

# CHILDREN'S HEALTHY LIVING (CHL) PROGRAM DATA USE PROTOCOL AND GUIDELINES

Developed by the CHL Data Work Group  
for use in the CHL Pacific Region

For further information, please contact:

Ashley Yamanaka PhD, CHL Data Manager

Children's Healthy Living Program for Remote Underserved Minority Populations in The Pacific  
Region

Ag Sciences 302H, 1955 East West Road, Honolulu, HI 96822

Phone: 808 956-9832 Email: [aby@hawaii.edu](mailto:aby@hawaii.edu) Website: [www.chl-pacific.org](http://www.chl-pacific.org)

This project is supported by the Agriculture and Food Research Initiative  
Grant no. 2011-68001-30335 from the USDA National Institute of Food and  
Agricultural Science Enhancement Coordinated Agricultural Program.



United States Department of Agriculture  
National Institute of Food and Agriculture

# Table of Contents

<b>GLOSSARY OF ABBREVIATIONS</b> .....	<b>3</b>
<b>INTRODUCTION</b> .....	<b>4</b>
<b>PROTOCOL FOR DATA REQUESTS</b> .....	<b>7</b>
ELIGIBILITY .....	7
DATASET FORMAT .....	7
DATASET DELIVERY .....	8
REQUESTS FOR SUMMARY STATISTICS .....	8
<b>TERMS OF USE AGREEMENT</b> .....	<b>9</b>
I.    OWNERSHIP OF DATA .....	9
II.   ACCESS TO THE DATA .....	9
III.  USES OF THE DATA .....	10
IV.  LIMITS ON DISCLOSURE OF INFORMATION .....	10
V.   DATA CONFIDENTIALITY PROCEDURES .....	11
VI.  REPORTING AND PUBLICATION REQUIREMENTS .....	11
VII. DATA REQUEST PROCESS .....	14
VIII. RETURNING DATA UPON COMPLETION OF RESEARCH PROJECT .....	16
IX.  LIABILITY .....	16
X.   VIOLATION OF THIS AGREEMENT .....	16

## Glossary of Abbreviations

<b>Abbreviation</b>	<b>Definition</b>
CAP	Coordinated Agricultural Program
CAT	Community Assessment Tool
CHL	Children's Healthy Living Program for Remote Underserved Minority Populations in the Pacific Region
CITI	Collaborative Institutional Training Initiative
CNMI	Commonwealth of the Northern Mariana Islands
CSV	Comma-separated values
EPSCoR	Experimental Program for Stimulating Competitive Research
FAL	Food and Activity Log
FAS	Freely Associated States
FASE	Food and Agricultural Science Enhancement
FSM	Federated States of Micronesia
HIPAA	Health Insurance Portability and Accountability Act
HSR	Human Subjects Research
INT	Intervention Jurisdictions
IPS	Information Privacy Security
IRB	Institutional Review Board
PSC	Program Steering Committee
RCR	Responsible Conduct of Research
RMI	Republic of the Marshall Islands
SAS	Statistical Analysis System
SPSS	Statistical Package for the Social Sciences
USDA	United States Department of Agriculture

## INTRODUCTION

The Children's Healthy Living Program for Remote Underserved Minority Populations in the Pacific Region (CHL) is a partnership among remote Pacific states and other jurisdictions of the US: Alaska, American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Federated States of Micronesia (FSM), Hawai'i, Republic of Palau, and the Republic of the Marshall Islands (RMI).

The goal of this Food and Agricultural Science Enhancement (FASE) Coordinated Agricultural Program (CAP) among Pacific Region USDA-defined Experimental Program for Stimulating Competitive Research (EPSCoR) states/jurisdictions is to build social/cultural, physical/built, and political/economic environments that will promote active play and intake of healthy food to prevent young child obesity in the Pacific Region. To do this, CHL engages the community, and focuses on capacity building and sustainable environmental change.

