

CHILDREN'S HEALTHY LIVING (CHL) CENTER DATA USE GUIDELINES AND AGREEMENT

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

For further information, please contact: CHL Data Center Children's Healthy Living Center of Excellence for Remote Underserved Minority Populations in the Pacific Region Email: chldata@hawaii.edu Website: www.chl-pacific.org

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United States Department of Agriculture National Institute of Food and Agriculture

Table of Contents

| GLOSSARY OF ABBREVIATIONS | . 3 |
|--|-----|
| INTRODUCTION | . 4 |
| REQUESTING CHL DATA | . 8 |
| PROTOCOL FOR RESEARCH REQUESTS | . 9 |
| Eligibility | 10 |
| CHL DATA CENTER SUPPORT COST GUIDE | 11 |
| DATA CENTER RESEARCH AND SERVICE REQUEST FEES | 12 |
| Research Request Fee | 12 |
| DATA MODIFICATION REQUEST FEE | 12 |
| Service Requests Rates | 12 |
| Dataset Format | 13 |
| DATASET DELIVERY | 13 |
| DATA INQUIRY: REQUESTS FOR SUMMARY STATISTICS | 13 |
| TERMS OF USE AGREEMENT | 14 |
| Ownership Of Data | 14 |
| Access To The Data | 14 |
| Uses Of The Data | 15 |
| LIMITS ON DISCLOSURE OF INFORMATION | 15 |
| DATA CONFIDENTIALITY PROCEDURES | 16 |
| REPORTING AND PUBLICATION REQUIREMENTS | 16 |
| RETURNING DATA UPON COMPLETION OF RESEARCH PROJECT | 20 |
| LIABILITY | 20 |
| VIOLATION OF THIS AGREEMENT | 20 |

Glossary of Abbreviations

| Abbreviation | Definition |
|--------------|--|
| САР | 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 (time 1) and post-intervention at 24 months (time 2) and 72 months (time 3). 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 <u>CHL Collection forms</u>). Accelerometry data was also collected. Communities were assessed for readiness for change, food cost, physical activity and food environments (see <u>CAT Collection forms</u>). The figure below presents the data collected based on the socioecological framework (Figure 1).

Community Level Community Readiness Assessment Food Environment Accessibility, availability, and cost of healthy foods in food store outlets and fast food restaurants PA Environment Accessibility and availability of physical activity outlets (parks, schools, church grounds, indoor PA facilities) and community walkability Household Level- Household composition Income Religious affiliation Employment status Food insecurity/availability Acculturation Education Individual Level - Child demographics Anthropometry Sleep behaviors Acanthosis screening Screen time Physical activity Nutrition/diet

Figure 1. Summary of multilevel data collected by the Children's Healthy Living (CHL) Program

Tables 1 and 2 below give a detailed description of the data and measures that were collected at the individual, household, and community level. Data have been cleaned and aggregated for data analysis.

| Data Type | Target participant | Respondent participant | Jurisdictions | Goal number of participants |
|---|---------------------------------|------------------------------|---------------|--|
| INDIVIDUAL OR HOUSEHOLD | LEVEL DATA | | | |
| 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 time 1 (baseline) and time 2 (24 months). 50 per community (4-6 communities per jurisdiction) at time 3 (72 months). |
| Accelerometry data | Child | Child | FAS, INT | FAS: 100 per jurisdiction. INT: 100 per community (2-4 communities per jurisdiction) at two time points (time 1 [baseline] and time 2 [24 months]). Data was not collected at time 3 (72 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 (time 1 [baseline] and time 2 [24 months]), excluding temporal communities. 10 per community (4-6 communities per jurisdiction) at time 3 (72 months), including temporal communities. |
| 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. Data was not collected at time 2 (24 months) and time 3 (72 months). |
| COMMUNITY LEVEL DATA | | | | |
| Community readiness assessment | Key informants for community | Key informants for community | INT | 3-5 per community (2-4 communities per jurisdiction) at three time points (time 1 [baseline], time 2 [24 months], and time 3 [72 months]). |
| Inventory of physical activity and food outlets | Community | Community | FAS, INT | Counts of physical activity and food outlets in CHL communities. |
| Assessment of physical activity facilities (Community Assessment Tool (CAT)) | Community | Community | FAS, INT | FAS: Up to 10 facilities of each type per jurisdiction.INT: Up to 10 facilities of each type per community (4-6 communities per jurisdiction) at three time points (time 1 |

