

Contract Requirements	Independent Research
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PURPOSE

To ensure the privacy and confidentiality of WIC applicants, participants, parents, guardians, and caretakers and that research projects are aligned with the mission and goals of the WIC Program.

POLICY

Approval is needed from the CDPH/WIC Division before any independent research is conducted with WIC staff, WIC applicants, participants, parents, guardians, and caretakers—regardless of funding source—before applying for grants or implementing research. This includes not only research implemented in WIC clinics, but also recruitment activities within WIC clinics for external research projects. Research includes obtaining data and information directly from subjects through a variety of means including but not limited to surveys, focus groups and interviews or obtained indirectly by using existing administrative data from a CDPH/WIC authorized management information system.

Independent research is defined as research, articles, reports, and materials that are not necessary for performance of the Agreement, regardless of funding source.

REQUIRED PROCEDURE

A. Request for Approval

The WIC local agency shall submit a request for and receive CDPH/WIC Division approval prior to conducting independent research or collaborating with an outside party to conduct independent research.

The request for approval must:

1. be submitted to their Nutrition Consultant, using the CDPH/WIC “Research Project Request Form”, which includes information on the following:
 - a. the objective of the research,
 - b. the design, setting, data collection methods, and data analysis plan,
 - c. any materials developed for use with research participants; the parties involved,
 - d. how the research will benefit WIC participants, staff or the CA WIC Program, and
 - e. local Institutional Review Board (IRB) approval (if available), and
2. be signed by the local WIC Director.

B. Human Subjects Review and Data Use Agreement

Any research project interacting with human subjects may require approval from the California Health and Human Services Agency’s Committee for the Protection of

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Human Subjects (CPHS) in addition to approval from a local/university accredited Institutional Review Board (IRB).

Before approving an independent research project using existing CA WIC Program data, the CDPH/WIC Division may require the local agency to enter into a data use and confidentiality agreement to ensure proper use and security of the data.

Before providing any existing WIC data to a subcontractor and/or outside entity, the CA WIC local agency shall obtain approval of the CDPH/WIC Division and shall require the subcontractor to enter into a data use and confidentiality agreement with the CA WIC local agency approved by the CDPH/WIC Division.

C. Publication Approval

All publications or presentations by the local agency, subcontractor and/or outside entity resulting from independent research must be reviewed and approved by the CDPH/WIC Division prior to publication, presentation, or distribution.

D. Data Sharing

The data may not be shared with anyone outside the CA WIC Program or CDPH/WIC Division for any other purpose than the original purpose intended without prior approval from the CDPH/WIC Division.

Other entities will not be permitted to use the data or link or match the data with other data sets unless such a link or match was identified in the research proposal and that proposal was approved by the CPHS or accredited IRB.

E. Change to the Independent Research Project Scope of Work

The local agency must request additional approval from the CDPH/WIC Division to use the data for any purposes other than the independent research project originally approved by the CDPH/WIC Division regardless of the data source.

The CDPH/WIC Division must approve any additional analyses, reports, materials, presentations, publications or use of data that is beyond the scope of the original approved proposal.

F. Data Storage

Data generated by the WIC local agency, sub-contractor and/or outside entity through surveys, focus groups, etc., must take all necessary precautions outlined in the approved IRB regarding data storage, ensuring identity is protected.

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G. Intellectual Property

All publications generated from CDPH/WIC Division funded projects shall be “works” and the intellectual property of the California Department of Public Health, subject to the provisions in the WIC local agency Agreement, Exhibit D(F), Provision 10, Intellectual Property Rights.

CROSS-REFERENCE

WIC local agency Agreement, Exhibit D(F), Provision 10

WIC local agency Agreement, Exhibit E, Provision 5