A community-randomized intervention was conducted in the 5 jurisdictions of Alaska, Hawai'i, American Samoa, Guam and CNMI (called intervention jurisdictions or INT). Child and community level data were collected at baseline and post-intervention at 24 months. A prevalence survey was conducted in the Freely Associated States (FAS) of Federated States of Micronesia (FSM), Republic of Palau, and the Republic of the Marshall Islands (RMI).

Questionnaires were administered that collected information on lifestyle, particularly in regard to home environment, diet, physical activity, and anthropometry for children aged 2-8 years in each of the jurisdictions (see [CHL Collection forms](#)). Accelerometry data was also collected. Communities were assessed for readiness for change, food cost, physical activity and food environments (see [CAT Collection forms](#)). The table below gives a detailed description of the data that was collected (Table 1). Data have been cleaned and aggregated for data analysis.

Table 1. Summary of types of data collected by Children's Healthy Living Program (CHL)

Data Type	Target participant	Respondent participant	Jurisdictions	Goal number of participants
Surveys on Demographics, Family Size, Assistance Programs, Sleep, Screen Time, Culture	Child/Parent	Parent	FAS, INT	FAS:200 per jurisdiction INT: 150 per community (4-6 communities per jurisdiction) at two time points (baseline and 24 months)
Accelerometry data	Child	Child	FAS, INT	FAS:100 per jurisdiction INT: 100 per community (2-4 communities per jurisdiction) at two time points (baseline and 24 months)
Food, nutrient, and contextual data from two days of dietary records	Child	Child/Parent	FAS, INT	FAS:200 per jurisdiction INT: 100 per community (2-4 communities per jurisdiction) at two time points (baseline and 24 months)
Physical Activities by time from two days of activity logs	Child	Child/Parent	FAS, INT	FAS:100 per jurisdiction INT: 100 per community (2-4 communities per jurisdiction) at baseline
Community readiness assessment data	Key informants for community	Key informants for community	INT	3-5 per community (2-4 communities per jurisdiction) at two time points (baseline and 24 months)
Community Inventory of physical activity and food outlets	Community	Community	FAS, INT	Counts of physical activity and food outlets in CHL communities
Community evaluation of physical activity and park facilities (component of Community Assessment Tool (CAT))	Community	Community	FAS, INT	FAS: Up to 5 facilities of each type per jurisdiction INT: Up to 5 facilities of each type per community (4-6 communities per jurisdiction) at two time points (baseline and 24 months)
Community evaluation of food venues (component of CAT)	Community	Community	FAS, INT	FAS: Up to 5 facilities of each type per jurisdiction INT: Up to 5 facilities of each type per community (4-6 communities per jurisdiction) at two time points (baseline and 24 months)
Community evaluation of walkability (component of CAT)	Community	Community	FAS, INT	FAS: 1 to 2 walks per jurisdiction INT: 1 to 2 walks per community (2-4 communities per jurisdiction) at two time points (baseline and 24 months)
Food cost survey (component of CAT)	Community	Community	FAS, INT	FAS: 3 to 5 stores per jurisdiction INT: 3 to 5 stores per community (2-4 per jurisdiction) at two time points (baseline and 24 months)

The CHL program wishes to promote use of the data collected to aid researchers and policymakers in the Pacific, in accordance with human subject protection. This document provides guidelines, protocols and procedures for a data request and data sharing as established by the CHL Data Center Work Group. The purposes for requesting data as outlined below will determine the types of elements that can be shared:

1. Data at the record level (child/family) for manuscript publication, conference presentations and abstracts, reports, grant applications, dissertation / thesis, and program and policy development. The requested data sets will be generally limited use data sets (including dates as only PHI).
2. Summary statistics for manuscript publication, conference presentations and abstracts, reports, grant applications, and program and policy development.
3. Data for de-identified record level data for children/families or CAT elements. These may be requested for manuscript publication, conference presentations and abstracts, reports, grant applications, dissertation / thesis, program and policy development, and student projects (practicum, class, etc.).