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

| | | | | [baseline], time 2 [24 months], and time 3 [72 months]). Indoor PA Facilities were only collected in Alaska for time 3 (72 months). |
|--|-----------|-----------|----------|---|
| Community evaluation of food venues (component of CAT) | Community | Community | FAS, INT | FAS: Up to 10 facilities of each type per jurisdiction. INT: Up to 10 facilities of each type per community (4-6 communities per jurisdiction) at three time points (time 1 [baseline], time 2 [24 months], and time 3 [72 months]). Fast food restaurant data was not collected at time 3 (72 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 three time points (time 1 [baseline], time 2 [24 months], and time 3 [72 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 (time 2 [24 months] and time 3 [72 months]). |

| Measures | | | | Assessed in matched-pair communities | | | Assessed in temporal communities | | | Assessed in FAS [†] |
|------------------------------------|-------------------------------|--|--------------|---|--------|--------|-------------------------------------|--------|--------|---------------------------------|
| Category | Measurement | Measurement tools | completed by | Time 1 Time 2 | Time 2 | Time 3 | Time 1 | Time 2 | Time 3 | |
| INDIVIDUAL OR HOUSEHOLD L | EVEL MEASURES | | | | | | | | | |
| Demographic | Demographic | Questionnaire | Surrogate* | Х | Х | Х | Х | Х | Х | Х |
| Anthropometry | Height | Stadiometer | Staff | Х | Х | Х | Х | Х | Х | Х |
| | Weight | Portable Scale | Staff | Х | Х | Х | Х | Х | Х | Х |
| | Waist circumference | Circumference Tape | Staff | Х | Х | Х | Х | Х | Х | Х |
| Diet | 2 d [#] Food intake | Food & Activity Log | Surrogate* | Х | Х | Х | | | Х | Х |
| Physical Activity (PA) | 6 d PA | Accelerometer** | Child | Х | Х | | | | | Х |
| | 2 d# Activity Log | Food & Activity Log | Surrogate* | Х | | | | | | Х |
| Sedentary behavior | 6 d SB/ST | Accelerometer** | Child | Х | Х | | | | | Х |
| (SB)/Screen Time (ST) | 2 d [#] Activity Log | Food & Activity Log | Surrogate* | Х | Х | | | | | Х |
| | Usual SB/ST | Questionnaire | Surrogate* | Х | Х | Х | | | Х | Х |
| Sleep | 6 d Sleeping | Accelerometer** | Child | Х | Х | | | | | Х |
| | 2 d [#] Activity Log | Food & Activity Log | Surrogate* | Х | Х | | | | | Х |
| | Sleeping behavior | Questionnaire | Surrogate* | Х | Х | Х | | | Х | Х |
| Acanthosis Nigricans | Presence/Severity | Visual observation/ assessment form | Staff | Х | Х | Х | | | Х | Х |
| Culture | Language/culture | Questionnaire | Surrogate* | Х | Х | Х | | | Х | Х |
| COMMUNITY LEVEL MEASURE | s | | | | | | | | | |
| Parks | Physical Activity | BTG survey | Staff | Х | Х | | Х | Х | Х | Х |
| Schools | Physical Activity | BTG survey | Staff | Х | Х | | Х | Х | Х | Х |
| Churches | Physical Activity | BTG survey | Staff | Х | Х | | Х | Х | Х | Х |
| Indoor Physical Activity Facility | Physical Activity | BTG survey | Staff | Х | Х | | Х | Х | | Х |
| Walkability | Physical Activity | BTG survey | Staff | Х | Х | | Х | Х | Х | Х |
| Fast Food | Food Environment | BTG survey | Staff | Х | Х | | Х | Х | | Х |
| Food Availability and Marketing | Food Environment | CX3 survey | Staff | х | х | | х | х | Х | Х |
| Store Environment Walkability | Food Environment | CX3 survey | Staff | Х | Х | | Х | Х | Х | Х |
| Food Cost | Food Environment | USDA Thrifty Food Plan Survey | Staff | | Х | | | х | х | Х |

