WASHINGTON STATE INSTITUTIONAL REVIEW BOARD
Exempt Determination Request

Project Title: Outcome Evaluation of Family Assessment Response (FAR)

Principal Investigator (PI) (Name, Degree(s)): Marna G. Miller, Ph.D.

Agency or Organization Name: Washington State Institute for Public Policy

Complete Mailing Address: 110 5th Ave S.E, Suite 214

City: Olympia **State:** WA **Zip:** 98504

Office Telephone Number: 360-586-2745 **Alternate Number:**

Email: marna.miller@wsipp.wa.gov

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BEFORE completing this form, review the ***Washington State Institutional Review Board (WSIRB) Procedures Manual***, ***Section 5.1***, and then CALL or email the DSHS Human Research Review Section (HRRS) to arrange to discuss your proposed activity. Your lack of familiarity with WSIRB procedures or failure to discuss the proposed activity with HRRS staff will result in avoidable delay. When advised by HRRS staff, complete this *Exempt Determination Request* form, and attach all required documents and materials, including Appendices, as indicated herein.

IMPORTANT NOTE: Activities that involve use of birth or fetal death confidential information will not be disclosed without WSIRB review. STOP HERE and complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms.

SECTION 1: Is the Proposed Activity Research?

Research is defined in the federal regulations at 45 CFR 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

There are a wide range of activities that employ many of the features of research, such as rigorous design, systematic data collection, statistical analyses and scholarly dissemination, which may not necessarily be considered research under this federal regulatory definition. The key to distinguishing between research and non-research activities is to determine the intent of the activity. The intent of research is to increase the stock of knowledge, including knowledge of humankind, human and organizational behavior, culture and society, and the use of this stock of knowledge to devise new applications. Research, whether basic or applied, may involve the study of the fundamental aspects of phenomena and of observable data, and may include hypotheses generation or testing, drawing outcomes, inferences or conclusions, and/or advancing or informing theories, principles and statements of relationships. Research is often characterized by creative work undertaken on a systematic basis whose objectives may include developing and evaluating the feasibility and practicality of proposed solutions and determining their parameters, and expanding and applying acquired knowledge through the extrapolation of findings to wider or other populations or contexts.

An activity that combines both research and non-research is considered research for purposes of this Exempt Determination Request.

Check the box below that best describes the activity being proposed and explain your answer:

☐ A. **Research** -- as defined above. IMPORTANT NOTE: Research that involves newborn dried blood spots and/or specimen information cannot in accordance with applicable laws[1] be exempt from IRB review. For these activities, STOP HERE and complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms. Otherwise, proceed to Section 2, REGARDLESS of whether any other category below may also describe the activity.

Explain:

☒ B. **Program Evaluation activities** – in which the primary intent is to assess 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, **are generally not considered research**.

Explain:
The intent of this evaluation is to inform the legislature of the results of implementing FAR in Washington. Specifically, the legislature wants to know the effect of FAR on child safety and out-of-home placements.

The differential response model, upon which FAR is based, is only loosely specified. Eligibility criteria for the differential pathway, services offered, and case duration vary from state to state. Likewise, outcomes differ among the states.

In its application for a Title IV-E waiver featuring FAR as the main innovation, based on evaluations conducted in Minnesota, DSHS assumed that FAR would significantly reduce the rate of out-of-home placement and re-reports to CPS. This evaluation will determine whether the differential response model – as implemented in Washington –is producing similar findings. And of most concern, compared to the investigative path, does FAR, result in decreased child safety.

☐ C. **Surveillance activities** - which involve the regular, ongoing collection and analysis of health-related data in order to monitor the frequency of occurrence and distribution of diseases and/or health conditions in a population, and which are authorized by state statute or regulation which specify the intent of the activity, its purpose, and uses of the data, and in which all the data collected are used only for these purposes, **are generally not considered research**.

Explain:

☐ D. **Disease Investigation and/or Emergency Response activities** - authorized under state statute or regulation which are undertaken to identify, characterize, and solve an immediate health problem, and in which the information gained will directly benefit those participants involved in the investigation or their communities, **are generally not considered research**.

Explain:

☐ E. **Quality Assurance and/or Quality Improvement activities** - in which existing individual level data will be collected and analyzed by or on behalf of an institution and in which there is a formal commitment by the institution in advance of data collection to a corrective action plan related to any of a number of possible outcomes of the analyses **are generally not considered research**.

