

PROTOCOL
Determination for Exempt
Research/Not Research
Committee for the Protection of Human
Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).
Protocol Type: Determination for Exempt Research/Not Research
Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol.

***** Personnel Information *****

Principal Investigator
color="red">required

Name	Title	Credentials
Dodds, David	Deputy Director, Evaluation	PhD MPH
Email	Phone	Mailing Address
ddodds@ccfc.ca.gov	916-263-1151 916-263-1360	916-263-1360
Organization Name	Additional Organizational Information	Fax
California Children and Families Commission		
Alternate Phone		

Training data is not currently needed

Co-Principal Investigator if applicable

Name	Title	Credentials
Neville-Morgan, Sarah	Deputy Director	MS
Email	Phone	Mailing Address
snevillemorgan@ccfc.ca.gov	916-263-2547	
Organization Name	Additional Organizational Information	Fax
California Children and Families Commission		
Alternate Phone		

Administrative Contact

Name	Title	Credentials
Williams, Gretchen	Research Program Specialist II	Bachelor of Arts
Email	Phone	Mailing Address
gwilliams@ccfc.ca.gov	916-263-5341	

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

Organization Name	Additional Organizational Information	Fax
First 5 California Children and Families Commission		
Alternate Phone		
Curriculum Vitae	View CV	

Responsible Official *

Name	Title	Credentials
furtek, frank	Chief Counsel	JD
Email	Phone	Mailing Address
ffurtek@ccfc.ca.gov	916-262-1313	
Organization Name	Additional Organizational Information	Fax
First 5 California Children and Families Commission		
Alternate Phone		
Curriculum Vitae	View CV	
	Training data is not currently needed	

Another Contact

Name	Title	Credentials
Dean, Robert	Research Analyst	MA
Email	Phone	Mailing Address
rdean@ccfc.ca.gov	916-263-1021	C-07
Organization Name	Additional Organizational Information	Fax
California Children and Families Commission		
Alternate Phone		
Curriculum Vitae	View CV	

***** Vulnerable Population *****

Vulnerable Population(s) Checklist
Select All That Apply :

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

- X **Minors (In the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted)**
Prisoners
Pregnant Women/Fetuses/Neonates
Not Applicable
Other (i.e., any population that is not specified above)
-

***** General Checklist *****

General Checklist

- Request Type
Indicate if you are requesting:
Not Research Determination
X Exempt Research Determination
Not Research and Exempt Research Determination
Institution Type
X Governmental
For-Profit
Nonprofit
-

***** Study Details *****

Title

Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

Complete Sections 1 - 5. Specify N/A as appropriate. Do not leave any required sections blank.

1. Study Details

- a) **Provide the rationale for why this request is being submitted to CPHS for approval (e.g., involvement of state data, state funding or state research staff).**

First 5 IMPACT (Improve and Maximize Programs so All Children Thrive) is sponsored and funded by the California Children and Families Commission (First 5 California), a state agency funded by state tobacco tax revenue (California Children and Families Act of 1998, Health and Safety Code, sections 130100-130155). The evaluation will use aggregate data files derived from local Quality Rating and Improvement System (QRIS) databases maintained by participating First 5 county commissions. Aggregate data files will be analyzed by civil servant staff at First 5 California. Though legal authority of the CPHS likely does not

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

extend to this program evaluation, First 5 California requests review under “determination of exempt research” to ensure reasonable standards of human subjects protection are in place.

During Fiscal Year 2015-16, First 5 IMPACT will run concurrently with the Child Signature Program (CSP) extension, also sponsored by First 5 California, for ten counties that participated in the original Child Signature Program (2012-13 through 2014-15). CPHS approved a Determination of Exempt Research for the CSP extension under CPHS Protocol ID 15-04-1951 in May 2015. Both the CSP extension and First 5 IMPACT utilize a similar evaluation design: aggregation of classroom data (child demographics, teacher demographics, averaged quality assessment scores) for each participating site into a common data elements file to be shared with First 5 California. When the CSP extension ends (June 30, 2016), the ten CSP extension counties may opt in to evaluation activities of First 5 IMPACT.

b) Provide a brief, non-technical description of the project, including a summary of the purpose and goals, project design and procedures.

