Bare	n/a	n/a	n/a	n/a	Co-Investigator	gbare@neha.org		National Environmental Health Association
Jesse Bliss	n/a	n/a	n/a	n/a	Contract Official	jbliss@neha.org		National Environmental Health Association
Laurel Berman	10/09/2023		10/29/2022		Principal Investigator		312-886-7476	COMMUNITY ENGAGEMENT SCIENCES & INTERVENTION SECTION
Michael Lewin	05/25/2025	07/09/2023			Statistician		770-488-3812	RESEARCH ACTIVITIES TEAM
Rebecca Labbo	08/07/2022	07/09/2023			Statistician	rlabbo@neha.org		National Environmental Health Association
Sharon Unkart	08/07/2022	07/09/2023			Co-Investigator	sdunkart@neha.gov		National Environmental Health Association

Data

DMP

Proposed Data Collection Start Date:

7/31/23

Proposed Data Collection End Date: 8/1/25

Proposed Public Access Level: Public

Public Access Justification: Results of training, such as self-reported competency increases or aggregated self-assessment data may be used in publications by ATSDR and NEHA. All individuals will be de-identified and no PII will be released. Because we are reviewing literature and presenting the summaries of our findings, no people will be named or identified. The data may also summarize public environmental regulations, policies, and practices. Our focus geographic areas are N. America, European Union states, and non-EU Eastern European regions.

How Access Will Be Provided for Data: All PII (person identifiers) will be removed from data.

Plans for Archival and Long Term Preservation: Personally identifiable information will be stored in NEHA's secured learning management system or in ATSDR secured PI's files and will be relevant to issuing of certificates of completion and CEUs (by NEHA). ATSDR will not store PII for more than three years and typically only 2-3 months after NEHA issues a certificate of completion. ATSDR's Land Reuse Team Lead will follow federal records procedures for training health professionals (i.e., destroy records after 7 years). In terms of any collaborative trainings and related publications, there is not a need for data storage indirectly related to training results but may result in saving published journal articles or citing publicly available federal/state/regional website content.

Spatiality

Country	State/Province	County/Region
United States		
Romania	Bihor	

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	03/23/2023	EHLR 60-day FRN publication request package	Paperwork Reduction Act Form	EHLR 60D FRN Rqst to ICRO.zip
	Berman_Laurel A. (fjq0) CIO HSC	03/23/2023	Zipped file with corrections to FRN documents, SSA, etc.	Paperwork Reduction Act Form	Revised-FRN-docs-SSA-B-listAtt.zip
	Berman_Laurel A. (fjq0) Project Contact	03/23/2023	Clean versions of the corrected 60D FRN publication request and 60D FRN for EHLR certification are zipped and supplemented by updated SSA (burden table), SSB, and list of attachments.	Paperwork Reduction Act Form	Revised-FRN-docs-SSA-B-listAtt.zip
	Davis_Stephanie I. (sgd8) CIO HSC	03/23/2023	OS comments to 60D publication request package	Paperwork Reduction Act Form	EHLR 60D Rqst Reinstate w Chng.zip
	Berman_Laurel A. (fjq0) CIO HSC	03/22/2023	Zipped forms for latest revisions.	Paperwork Reduction Act Form	EHLR-PRA-Reinst-032223.zip
	Berman_Laurel A. (fjq0) Project Contact	03/22/2023	This zipped package contains clean and updated requested documents: DRAFT 60DFRN, 60D publication request form, all data collection instruments in burden table, SS-A (and SS-B), list of attachments.	Paperwork Reduction Act Form	EHLR-PRA-Reinst-032223.zip
	Davis_Stephanie I. (sgd8) CIO HSC	02/06/2023	ICR reviewed by OS	Paperwork Reduction Act Form	Files rev OS.zip
	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	All PRA Reinstatement documents zipped in one file.	Paperwork Reduction Act Form	PRA-Reinst-All-Files-zip-020623.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	All PRA Reinstatement files and forms are zipped within as one package.	Paperwork Reduction Act Form	PRA-Reinst-All-Files-zip-020623.zip
	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	This zipped package contains the 3survey instruments: Atts 4a-e adn 5a-c.	Paperwork Reduction Act Form	ATTS-4a-3-5-a-c-CLN-020423.zip