Explain:

☐ F. **Other Non-Research activities** – for example, program audits, resource utilization, service utilization and/or drug utilization studies using existing institutional records; client outcome

[1] See https://www.congress.gov/bill/113th-congress/house-bill/1281/text and http://app.leg.wa.gov/wac/default.aspx?cite=246-650&full=true.

monitoring in which individual level data are routinely collected and analyzed by or on behalf of an institution to determine the extent to which the institution's clients are experiencing intended program outcomes; client satisfaction and needs assessment surveys which collect data from persons eligible to receive the institution's program services; and other similar activities that are designed to directly benefit only an existing, well-defined and discrete client, patient or beneficiary population, **are generally not considered research**.

Explain:

☐ G. **Activities Conducted Solely for Educational Purposes** – which fall into one of the non-research categories above, but in which the primary intent is related to training in research methods in partial fulfillment of requirements for an undergraduate or advanced degree, **are generally not considered research**.

HOWEVER, activities for which the primary intent is related to training in research methods but which activities are also designed to develop or contribute to generalizable knowledge are generally considered research; for these activities do NOT check this box; instead, check the "Research" box above and proceed to Section 2.

Explain:

If any box 1.B—1.G is checked and box 1.A is NOT checked, proceed to Section 4. Note however that if we find that your activity is "research" as that term is defined above, you will be required to satisfy all requirements specified herein.

SECTION 2: Does the Research Involve Human Subjects as Defined in Federal Regulations?

A "human subject" is defined in federal regulations (45 CFR 46.102(f)) as a living individual about whom an investigator obtains (i) data through intervention or interaction with the individual, AND/OR (ii) identifiable private information.

Are the proposed research subjects living individuals?

☐ **No**. If none of the subjects are living, the activity **does not** involve human subjects. (Skip to Section 4)

☐ **Yes.** Indicate the type of information about subjects that would be collected in the research.

☐ A. If the research obtains data about subjects through interaction or intervention with individuals, including interviews, surveys, physical procedures, manipulations of the subject or the subject's environment, and any other direct contact or communication with the subject, **the research involves human subjects.** (Proceed to Section 3)

☒ B. If the research obtains identifiable private information about subjects from informants, or from confidential records, such as medical charts, computer databases, patient registries and/or personal records, **the research involves human subjects.** (Proceed to Section 3)

☐ C. The research does not involve obtaining data about subjects through interaction or intervention with individuals, and does not involve obtaining identifiable private information about subjects from confidential records. (Skip to Section 4)

SECTION 3: Is the Research Exempt from WSIRB Review?

Does this research involve prisoners as "human subjects"? The term "prisoner" (as defined at 45 CFR 46.303(c)) means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

☐ **Yes, the research involves prisoners.** STOP here. Research that involves prisoners cannot in accordance with federal law be exempt from IRB review. Complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms.

☒ **No, the research does NOT involve prisoners**. (Proceed to the next paragraph below)

If the activity checked in Section 1 is considered research, the activity involves "human subjects" as determined in Section 2, AND the activity does NOT involve prisoners as indicated above, then the activity may be exempt from WSIRB review if the only involvement of human subjects is in one or more of the following three categories A, B and/or C (check only as applicable):

☐ A. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, provided that:

1. The research does not involve children as subjects in survey procedures, interview procedures, or observations of public behavior when the researchers participate in the activities being observed (The term "children" means, as defined at 45 CFR 46.402(a), persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted);

2. The research does not involve use or disclosure of an agency's non-public information for purposes of contacting human research subjects or prospective subjects;

3. The information obtained does not deal with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, or physical, sexual, or emotional abuse, and is not likely to cause the subjects undue stress, fatigue, or other psychological or emotional reactions;

4. The information obtained is recorded in such a manner that human subjects cannot be identified by researchers directly or through identifiers linked to subject;

5. Any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and,

6. The research does not involve collecting information from subjects who are unable to provide legal consent for their own participation.

If the research does not meet ALL of the above conditions A.1 through A.6, STOP HERE and complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms.

☐ B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt above, if the human subjects are elected or appointed public officials or candidates for public office.

☒ C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, provided that:

1. These sources are publicly available; or,

2. Washington State agency records will be used by or disclosed to the researchers in such a manner that these records are not identifiable, (e.g., these records do not contain information which reveals or can likely be associated with the identity of the person or persons to whom

the information pertains), AND the records are not Protected Health Information (PHI) in accordance with 45 CFR 160.103, and 164.512(i) or 164.514(e)(3); and/or

3. Non-Washington State agency record information will be recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, AND the information is not PHI in accordance with 45 CFR 160.103, and 164.512(i) or 164.514(e)(3).

If the research does not meet the above conditions C.1 or C.2 and/or C.3, STOP HERE and complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms.