As stated in its Strategic Plan, First 5 California’s vision is to ensure that California’s children receive the best possible start in life and thrive. Working toward this vision, the First 5 California Commission approved First 5 IMPACT funding for Fiscal Years 2015-16 through 2019-20 to support a network of local quality improvement models, including QRIS, to improve the quality of early learning settings. For First 5 IMPACT, early learning settings include center-based settings (e.g., Head Start, state preschool program), family child care homes, and alternative settings such as family resource centers.

Purpose and Goals: The overarching purpose of First 5 IMPACT is to improve quality in early learning programs for children ages 0 to 5 by supporting local efforts to implement and sustain continuous quality improvement models. First 5 IMPACT emphasizes local flexibility along a continuum in three implementation steps: Step 1 includes counties focusing on a few select elements of early learning quality improvement (QI); Step 2, an intermediate set of efforts for Quality Improvement Systems (QIS); and Step 3, implementation of a robust QRIS. First 5 IMPACT funds allow counties to target funding toward their own unique quality improvement and rating needs in settings of early care and education, and to focus on partnerships, workforce development, fiscal strategies, and communication to sustain strong, effective QIS. County commissions may apply to participate in First 5 IMPACT with other county commissions or local entities such as a county office of education. The leading local entity participating in First 5 IMPACT is designated as a Lead Agency.

Project Design: First 5 IMPACT implementation begins with the development of an administrative asset map and action plan by each participating Lead Agency to describe the status of the local QIS, and identify specific strategies to further develop system functionality and improve quality in local programs. For the purposes of First 5 IMPACT, program quality is framed around the Quality Continuum Framework developed and approved by the federally funded Race to the Top–Early Learning Challenge (RTT-ELC) Grant administered by the California Department of Education. The First 5 IMPACT model includes a variety of rating and improvement criteria, including child development and school readiness, teachers and teaching, and program and environment. Lead Agencies will submit an annual Common Data Fields file of aggregate information about participating sites, quality rating status (if applicable), and continuous improvement activities. This information will be submitted by Lead Agencies in September of each year for the previous fiscal year. Use of the Common Data Fields file follows the data collection model adopted by county consortia participating in RTT-ELC and also used for the CSP extension funded by First 5 California (CPHS Protocol ID 15-04-1951).

Procedures: With an asset map and action plan to guide county IMPACT investments, Lead Agencies will engage a variety of program types and settings into their local IMPACT model. Upon enrollment in First 5 IMPACT, a program (i.e., early learning site) will receive technical assistance to determine strengths and needs, and improvement strategies will be coordinated. During the enrollment process, basic data related to First 5 IMPACT participation will be collected (program setting and funding sources, child and teacher demographics, teacher and director qualifications, relevant rating components, quality improvement plan), aggregated to the site-level, and reported by Lead Agencies to First 5 California in the Common Data Fields file.

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

A full description of the purpose and design of First 5 IMPACT is contained in the RFA on First 5 California's website at http://www.cfc.ca.gov/programs/programs_impact.html.

c) Provide a brief description of any data/specimens that will be used and the involvement of human subjects in the study.

Data/Specimens: For the evaluation of First 5 IMPACT, aggregated site data will be reported in the Common Data Fields file. First 5 IMPACT administrative agencies will collect data from participating sites, including center-based programs, family child care homes, and alternative settings such as family resource centers. The information contained in the Common Data Fields file (program setting and funding sources, child and teacher demographics, teacher and director qualifications, relevant rating components, quality improvement plan) reflect commonly accepted indicators of early learning setting quality and are used in quality improvement systems nationally. In addition to their use for program accountability and evaluation, these data are used by site administrators, teachers, advisors, and technical assistance providers to identify quality improvement needs and prioritize investments.