	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	This zipped package contains the PIA and IRB closure memo.	Paperwork Reduction Act Form	Att6-PIA-Att7-IRBclose-CLN-020423.zip
	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	This zipped package contains the 30-day, SSA, SSB, Privacy Act Checklist, FRN Publication Notice.	Paperwork Reduction Act Form	30-d-SSA-B-PACHkfst-FRNPubReq-CLN-020423.zip
	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	This zipped package contains Worksheets: Wksht1 and all Wksht2s.	Paperwork Reduction Act Form	Wrksht1-2-all-CLN-020423.zip
	Berman_Laurel A. (fjq0) CIO HSC	02/06/2023	This zipped package contains the List of Attachments, Att 1, Att 2, Att 3,3a-b	Paperwork Reduction Act Form	ListAtt-Att1-2-3-3a-3b-CLN-020423.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	This zipped package contains the Worksheets for the PRA packet - the overall training (Wksht1) and registration and survey form Wrkshts 2s. I submitted this on 2/4/23, but the files do not appear as submitted, so resubmitting.	Paperwork Reduction Act Form	Wrksht1-2-all-CLN-020423.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	This zipped package contains the survey instruments for EHLR Basic and Immersion (4a-e and 5a-c). I submitted this on 2/4/23, but the files do not appear as submitted, so resubmitting.	Paperwork Reduction Act Form	ATTS-4a-3-5-a-c-CLN-020423.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	This zipped package contains the List of Attachments, Att1, 2, 3, 3a, 3b (3ab - registration and opt out) I submitted this on 2/4/23, but the files do not appear as submitted, so resubmitting.	Paperwork Reduction Act Form	ListAtt-Att1-2-3-3a-3b-CLN-020423.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	This zipped package contains the 30-day, SSA, SSB, Privacy Act Checklist, FRN Publication Notice. I submitted this on 2/4/23, but the files do not appear as submitted, so resubmitting.	Paperwork Reduction Act Form	30-d-SSA-B-PACHkfst-FRNPubReq-CLN-020423.zip
	Berman_Laurel A. (fjq0) Project Contact	02/06/2023	This zipped package contains the Privacy Assessment and IRB Closure Notice. I submitted this on 2/4/23, but the files do not appear as submitted, so resubmitting.	Paperwork Reduction Act Form	Att6-PIA-Att7-IRBclose-CLN-020423.zip