Table 2. Summary of the types of measures collected by Children's Healthy Living (CHL) Program

[†]FAS = Freely Associates States of Micronesia (FSM, Palau, RMI).

X = indicates measurement completed.

*Surrogate reporter = parent/caregiver.

**A minimum of 100 children in each matched-pair community and FAS jurisdiction will wear an accelerometer.

*Randomly assigned non-consecutive days.

REQUESTING CHL DATA

The CHL Center strives to promote the 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 research 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, community-level data, or qualitative data. 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 and students
- 2. Researchers and students from an academic institution
- 3. Community partners in the Pacific region
- 4. COBRE investigators
- 5. Other interested parties

The CHL Data Center 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 RESEARCH REQUESTS

Research requests include request for record level data, community level data, and CHLrelated topics for publication. CHL data may be used for the purposes of conducting a research study, evaluation project, or community project. Publications may be of peerreviewed manuscripts, abstracts, presentations, or reports.

At the first stages of inquiry about using the CHL data, the CHL Data Dictionaries (Individual-level Data Dictionary & CAT Data Dictionary), CHL variable form, and these protocols and guidelines will be provided for the purpose of preparing a research request.

Research requests will be considered for approval by the CHL Center 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 Center Steering Committee (PSC) using Form 1. For Purposes 2 and 3, no Protected Health Information (PHI) will be provided.

The figure below briefly outlines the <u>CHL Research Request Process</u> step by step.

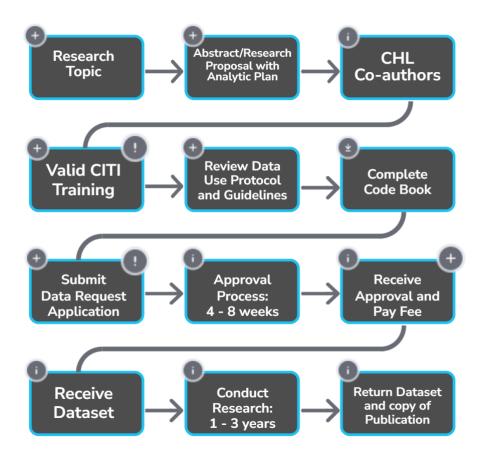


Figure 2. Children's Health Living (CHL) Program Research Request Process

<u>Eligibility</u>

Eligible individuals who make a research request will be hereinafter called INVESTIGATOR of this research request.

Students must obtain approval from the Academic Advisor/CHL mentor prior to research request submission. For CHL trainees, research 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 <u>https://about.citiprogram.org/</u>).

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.

CHL Data Center Support Cost Guide

Beginning April 1st, 2021, the CHL Center began a fee-for-service charge for approved research requests, data inquiries, and consultation services. The CHL Data Center plays a vital role in research activities with the US-affiliated Pacific region. We provide services that include review of data requests, consultation on developing new and sound methods for designing and analyzing studies in basic, translational, community and clinical trial research, and assisting with analyses for grant development or manuscript preparation. All investigators are welcome to utilize CHL data and services. For sustainability of our data center, not-for-profit fees are applied for these services. In collaboration with the <u>UH Centers of Biomedical Research Excellence (COBRE</u>), special considerations are provided to COBRE investigators and students.