Requestors will include:

1. CHL researchers
2. CHL students
3. Community stakeholders in the CHL jurisdictions
4. Other interested parties

The Data Center of the CHL Center of Excellence will serve as a repository for all CHL data, including community readiness assessments, and CAT and child data from all jurisdictions. Additionally, each jurisdiction with sufficient resources will maintain a copy of CHL data collected at their location. To receive back the cleaned jurisdiction specific data from the CHL Center, the jurisdiction needs to identify an entity, such as the land grant extension or public health office that is willing to house the data securely and be responsible for learning of its use. All requests for data will be made to the CHL Center, except requests for summary statistics for a specific jurisdiction, which can be requested directly from the jurisdiction office holding the data.

# PROTOCOL FOR DATA REQUESTS

At the first stages of inquiry about using the CHL data, the CHL Data Dictionary, CHL variable form, and these protocols and guidelines will be provided for the purpose of preparing a data request.

Data requests will be considered for approval by the CHL Program Steering Committee (PSC) and approved requests will be managed at the CHL Data Center by the Data Coordinator. Dataset requests for Purposes 1 and 3 will be submitted to the CHL Data Center, after approval is obtained from the CHL Program Steering Committee (PSC) using Form 1. For Purposes 2 and 3, no Protected Health Information (PHI) will be provided.

## Eligibility

Eligible individuals who make a data request will be hereinafter called investigator of this data request.

Students must obtain approval from the Academic Advisor/CHL mentor prior to data request submission. For CHL trainees, data requests may be made through their CHL Advisors. Documentation of approval should be attached.

For Purposes 1 and 3, Investigators must complete and present documentation of IRB and HIPAA training prior to receiving datasets. IRB training and HIPAA training is available via CITI (available at <http://www6.miami.edu/citireg/>).

- CITI Training Certificates:
  1. Human Subjects Research (HSR) - Non-exempt Social & Behavioral Sciences Researchers and Key Personnel
  2. Information Privacy Security (IPS) - Non-exempt Social & Behavioral Sciences Researchers and Key Personnel IPS
  3. Responsible Conduct of Research (RCR) course - Social and Behavioral Responsible Conduct of Research

For requestors outside of the CHL research team, a data use agreement will be set up between University of Hawai'i and the requestor's institution for Purpose 1. For Purpose 3, a data use agreement is not needed for de-identified data. The costs of data preparation and consultation will need to be recovered based on the effort required.

## Dataset Format

Datasets will usually be distributed in a SAS compatible format. For those who prefer SPSS, please note that SPSS can open a SAS data set directly. Also, R can

read a SAS data set via the read.sas7bdat package. Other formats of datasets that can be requested include .csv file, .xlsx or other versions of Excel files. Please indicate in the data request the preferred data format, e.g., SAS, CSV.

### Dataset Delivery

For sharing data with the CHL research team, the CHL server will be used for data distribution whenever possible. The requested data set will be uploaded to the CHL server to the specific jurisdiction folder that the Investigator is associated with. For non-CHL personnel who do not have access to the server, datasets will be distributed via SyncThing, a network data sync tool. SyncThing is operated through a locally generated web interface. This is generated on the computer it is installed on, unlike most web sites. Once your data request is approved, please contact CHL IT manager, Erik Hill ([erikhill@hawaii.edu](mailto:erikhill@hawaii.edu)) for installation instructions.

**Timeline: The goal will be to provide data within 6 weeks after PSC approval.** In cases where there are deadlines, such as for an abstract or student project, we will make every effort to meet the deadlines. We recommend informing the Data Center in advance of your PSC approval when data will be needed on a short timeline. The 6-week timeline is to account for workforce and workload issues.

### Requests for Summary Statistics

Descriptive statistics for key CHL outcomes are available on the CHL website.

For other requests by members of the CHL research team for summary statistics requiring data analysis, fulfilment of and timeline for requests for the CHL Data Center to run analyses will be handled on a case-by-case basis. In these cases, the CHL data analyst will usually become an author (member of the writing team). Requests must be in alignment of the project with the overall program objectives and availability of funding support for the request.

Requests for summary statistics requiring data analysis for researchers outside of the CHL team will be entertained when possible and will likely require cost recovery.