	Davis_Stephanie I. (sgd8) CIO HSC	01/18/2023	Zipfile of reinstatement with change ICR with OS comments	Paperwork Reduction Act Form	Files rev OS.zip
	Berman_Laurel A. (fjq0) Project Contact	01/13/2023	Att4 through Att 5: EHLR Basic and Immersion Knowledge Assessments zipfile 010523	Paperwork Reduction Act Form	Att4-Att5-Basic-Immers-KnowledgeAssessm-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/13/2023	Att 3c - emailed registration form (Word)	Paperwork Reduction Act Form	Att3c-EHLR Emailed Online Registration Form (classroom)-12-2022.docx
	Berman_Laurel A. (fjq0) Project Contact	01/13/2023	All EHLR worksheets zipfile 010523	Paperwork Reduction Act Form	Worksheets-EHLR-all-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/13/2023	EHLR Registration Forms: 3, 3a, 3b, 3c1 (opt-out form), zipfile 010523	Paperwork Reduction Act Form	EHLR-RegistrationForms-3-3a-3b-3c-3c1-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/13/2023	Package contains Authorization (Att1), 30-day, Att 6, PIA, SSA, SSB, List of attachments, zipfile dated 10523	Paperwork Reduction Act Form	Att1Auth-30Day-Att6-PIA-SSA-SSB-ListAttach-01052023.zip
	Berman_Laurel A. (fjq0) Project Contact	01/06/2023	Attachment 7: Research Redetermination IRB Closure	Other	Att7- Research Re-determination IRB Closure Memo-12152022.pdf
	Berman_Laurel A. (fjq0) Project Contact	01/06/2023	Zip File: EHLR Basic and Immersion Knowledge Assessments (Atts 4a,b,c,d,3 # Basic and Atts 5a,b,c # Immersion)	Other	Att4-Att5-Basic-Immers-KnowledgeAssessm-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/06/2023	Zip File: EHLR PRA Worksheets	Other	Worksheets-EHLR-all-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/06/2023	Zip File: EHLR Registration # Basic and Immersion (Classroom) (Att3), EHLR Conference Registration (Att3a), EHLR Online Registration Form (Att 3b), EHLR Emailed Registration form (Att3c), EHLR Online Regist form opt out (Att3c1)	Other	EHLR-RegistrationForms-3-3a-3b-3c-3c1-010523.zip
	Berman_Laurel A. (fjq0) Project Contact	01/06/2023	Zip File: Authorization, 30-day, SSA, SSB, List of Attachments, and the Att 6 PIA	Other	Att1Auth-30Day-Att6-PIA-SSA-SSB-ListAttach-01052023.zip

	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/07/2022	NOA 0923-0060 (2019)	Notice of Action	NOA 0923-0060.pdf
	Berman_Laurel A. (fjq0) CIO HSC	03/02/2022	CLEAN Word document. Also loaded as supporting info in STARS tab. Marked version is in comments.	Other	fjq0_0900f3eb81ea3ec7-CLEAN-030222.docx
	Berman_Laurel A. (fjq0) CIO HSC	03/02/2022	60D FRN documents (registrations, pre- and post-test, self-assessments, NEHA Online evaluation)	Other	0923-0060 EHLR Crtfctn Trng 60-day FRN-forSTARS.zip
Current	Berman_Laurel A. (fjq0) Project Contact	03/02/2022	CLEAN version of the file (comments/Marked version are within STARS comments tab)	Other	fjq0_0900f3eb81ea3ec7-CLEAN-030222.docx
Current	Berman_Laurel A. (fjq0) Project Contact	03/02/2022	Correct zip file containing the PRA documents for burden (registration forms, pre- and post-test, self-assessment, NEHA online evaluation)	Other	0923-0060 EHLR Crtfctn Trng 60-day FRN-forSTARS.zip
	Berman_Laurel A. (fjq0) Project Contact	02/28/2022	Zipped file containing all documents related to 60-day FRN and activities requiring PRA approval (e.g., conference registrations, pre- and post-tests, training registrations, self-assessment, online course evaluation)	Other-Enter new type	Modules-1-3-files-022322.zip



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



Memorandum

Date May 10, 2022

From Jerrell Little
IRB-Committee Administrator
Human Research Protection Office

Subject Closure of CDC Protocol 7175 “Environmental Health and Land Reuse Certification.”

To LAUREL BERMAN, PhD, MS
ATSDR/OCDAPS

On behalf of the CDC Human Research Protection Office (HRPO), I have reviewed the request to close protocol 7175 “Environmental Health and Land Reuse Certification.” The study stopped for reasons other than risk or noncompliance. Study received IRB/HRPO approval and completed the terms of the approved protocol. NCEH/ATSDR Office of Science has reviewed the protocol and has made a determination that this activity is not research. The request for closure is associated with STARS project ID 0900f3eb81bf3c9d. No study data has been collected. Data have not yet been collected. No biospecimens have been stored. This includes the case where none were collected.

Please update your records accordingly.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or by e-mail at huma@cdc.gov.

cc: NCEH/ATSDR HS mailbox (CDC)