| TYPES OF CHL SERVICE | UH and Non-UH Investigator | UH COBRE Investigator | Students* |
|---|-------------------------------|--------------------------|---------------|
| RESEARCH REQUESTS | FEE | FEE | FEE |
| <u>New Request:</u> requesting analytic or qualitative CHL datasets for research study, abstracts, manuscripts, or presentations | \$1,000 | \$1,000 | \$1,000 |
| Modification Request: approved requests that require additional data or changes to research questions/study design | \$125 | \$60 | \$0 (waived) |
| SERVICE REQUESTS | RATE | RATE | RATE |
| CONSULTATION | | | |
| <u>1st consultation:</u> Expert advice on CHL data, support on how to make a research request, or interest in study support, data analytic support, research planning, manuscript writing, or other types of services | FREE | FREE | FREE |
| Additional consultation: Additional expert advice needed on CHL data to make a research request or interest in study or analytic support, research planning, and manuscript writing. | \$125 per hour | \$60 per hour | \$60 per hour |
| IT SUPPORT | | | |
| Any technical support outside the research request | \$125 per hour | \$60 per hour | \$60 per hour |
| STUDY DESIGN AND PLANNING SUPPORT | | | |
| Development, review, and consultation on sample size determination; optimal study design; randomization Schemes; plans for data management, integration, and analysis | \$125 per hour | \$60 per hour | \$60 per hour |
| DATA ANALYSIS SUPPORT | | | |
| Support for data analysis such as identification of appropriate statistical analysis methodology; implementation of statistical analysis; advice on and support for statistical programming | \$125 per hour | \$60 per hour | \$60 per hour |
| RESEARCH PLANNING SUPPORT | | | |
| Support for manuscript preparation such as review and writing of research; advice on presentation & interpretation of results; provision of contents; advice for addressing reviewer critiques *Students must obtain approval from the Academic Advisor/CHL mentor prior to re | \$125 per hour | \$60 per hour | \$60 per hour |

*Students must obtain approval from the Academic Advisor/CHL mentor prior to research or service request submission.

Data Center Research and Service Request Fees

Research Request Fee

A flat fee of \$1,000.00 per data request will be assessed which will cover staff and computing time to review the request, work with the requestor to refine their request per Program Steering Committee (PSC) guidance, and staff time to organize the data and to conduct a safe data transfer. The fee will be split into two payments:

- \$500.00 due after PSC approval
- \$500.00 due before transfer of the dataset

Dataset request charges may be waived by the PSC for acceptable reasons. Requests for waivers may be emailed to the CHL Data Center at <u>chldata@hawaii.edu</u> and will not affect review or delay of request. Please review the table below for rate per effort.

| Effort | Rate |
|---|------------------|
| Dataset Request Application status is DISAPPROVED | No fee |
| Dataset Request Application status is APPROVED - or - APPROVED PENDING CLARIFICATION | \$1,000 flat fee |

Data Modification Request Fee

A flat fee of \$125 for UH and non-UH investigators or \$60 for COBRE investigators per data modification will be assessed to cover staff and computing time to review the modification, work with the requestor to refine their request per Program Steering Committee (PSC) guidance (if needed), and staff time to organize the data and to conduct a safe data transfer. After the modification is reviewed and approved by the PSC (if needed), the requester shall be invoiced the total fee.

Service Requests Rates

A rate of \$125 per hour for UH and non-UH investigators or \$60 per hour for COBRE investigators and students will be used for all service requests. The total cost for service requests varies based on an hourly rate for the amount of time spent on the service needed.

Upon receiving a service request, the CHL Data Center will estimate the number of hours to complete the service and provide a quote with the estimated hours and cost of the service and completion timeline. You will be invoiced monthly or at the completion of the project. Final cost of services subject to change from price quote, depending on total hours to complete project.

Please contact the CHL Data Center for any questions about requests or fee payments, you can email us at <u>chldata@hawaii.edu.</u>

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 dataset 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 dataset 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 research request is approved, please contact CHL IT manager, Erik Hill (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.

Data Inquiry: 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 Center 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. <u>OWNERSHIP OF DATA</u>

- 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 research request.