All human subject research which is exempt as specified in Sections 3.A—3.C above must be conducted in accordance with: (1) The Belmont Report[2]; (2) Washington State Agency administrative procedures to ensure valid claims of exemption; and (3) orderly accounting for such activities.

If any exempt category A, B and/or C above is checked, proceed to Section 4.

If NO exempt category A, B and/or C above is checked, then the **proposed activity is not exempt** – STOP here. Complete the Research Application available at: http://www.dshs.wa.gov/sesa/human-research-review-section/forms.

SECTION 4: Use or Disclosure of Washington State Agency Records

4.1 Does this activity involve use or disclosure of DSHS, DOH, HCA, L&I, DEL and/or OFM personal records? ("Personal records" mean any information obtained or maintained by a state agency which refers to a person and which is declared exempt from public disclosure, confidential, or privileged under state or federal law).

☐ No (Proceed to Section 4.6)
☒ Yes (Proceed to Section 4.2)

4.2 Does this activity involve use or disclosure of DSHS, DOH, HCA, L&I, DEL and/or OFM data that may, alone or through linkage to ANY other data, be identifiable or PHI?

☐ No (Proceed to Section 4.3)
☒ Yes; prepare an Appendix G form for each system of DSHS, DOH, HCA, L&I, DEL and OFM records from which data are requested; under the Investigator section of Appendix G, insert the description of your proposed activity from Section 6 of this Exempt Determination Request. If DSHS, DOH, HCA, L&I, DEL and/or OFM records will be accessed or disclosed in electronic form, also complete and submit Appendix J, following all instructions therein. Proceed to Section 4.4.

4.3 The PI must discuss the request for disclosure and use of any agency's records with the dataset's data manager (see contact information here). You may be asked to provide a data manager with an Appendix G form with your portion completed. Plan accordingly. (Proceed to Section 4.5)

4.4 The PI must discuss the request for disclosure and use of any agencies' personal records with the dataset's data manager (see contact information here). Provide each data manager with the separate Appendix G form with your portion completed. (Proceed to Section 4.5)

4.5 Is the PI a current employee of an agency (DSHS, DOH, HCA, L&I, DEL or OFM) from whose dataset(s) records will be requested?

☒ No; You may be expected to produce for a data manager a letter, provided by DSHS, DOH, HCA, L&I, DEL and/or OFM leadership, that documents support of your project, including disclosure and use of these agency's records. Plan accordingly. (Proceed to Section 4.6)
See section 9 of the attached legislation, ESSB 6555, 2012 and note in RCW 26.44.260.

☐ Yes (Proceed to Section 4.6);

4.6 Does this activity require other assistance or resources from DSHS, DOH, L&I, HCA, DEL and/or OFM (e.g., identification of and/or direct recruitment or distribution of study-related information to prospective subjects; extraction or linkage of agency records; use of agency staff, facilities or equipment to conduct study activities)?

☐ No (Proceed to Section 4.7)
☒ Yes; complete Appendix H, following all instructions therein; under the Investigator Section of Appendix H, insert the description of your proposed activity from Section 6 of this Exempt Determination Request. Proceed to Section 4.7.

4.7 Will signed or verbal informed consent, assent and/or parental permission for study participation and/or authorization for use or disclosure of identifiable Washington State Agency records or PHI be obtained from all study subjects?

☒ This activity does not involve interaction or intervention with study subjects NOR the disclosure or use of identifiable Washington State Agency records or PHI. (Proceed to Section 4.8).
☐ Check here IF signed or verbal informed consent, assent and/or parental permission for study participation and/or authorization for use or disclosure of identifiable Washington State Agency records or PHI will NOT be obtained from study subjects. Complete sections 1-4 of Appendix I, as applicable. Go to the following statement before proceeding to Section 4.8.
☐ Check here IF signed or verbal informed consent, assent and/or parental permission for study participation, and/or authorization for use or disclosure of identifiable Washington State Agency records or PHI WILL be obtained from study subjects. Complete Appendix F, following all instructions therein as applicable. Proceed to Section 4.8.