It is important to note that quality rating information may include observation data on the Classroom Assessment Scoring System® (CLASS®) and Environment Rating Scales (ERS), as determined by the local Lead Agency. Both CLASS and ERS are commonly used observational assessment tools used in the field of early care and education (see grisnetwork.org). CLASS and ERS observation data qualify as exempt research under Title 45 Code of Federal Regulations, section 46.101(b): "Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy: (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."

Involvement of Human Subjects: While First 5 IMPACT participation is site-based, teachers and other staff may receive training, education, or other technical assistance for site quality improvement purposes. Persons who might be considered subjects include teachers observed in early learning classrooms or care settings, and parents who provide demographic data about their families and children. Children are not directly human subjects for this evaluation because the observational assessments are made naturalistically in the course of everyday activities related to the quality of interaction provided by teachers (CLASS®) or physical environment (ERS). For teachers, evaluation data that might be potentially sensitive are the CLASS and ERS observations. To minimize risk to participating teachers, First 5 California has established a formal data ethics policy stating that evaluation data must "...not be used for individual performance review, promotion, discipline, or retention decisions related to teachers, assistants, or other classroom staff." This policy is clearly stated in the First 5 IMPACT Evaluation Notice for Teachers. Similar language was included in forms provided to teachers in the Child Signature Program evaluation (Protocol ID 12-08-0632) and was successful in limiting data use to evaluation purposes. No adverse events were reported by teachers to First 5 California under that protocol. To address any possible concerns by parents, a First 5 IMPACT Evaluation Notice for Parents is provided. The First 5 IMPACT RFA requires participating Lead Agencies to use evaluation notices or consent forms approved by CPHS.

d) Describe the data elements/specimens to be used or collected and the source(s) of data/specimens. List or attach the variables to be used in this project.

Data used to derive the Common Data Fields file are maintained by Lead Agencies in local data systems designed to support site rating and quality improvement efforts. First 5 California will receive annually one data file from each Lead Agency that includes only aggregate site-level information. No personally identifiable information is shared with First 5 California in the Common Data Fields file.

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

- e) **Describe any subject recruitment methods, if applicable. Attach surveys to be used in the Attachments section.**

Lead Agencies participating in First 5 IMPACT will recruit and engage sites to participate. Participation in First 5 IMPACT is at the discretion of program administrators and staff. However, a teacher employed in a classroom at a participating site that is sampled for observation is required to be observed as part of a quality improvement process. For this reason, First 5 California has established safeguards to ensure data from sampled classrooms are used only for evaluation purposes. For teachers, evaluation data that might be potentially sensitive are the CLASS® and ERS observations. To minimize risk to participating teachers, First 5 California has established a formal data ethics policy stating that evaluation data must "...not be used for individual performance review, promotion, discipline, or retention decisions related to teachers, assistants, or other classroom staff." This policy is clearly stated in the First 5 IMPACT Evaluation Notice for Teachers. To address any possible concerns by parents, a First 5 IMPACT Evaluation Notice for Parents is provided. The First 5 IMPACT RFA requires participating Lead Agencies to use evaluation notices or consent forms approved by CPHS. First 5 California will provide evaluation notices in English and Spanish to Lead Agencies participating in IMPACT. English versions are attached for this Determination of Exempt Research, to enable review of content. Lead Agencies, at their discretion, may translate evaluation notices into additional languages if needed.

- f) **Indicate the number of subjects or their data that will be involved in the study and the geographic areas to be covered.**

First 5 California estimates that 4,600 sites in up to 58 counties will participate in First 5 IMPACT. An exact count of research subjects cannot be provided because participating Lead Agencies are in planning stages at the time of this writing.

- g) **Provide a brief description of the end product, such as a report or article in a peer-reviewed journal, and the plan for disseminating the findings.**

First 5 California will report evaluation findings through various means, including: 1) narrative program reports on its website (www.cfc.ca.gov); 2) presentations at quarterly First 5 California commission meetings; and 3) First 5 California's Annual Report required by statute.