II. ACCESS TO THE DATA

- A. Access to the Data will be limited to investigators (the individual who makes this research request and signs this request). The data must not be "loaned" or otherwise conveyed to anyone other than the signatories to the research request. Other people, e.g., students, or coauthors who will use the data should be identified in the research request and must submit their certificate of IRB training documents during research 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.
- E. All manuscripts and grant applications containing CHL data must be reviewed and approved by the CHL PSC before submission. The online CHL Research Request form must be submitted <u>online</u>. 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 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. Requests will receive one of three designations:

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

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 research 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 research 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 research 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

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.

- A. 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."
- B. Authorship

The authorship guidelines of the CHL Center 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.

- C. 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:
 - The 2nd World Conference on Research Integrity Position Statement

"Responsible Research Publications: International Standards for Authors"

(http://www.publicationethics.org/files/International%20standards_a uthors_for%20website_11_Nov_2011.pdf)

 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 Contributor-ship (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 authorship contributions: | Types of acknowledgement contributions: |
|---|---|
| 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 | Provided and cared for study participants |
| Content above provided by: | information for authors (statements |

• The Lancet (http://www.thelancet.com/lancet-information-for-authors/statements-

permissions- signatures#)

• The Journal of Nutrition (http://jn.nutrition.org/site/misc/ifora_4-ms-prep.xhtml)

- 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 Center, some particular authorship conventions will be followed:
 - a. The lead (first) author for all manuscripts should lead the development of the manuscript (concepts, analysis, and interpretation).

- b. 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).
 - i. Rachel Novotny, CHL Center Director All jurisdictions/Hawai'i
 - ii. 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:
 - 1. Rachel Novotny, CHL Center Director All jurisdictions and Hawai'i
 - 2. Tanisha Aflague Guam
 - 3. Patricia Coleman CNMI
 - 4. Leslie Shallcross Alaska
 - 5. Travis Fleming American Samoa
 - 6. Jonathan Deenik Freely Associated States (FAS)
- c. 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).
 - i. 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.
 - ii. Outside of the conventions outlined above, authorship order will be based on contribution.
- d. Other CHL Investigators may be suggested as co-authors during PSC review.
- e. For studies requiring use of complex modeling or the food and activity log (FAL) data, the following individuals may be considered.
 - i. Lynne Wilkens Hawai'i (study design/methods, multilevel modeling, nutrition/diet and physical activity data)
- f. For studies requiring intervention methods support, the following individuals may be considered.
 - i. Jean Butel Hawai'i (intervention methods, socio-ecological model, community engagement, collective efficacy)

- g. For studies requiring data analysis support, the following individuals may be considered.
 - i. Ashley Yamanaka Hawai'i (analysis support, Food Cost Survey, CAT, multilevel modeling, activity log data)
 - ii. Yurii Shvetsov Hawai'i (analysis support, HEI)
 - iii. Rica Dela Cruz Hawai'i (analysis support)
- h. Although CHL considers costs for data analysis support, analysts can be coauthored if support is treated as a collaboration in the follow scenarios:
 - i. AUTHORSHIP: Data analysis and consultation or advice are waived as part of the collaborative effort.
 - ii. AUTHORSHIP: Data analysis time is charged, but advice or consultation time is donated for interpreting results, edits/suggestions on manuscript etc. as part of the collaboration.
 - iii. NO AUTHORSHIP: If all data analysis and advice or consultation services are charged and invoiced by the CHL Data Center, analysts are not listed as co-authors and instead, are included under the acknowledgement section.
- E. The first author will submit a manuscript to co-authors for review prior to journal submission.
 - a. All manuscripts and grant applications containing CHL data must be reviewed and approved by the CHL co-authors before submission.
- F. CHL Recommended Journals for publication:

| Che Recommended Southuis for publication. |
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| American Journal of Epidemiology |
| American Journal of Health Promotion |
| Epidemiology |
| Hawai'i Journal of Health and Social Welfare |
| 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 |
| |

VII. <u>RETURNING DATA UPON COMPLETION OF RESEARCH PROJECT</u>

- 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.

VIII. <u>LIABILITY</u>

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.

IX. 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 access to CHL data.