



August 10, 2015

Re: Request for Determination of Exempt Research, Evaluation of First 5 IMPACT

Dear Committee Members:

By means of this online submittal and attached documents, we request the Committee for Protection of Human Subjects (CPHS) make a Determination of Exempt Research for evaluation activities related to First 5 (F5CA) IMPACT (Improve and Maximize Programs So All Children Thrive). This determination of exempt research would apply to evaluation activities in preschool classrooms or other early learning settings during five fiscal years, July 1, 2015 through June 30, 2020.

In April 2015, the California Children and Families Commission of F5CA approved \$190 million to support First 5 IMPACT. IMPACT is a system-building innovative approach that partners First 5 California (F5CA) with First 5 county commissions and/or local public entities to increase access to high-quality early learning programs and services for children and families, and helps ensure children enter school with the skills, knowledge, and dispositions necessary to be successful. The centerpiece of First 5 IMPACT is a network of local Quality Rating and Improvement Systems (QRIS) that better coordinate, implement, and evaluate early learning programs with a focus on improving their quality. This will give families the information and support they need to promote, support, and optimize their child's development and learning by selecting the best program for their child. In July 2015, F5CA released a Request for Application (RFA) to all 58 First 5 county commissions. Fifty-seven counties responded with affirmative Letters of Intent to apply during August 2015.

During fiscal year 2015–16, First 5 IMPACT will run concurrently with the Child Signature Program (CSP) extension, also sponsored by F5CA for ten counties that participated in the original CSP (2012–13 through 2014–15). CPHS approved a Determination of Exempt Research for the CSP extension under CPHS Project Number 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 F5CA. When the CSP extension ends on June 30, 2016, the ten CSP extension counties may opt in to First 5 evaluation activities of First 5 IMPACT.

## REASONS FOR REQUEST

Specific reasons for requesting the determination of exempt research include:

- 1. CPHS legal authority likely does not extend to this program evaluation. However, F5CA requests review under “determination of exempt research” to ensure that reasonable standards of human subjects protection are in place.** The California Children and Families Commission (aka First 5 California) is an independent state commission (California Children and Families Act of 1998, Health and Safety Code, sections 130100–130155). State tobacco tax revenue is the source of funding for the Commission and First 5 IMPACT. F5CA is not under authority of the California Health and Human Services Agency. (See: [http://www.oshpd.ca.gov/Boards/CPHS/legal\\_authority.html](http://www.oshpd.ca.gov/Boards/CPHS/legal_authority.html))
- 2. First 5 IMPACT evaluation activities focus on commonly accepted educational settings involving normal educational practices.** The First 5 IMPACT evaluation can be considered exempt 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.” Key research-like activities of the 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<sup>®</sup> (CLASS<sup>®</sup>) 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](http://qrisnetwork.org)).
- 3. The Common Rule does not apply because research-like activities for First 5 IMPACT are part of a government program evaluation for improving the quality of early care and education.** Research-like activities for CSP are part of a government program evaluation. The evaluation of classroom quality in CSP follows a national movement by many states to develop QRIS (see [qrisnetwork.org](http://qrisnetwork.org)). QRIS counties commonly collect data on structural aspects of early care and education (e.g., teacher-child ratios, teacher and administrator qualifications); observational assessments such as CLASS and ERS; and demographics related to children, families, and teachers.

4. **The standard CPHS Non-Medical Bill of Rights, following the Common Rule, conflicts with requirements of government program evaluation because teachers sampled for observation may not opt out of observation.** Statements in the standard CPHS Non-Medical Bill of Rights conflict directly with the program evaluation by stating, "Any participant in a research study has the right to: .... g. Be told that you may withdraw your consent and participation in the study at any time, and that your withdrawal will not affect your services" and "h. Be told that you may refuse to answer any question." The standard CPHS Non-Medical Bill of Rights conflicts with the ability of F5CA to conduct evaluation in support of accountability for a taxpayer-funded program. If classrooms are selected for observation, teachers will be required to participate—with safeguards provided below.
5. **As a safeguard to teachers and other participants, uses of observational data for this program are expressly limited to evaluation. Safeguards are made explicit in documents provided to counties by F5CA.** Safeguard documents include the Evaluation Notice for Teachers and Evaluation Notice for Parents (with supporting Guidelines). To reduce risk for teachers, First 5 California has established and communicated to participating county commissions a formal data ethics policy stating that data must "...not be used for individual performance review, promotion, discipline, or retention decisions related to teachers, assistants, or other classroom staff."
6. **Data reported by counties to F5CA will be aggregated across multiple classrooms or early learning settings. Data files will not include personally identifiable data.** Data aggregation protects anonymity of children, families, and teachers in the data files prepared by each county for this program. F5CA requires that participating county commissions meet data security requirements.

#### MATERIALS SUBMITTED WITH THE REQUEST

The following documents are submitted for your review through the CalPROTECTS system as part of this request for determination of exempt research:

##### Participant Safeguard Documents

Guidelines for First 5 IMPACT Evaluation Notices  
First 5 IMPACT Evaluation Notice for Teachers  
First 5 IMPACT Evaluation Notice for Parents

##### List of Variables

First 5 IMPACT Common Data Fields

Thank you for considering this request of determination of exempt research. Please let us know if we can provide additional information in support of this request.

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Sincerely,

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