- h) **Does the researcher collect or obtain the data or specimens that are considered personal information? CPHS defines personal information as being any of the following 18 Health Information Portability and Accountability Act identifiers.**

N If yes, please check any of the identifiers below that apply to your project.

Names

Telephone numbers

Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older

Geographic subdivisions smaller than a state (except the first three digits of a zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000).

Fax numbers

Electronic mail addresses

Social security numbers

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

Medical record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers (VIN), including license plate numbers
Device identifiers and serial numbers (e.g., implanted medical device)
Web universal resource locators (URLs)
Internet protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
Full face photographic images and any comparable images
Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
Other variables not listed above. An attached listing may be included.

***** Determination of Not Research *****

2. Determination of Not Research

1. Is an intent of this project to conduct a systematic investigation including development, testing and evaluation designed to develop or contribute to generalizable knowledge, which might include information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge?

(Note: A project may involve research and non-research components. If any component of the project is deemed to be research, the project must be approved by CPHS)

2. Check the box which best describes the project for which these human subjects and/or their data or specimens will be used

Public Health Practice/Surveillance or Emergency Response:

The activity is carried out under the direct supervision of a governmental public health agency. The public health authority involved in the project has pre-existing legal authority to receive any confidential, identifiable information to be used in the activity. The activity addresses an important health issue for the population under the authority of the public health agency and is carried out for the benefit of that population. The activity constitutes accepted public health or medical practice and is not designed to test an experimental hypothesis, drug, or device. The activity involves the collection and analysis of health-related data in order to monitor the frequency of occurrence and distribution of diseases and/or health conditions and known risk factors in a population. All the data collected will only be used for this purpose.

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

Additional Considerations: Surveillance or study of highly personal behaviors, particularly with vulnerable populations, in general, should be considered research, and thus requires institutional review board approval. Publication of information obtained from public health practice or surveillance does not, in itself, indicate that the activity is research. Identifiable data obtained from public health surveillance activities may not be shared or used for research purposes without institutional review board approval

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

Quality Assurance (QA) or Quality Improvement (QI):

Existing individual level data will be collected and analyzed and there is a formal commitment in advance of data collection to a corrective action plan related to outcomes of the analysis.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

Medical or Behavioral Practice:

1. Therapy, designed solely to benefit individual patient(s). The desired outcome is unproven, but there is an expectation of success for the patient's condition. This class of project could be termed "off-label" use of a medication or "humanitarian use" (does not include investigation new drugs) or...
2. Medical or behavioral practice to benefit a well-defined group of patients in a predictable way.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

Program Evaluation:

Assessment of the success of an established program or intervention in achieving its objectives in a specific population, and in which the information gained will be used only to provide feedback to the program, to ensure service quality or to make improvements in the program.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

Project is Resource Utilization Review:

Activity uses existing institutional records for client outcome monitoring in which individual level data

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

are routinely collected and analyzed to determine the extent to which clients are experiencing intended program outcomes, client satisfaction and needs assessment surveys which collect data from persons eligible to receive the program services.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

Case Report:

Data concerning one individual, their family, and/or environment, including medical history and any other information, collected for the purposes of analyzing and diagnosing the individual's condition or for instructional purposes or publication. It does not involve a testable hypothesis.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below:

3. Is the information being requested already existing data that was gathered for another reason and is the research staff not able to determine the identity of the individuals? This may include coded data if the research staff does not have a key to the code.
-

***** Determination of Exempt Research *****

3. Determination of Exempt Research

1. Does this project involve any of the following:

Prisoners as human subjects

HIPAA Protected Health Information

Survey or interview of children (up to 18 years of age)

Observation of public behavior of children when researcher interacts with children

Regulated by the Food and Drug Administration (except category #6)

Greater than minimal risk (the probability and magnitude of harm or discomfort anticipated are not greater than normally encountered in daily life or routine exam or procedure)

Note: If you checked any of the categories above, your project cannot be considered exempt under federal regulations. Do not complete the remainder of this form. You will need to apply for CPHS review.