## TERMS OF USE AGREEMENT

The CHL program has collected data on young children and their families in the Pacific region. The CHL Data Center is designated to provide data from this study to qualified individuals for the purpose of statistical analysis and reporting.

The Investigator agrees to the following terms and conditions:

### I. OWNERSHIP OF DATA

- a. Ownership of the Data will be retained by CHL. Permission to use the Data by the Investigator may be revoked by CHL at any time, at their discretion. The Investigator must return or destroy all originals and copies of the Restricted Data, on whatever media it may exist, within 5 days of written request to do so.
- b. The Investigator will not make any claim to copyright ownership of the data or any accompanying documentation. The Investigator will not distribute copies of the data and accompanying documentation to others or make copies for reasons other than research in accordance with the conditions outlined in this data request.

### II. ACCESS TO THE DATA

- a. Access to the Data will be limited to investigators (the individual who makes this data request and signs this request). The data must not be "loaned" or otherwise conveyed to anyone other than the signatories to the data request. Other people, e.g., students, or coauthors who will use the data should be identified in the data request and must submit their certificate of IRB training documents during data request.
- b. Copies of the Restricted Data or any subsequent variables or data files derived from the Restricted Data will not be provided to any other individual or organization, except in summarized (e.g., tabular) form where cells contain 5 or more individuals.
- c. The Investigator will protect the Data and any data derived from the Data from access by unauthorized individuals.
- d. The Investigator will not store the data on a networked computer or other electronic storage device without taking steps to prevent unauthorized access. Such steps include password protection of shared devices, data encryption, and the use of firewall technology. Data sets should not be stored or transferred on flash drives, which are easily lost

### III. USES OF THE DATA

- a. The Data will be used solely for the purpose of scientific and public policy research and program planning, as stated in the request, and not for proprietary or law enforcement purpose.
- b. The Data will be used to generate only statistical summary information that does not allow any individual, family, household, business, or organization to be identified.
- c. No attempt will be made to identify any individual, family, household, business, or organizations. If an individual, family, household, business, or organization is inadvertently identified, or if a technique for doing so is discovered, the identification or discovery will be immediately reported to CHL, and the identification or discovery will not be revealed to any other person who is not a signatory to this data request.
- d. No attempt will be made to link this Data with any other dataset without written authorization from the CHL Principal Investigator, Rachel Novotny.
- e. Use of the Data will be consistent with the CHL policy regarding scientific integrity and human participant research.
- f. This data sharing document may be modified at any time when new experiences or insights necessitate it. In general, the requestor should follow the version of this document in force at the time of the data request, unless otherwise instructed.

### IV. LIMITS ON DISCLOSURE OF INFORMATION

- a. Identifying information concerning research participants from the Restricted Data will not be revealed to unauthorized individuals through personal communication, publication, or other data release.
- b. CHL will be notified immediately if the Investigator receives any legal, investigatory, or other demand for disclosure of the Data, including any request or requirement to provide data to any State agency or State contractor under conditions that are inconsistent with any requirement of this data request. CHL is authorized to revoke this agreement and take possession of the Data, or take any other action necessary to protect the confidentiality of the data

## V. DATA CONFIDENTIALITY PROCEDURES

- a. CHL will be notified immediately if the Investigator discovers a suspected breach of security or any actual disclosure of subject data to unauthorized individuals.

## VI. REPORTING AND PUBLICATION REQUIREMENTS

- a. **The Investigator will provide CHL with a copy of published works or reports based wholly or in part on the CHL Data, and a listing of presentations at professional meetings based upon the CHL Data.** In the case of publications, specifically, the copy will be sent concurrently with submission of the manuscript. Publications are considered to be any work that is made available to the public in a distributed fashion, including but not limited to journal articles, book chapters, and articles distributed through a Web site.
- b. The Investigator will acknowledge CHL in any publication or presentation based wholly or in part on the CHL Data. The following acknowledgement should be used: “This document includes data from the Children’s Healthy Living Program for remote Underserved Minority Populations in the Pacific Region (CHL). CHL is a project funded by the Agricultural and Food Research Initiative Grant no. 2011-68001-30335 and Grant no.2018-69001-27551 from the USDA National Institute of Food and Agricultural Science Enhancement Coordinated Agricultural Program. The information and opinions expressed herein reflect solely the position of the author(s). Nothing herein should be construed to indicate the support or endorsement of its content by USDA or by CHL.”