4.8 All activities involving use or disclosure of identifiable DSHS, DOH, L&I, HCA, DEL, Department of Corrections (DOC) and/or OFM records without the informed consent of the person to whom the records pertain—or their legally authorized representative—are subject to the Washington State RCW 42.48 legal requirement for a Confidentiality Agreement. A Confidentiality Agreement may be required under other circumstances. A Confidentiality Agreement must be executed before such records may be used or disclosed. You will be informed accordingly. (Proceed to Section 5)

SECTION 5: Conflicts of Interest

State agency policy, as well as federal regulatory requirements under 42 CFR 50 or 45 CFR 94 applicable to research funded by any U.S. Public Health Service component (e.g., CDC, FDA, NIH, and SAMHSA), regarding conflicts of interest require that the WSIRB and HRRS screen all research activities to determine how these requirements may apply. Complete Appendix N ONLY if you checked box 1.A above, following all instructions therein as applicable. Additionally, you may be required to comply with your own institution's policy for disclosing significant financial interests, completing related training, and managing financial conflicts of interest. See your institutional official and the HRRS Financial Conflicts of Interest page at https://www.dshs.wa.gov/sesa/human-research-review-section/financial-conflicts-interest for further information.

Proceed to Section 6

SECTION 6: Description of Proposed Activity (Required for ALL activities)

Attach supporting documents (e.g., abstract, applicable parts of a grant application, a contract, a work plan, thesis prospectus, etc.) that describe the purpose and intent of the activity, the proposed study methods, and the methods of contacting and recruiting subjects and/or accessing, using, and linking confidential records needed to conduct the activity. Attach all required materials and documents, including all Appendices, as directed above, and all data collection instruments and related materials.

Specify source of funding: This project is funded in the state budget, based on the fiscal note submitted for ESSB 6555. See the Evergreen State College section in the fiscal note.
https://fortress.wa.gov/binaryDisplay.aspx?package=32524

Amount of funding: $157,679.

Description of proposed activity (use additional pages as needed):

The Family Assessment Response (FAR, also known as differential response and alternative response) represents a change in the way Child Protective Services (CPS) responds to low-risk, screened-in reports of child abuse and neglect (CAN). Prior to FAR, all accepted reports of CAN received a forensic investigation; the investigation would result in a finding that CAN had occurred or was unfounded. Under FAR, caseworkers serving low-risk families assess the needs of the family and provide services and concrete materials necessary to prevent further allegations of maltreatment.

In 2012, the Washington State Legislature (ESSB 6555) directed the Department of Social and Health Services (DSHS) to implement FAR and directed the Washington State Institute for Public Policy (WSIPP) to evaluate the effect of this program on child safety and out-of-home placements. DSHS began a phase-in of FAR in January 2014 in 3 offices and continued to expand the program. To date the program has been implemented in 33 of 46 CPS offices.

Cohort 1	January 2014
Cohort 2	July 2014
Cohort 3	October 2014
Cohort 4	January 2015
Cohort 5	April 2015

The WSIPP evaluation will examine the effect of FAR on new reports to CPS, filing of dependency cases, and out-of-home placements. The approach will be to match families receiving FAR to families eligible for FAR but served in offices where FAR had not yet been implemented. We will use a propensity score protocol that includes parent race, parent age, age of youngest child, type of alleged maltreatment, family zip code, date of the CPS report, TANF receipt at the time of the report (as a measure of family poverty), and urban/rural status of local offices.

We assume we should allow 6 months following the initial date to reflect full implementation of FAR. We will be evaluating the effect of FAR on new screened-in reports to CPS within discrete time periods following the report (i.e. 6 months, 12 months) of the initial intake, out-of-home placements tied to the index report (within 90 days of intake) and later placements tied to subsequent reports, and dependency filings within 6 months and one year following intake. Because of a lag in data, to limit evaluation to offices with at least a 6 month follow-up, we will evaluate outcomes for just the first 3 cohorts. Families will have varying follow-up periods; therefore, we will also conduct survival analysis.

We will ask DSHS Research and Data Analysis (RDA) to create a dataset with information on screened-in CPS reports where the alleged subject is a parent or guardian received between January 1, 2008 and April 1, 2016 and out-of-home placements where removal dates occurred between January 1, 2008 April 1,

2016. We will request intakes and placements prior to the start of FAR (January 1, 2014) to create a history of prior intakes and placements for families. We request that TANF eligiblity be matched for all screened-in intakes in this period.

We will ask that RDA create bogus case and child IDs, then forward the dataset to the Washington State Center for Court Research (WSCCR). WSCCR will match cases against dependency filings to identify children for whom dependency petitions were filed. After matching, WSCCR will strip names and FamLink identifers from records before tranmitting to WSIPP via secure file transfer protocol.

PROJECT DIRECTOR'S STATEMENT:

By submitting this form I affirm that the information provided is accurate and complete to the best of my knowledge.

Send an electronic copy of this form and all attachments to: wsirb@dshs.wa.gov

Phone: 360.902.8075
http://www.dshs.wa.gov/sesa/research-and-data-analysis/human-research-review-section

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2 The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.