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

2. Select only one exemption category below that is appropriate for your project.

- X (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies or research on effectiveness of or comparison among instructional techniques, curricula or classroom management methods

The First 5 IMPACT evaluation can be considered exempt under Title 45 Code of Federal Regulations, section 46.101(b): key research-like activities of the program evaluation include commonly used instruments in preschool settings. These instruments are based on naturalistic observation of participant teachers in classrooms: (1) to assess quality of interaction with children, the Classroom Assessment Scoring System® (CLASS®) instrument; and (2) to assess physical classroom environment, the Environment Rating Scales (ERS) family of instruments. Both CLASS and ERS are commonly used observational assessment tools used in the field of early care and education (see qrisnetwork.org). CLASS and ERS observers do not interact directly with children.

- (2) Research involving only the use of educational tests, survey procedures, interview procedures or observation of public behavior unless:
- a) Information is recorded in such a manner that subjects can be identified directly or through identifiers; and
 - b) Any disclosure of responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

This exemption is not allowed for research involving surveys or interviews with children (up to 18 years) or observation of public behavior of children if the investigator interacts with the children.

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below.

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if:
- (i) Human subjects are elected or appointed officials or candidates for public office or
 - (ii) Federal laws require, without exception, that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below.

- (4) Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens. If:
- (i) The sources are publicly available
 - (ii) The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below.

- (5) Research and demonstration projects which are conducted by or subject to the approval of a federal department or agency head, and are designed to study, evaluate or otherwise examine:
(Please note that projects that are federally funded but not directly supervised by a federal department or agency head do not qualify for this exemption)
- (i) Public benefit or service programs
 - (ii) Procedures for obtaining benefits or services under those public benefit or service programs
 - (iii) Possible changes in or alternatives to public benefit or service programs or
 - (iv) Possible changes in methods or levels of payment for benefits or services under public benefit or service programs

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below.

- (6) Taste and food quality evaluation and consumer acceptance studies. If:
- (i) Wholesome foods without additives are consumed or
 - (ii) The food consumed contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below levels found to be safe by FDA or approved by the EPA or Food Safety and Inspection Service of USDA?

Provide an explanation for why this project qualifies for this category by addressing the relevant requirements below.

***** Attachments *****

4. Attachments

Add appropriate attachments (e.g., grant proposal, questionnaires, surveys, advertisements, list of variables, etc.) in this section.

To update or revise any attachments, please delete the existing attachment and add the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Cover Letter	Dodds_15-06-2103_IMPACT_F5CA_CP HS_CoverLetter_v0810_2015	08/10/2015	08/10/2015
Explanatory diagram (Sequence of events)	Dodds_15-06-2103_Guidelines for Evaluation Notices_IMPACT V2 (8-10-15)	08/10/2015	08/10/2015

PROTOCOL
Determination for Exempt Research/Not
Research
Committee for the Protection of Human Subjects

Protocol Title: Evaluation of First 5 IMPACT (Improve and Maximize Programs So All Children Thrive).

List of study variables	Dodds_15-06-2103_IMPACT Common Data Fields Detail V2 081015	08/10/2015	08/10/2015
Any Other Documents (Please title file clearly)	Dodds_15-06-2103_IMPACT Evaluation Notice to Parents V3 English (8-10-15)	08/10/2015	08/10/2015
Any Other Documents (Please title file clearly)	Dodds_15-06-2103_IMPACT Evaluation Notice to Teachers V3 English (8-10-15)	08/10/2015	08/10/2015

***** Assurance *****

Principle Investigator's Statement:

I affirm that the information provided is accurate and complete to the best of my knowledge

***** Event History *****

Event History

Date	Status	View Attachments	Letters
06/29/2015	NEW FORM CREATED		
08/10/2015	NEW FORM SUBMITTED	Y	