### c. Authorship

The authorship guidelines of the CHL Program are written to reflect the collaborative nature of the project while also meeting international standards for authorship. All CHL investigators, staff and students are eligible and encouraged to initiate and contribute to writing projects. Student advisors are encouraged to foster potential writing opportunities for students including noting opportunities for student participation. Students are welcomed to initiate ideas in conversation with their advisors. Student projects must also follow these guidelines. We recommend that all CHL investigators, staff and students to work closely with their Lead Site Co-I and to plan ahead when developing their writing projects.

1. To be an “author” on a paper (primary, secondary, or tertiary) or grant related to CHL, the general principle is “significant contribution”, such that the individual can publicly defend the work. All authors must meet the following international guidelines for authorship”, which include:
  - a. Substantial contributions to manuscript development
  - b. Drafting the article or revising it critically for important intellectual content
  - c. Reviewing and approving the final approval of the version to be published. Based on international standards, conditions 1, 2, and 3 should be met to be considered an author. For further information on international standards from authorship please see:
    1. The 2<sup>nd</sup> World Conference on Research Integrity  
Position Statement “Responsible Research Publications:

International Standards for Authors”

([http://www.publicationethics.org/files/International%20standards\\_authors\\_for%20website\\_11\\_Nov\\_2011.pdf](http://www.publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011.pdf))

2. The International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship ([http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html))

The table below designates common roles that meet the criteria for authorship and those that are other contributions for the acknowledgement section.

Types of <b>authorship</b> contributions:	Types of <b>acknowledgement</b> contributions:
1. Designed research (project conception, development of overall research plan, and study oversight)	1. Technical help
2. Conducted research (hands-on conduct and data collection)	2. Writing assistance (e.g., comments on manuscript)
3. Provided essential materials (applies to authors who contributed by providing constructs, databases, etc, necessary to conduct the research)	3. General support and scientific advisement
4. Analyzed data, performed statistical analysis, data interpretation	4. Financial support (e.g., obtained funding)
5. Wrote paper (only authors who made a major contribution)	5. Critically reviewed manuscript
6. Had primary responsibility for final content	6. Provided and cared for study participants
Content above provided by: <ul style="list-style-type: none"> <li>• The Lancet (<a href="http://www.thelancet.com/lancet-information-for-authors/statements-permissions-signatures#">http://www.thelancet.com/lancet-information-for-authors/statements-permissions-signatures#</a>)</li> </ul> The Journal of Nutrition ( <a href="http://jn.nutrition.org/site/misc/ifora_4-ms-prep.xhtml">http://jn.nutrition.org/site/misc/ifora_4-ms-prep.xhtml</a> )	

- d. The investigator will include CHL co-authors to represent relevant jurisdiction data in published works. Due to the large size and collaborative nature of the CHL program, some particular authorship conventions will be followed:
  1. The lead (first) author for all manuscripts should lead the development of the manuscript (concepts, analysis, and interpretation).
  2. For manuscripts that are aimed at one of the primary outcomes of the 6 CHL objectives, an author from each CHL jurisdiction must be included. This author can either be the Lead Site Co-I or designated by the Lead Site Co-I. Manuscripts aimed at primary outcomes of the 6 CHL objectives will have the CHL Principal Investigator named last (if not PI not leading the thinking, writing, or data analysis).
    - a) Rachel Novotny, CHL Center Director – All jurisdictions/Hawai'i
  3. For manuscripts that are site specific, the Lead Site Co-I should facilitate discussion among all Site Co-Is about authorship for Site papers. The Lead Site Co-I will assume the last author position (if not leading the thinking, writing, or data analysis). The following list of CHL authors by jurisdiction should be used:
    - a) Rachel Novotny, CHL Center Director – All jurisdictions/Hawai'i
    - b) Tanisha Aflague – Guam
    - c) Patricia Coleman – CNMI
    - d) Leslie Shallcross – Alaska
    - e) Travis Fleming – American Samoa
    - f) Jonathan Deenik – Freely Associated States (FAS)
  4. Authorship for manuscripts that involve a secondary or tertiary outcome of one of the 6 CHL objectives should invite authorship following conventions outlined above. Manuscripts must be reviewed by the Lead Site Investigator(s) of the data origins, who will be named last (alphabetically if more than one) if above authorship conventions are met. If the manuscript involves data from all CHL jurisdictions the CHL Principal Investigator should review the manuscript and will be named last (if not leading the thinking, writing, or data analysis).
  5. Given the large number of individuals involved in CHL work, and rules limiting authorship of some publications, if the number of authors must be limited, the acknowledgement section will be used to recognize contributors who are not authors.
  6. Outside of the conventions outlined above, authorship order will be based on contribution.
- e. Other co-authors may be suggested during PSC review.
  1. For studies requiring use of complex modeling or the food and activity log (FAL) data, the following individuals may be considered.
    - a) Lynne Wilkens – Hawai'i (study design/methods, multilevel

- modeling)
- b) Carol Boushey – Hawai'i (nutrition/diet and physical activity data)

2. For studies requiring intervention methods or data analysis support, the following individuals may be considered.

- a) Jean Butel – Hawai'i (intervention methods, socio-ecological model, community engagement)
- b) Ashley Yamanaka - Hawai'i (analysis support)

## VII. DATA REQUEST PROCESS

All manuscripts and grant applications containing CHL data must be reviewed and approved by the CHL PSC before submission. The online CHL Data Request form must be submitted [online](#). The CHL Data Center will coordinate the manuscript tracking and review process. In order to be eligible for review, requests should be submitted at least two months prior to deadline. The CHL Data Center will facilitate the review and CHL PSC decision via email. CHL PSC will be given two weeks for approval process. The CHL Data Center will follow up with the first author on the CHL PSC's decision. Requests will receive one of three designations:

1. Approved
2. Approved with CHL PSC requested modifications
3. Not approved

Requests receiving the designation of approved with modifications will need to re-submit the modified proposal to the CHL Data Center for record keeping within one week of decision receipt.

### *CHL Recommended Journals for publication*

American Journal of Epidemiology
American Journal of Health Promotion
Epidemiology
Hawai'i Journal of Medicine and Public Health
Health Promotion International
International Journal of Behavior, Nutrition, and Physical Activity
International Journal of Circumpolar Health
International Journal of Epidemiology

International Journal of Obesity
Journal of Community Health
Journal of Nutrition
Journal of Nutrition Education and Behavior
Journal of Physical Activity and Health
Journal of the Academy for Nutrition and Dietetics
Journal of the American Medical Association
Obesity
Pediatrics
Preventative Medicine
Public Health Nutrition
Social Science and Medicine

## VIII. RETURNING DATA UPON COMPLETION OF RESEARCH PROJECT

- a. When returning the dataset, the author will share SAS/or any other statistical package commands used for the analyses and calculations of new variables created so that we can be cognizant of and consistent with the use of variables, which will be added to the Data Dictionary. A description of newly derived variables should be included.
- b. Data used for publication will be the investigators responsibility and will maintain a copy of the restricted data on an encrypted media or computer. If the Investigator does not publish, they will certify to CHL that all originals and copies of the restricted data will be destroyed after 1 year of completing the research project.

## IX. LIABILITY

- a. The receiving Investigator agrees that CHL and the University of Hawai'i are not responsible or liable for the Receiving Investigator's acts, errors, or omissions.

## X. VIOLATION OF THIS AGREEMENT

- a. If CHL determines that the Agreement may have been violated, CHL will inform the Investigator of the allegations in writing and will provide an opportunity to respond in writing within 10 days. CHL may also, at that time, require immediate return or destruction of all copies of the Data in possession of the Investigator. If CHL determines that any aspect of this Agreement has been violated, the Investigator will be subject to Revocation of the existing agreement and denial of

