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APPENDIX A

RESEARCH QUESTIONS AND SOURCES

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Research questions	Constructs	Measures*	Study Instrument
1. Can We Grow Together be used effectively by early childhood professionals to support improvement in caregivers' interactions with infants and toddlers? [Primary/Secondary]			
a. Is five months' implementation of We Grow Together associated with change in the quality of caregiver-child interactions, as measured by Q-CCIIT instrument scores (fall to spring)? [Primary]	<ul style="list-style-type: none"> Quality of caregiver-child interactions: <ul style="list-style-type: none"> - Support for social-emotional development - Support for language and literacy development - Support for cognitive development - Areas of concern 	Q-CCIIT <i>Observation</i> (Atkins-Burnett et al. 2015)	Q-CCIIT observational measure (fall 2018 and spring 2019)
b. Is five months' implementation of We Grow Together associated with change in caregivers' and PD providers' beliefs and knowledge about child development and caregiving (fall to spring)? [Primary]	<ul style="list-style-type: none"> Knowledge and beliefs about child development Knowledge of and beliefs about caregiving 	Original (developed for this study) *Modified <i>Knowledge of Infant Development Inventory</i> (MacPhee 1981) *Baby <i>FACES Teacher Survey 2018</i>	Background survey (Caregiver, PD provider): Sections B and D Feedback survey (Caregiver, PD provider): Sections A and C
c. Does the PD Provider perceive change in his or her own practice after PD providers' training and five months' implementation of We Grow Together? [Primary]	<ul style="list-style-type: none"> Change in beliefs about PD and use of PD strategies 	Original *LA <i>Advance Early Educator Survey 2016</i> *UPCOS-5 <i>Teacher Interview</i> *National Center for Research on Early Childhood Education <i>Teacher Interview (NCRECE)</i> (Pianta et al. 2016)	Background survey (PD provider): Questions H2 and I6 Feedback survey (PD provider): Questions B2 and K1

Research questions	Constructs	Measures*	Study Instrument
d.1. Do answers to these primary questions differ by subgroups (caregivers and PD providers associated with FCCs versus center-based settings)? [Primary]	<ul style="list-style-type: none"> Includes all constructs in RQ1 analyzed by respondent type (e.g., caregivers and PD providers associated with FCCs or center-based settings) 	<p>Original</p> <p>*Q-CCIIT Caregiver SAQ, 2012</p> <p>*LA Advance Administrator Survey 2016</p> <p>*UPCOS-5 Teacher Interview</p> <p>*Baby FACES Teacher Survey 2018</p> <p>*SCOPE Coach Survey</p> <p>*Teacher Opinion Survey (TOS; Geller and Lynch, 1999)</p> <p>*Teachers' Attitudes About Professional Development (Torff et al. 2005)</p> <p>Center for Epidemiologic Studies Depression Scale (CES-D – short form; Radloff, 1977)</p> <p>Kessler-6 (K-6: Kessler et al. 2003; Kessler et al. 2010)</p>	<p>Background survey (Caregiver, PD provider): Sections B, D, L and Questions H1, I6</p> <p>Feedback survey (Caregiver, PD provider): Sections A, C, B1 and Question K1</p> <p>Q-CCIIT observational measure</p>
d.2 How are answers to these primary questions associated with characteristics of caregivers and providers (for example, demographics ^a , FCC/classroom characteristics ^b , caregiver mental health ^c , PD provider experience and beliefs)? [Secondary]	<ul style="list-style-type: none"> Includes all constructs in RQ1 analyzed by relations to characteristics of caregivers and PD providers (for example, demographics^a, FCC/classroom characteristics^b, caregiver mental health^c, PD provider experience and beliefs) 	<p>Original</p> <p>*Q-CCIIT Caregiver SAQ, 2012</p> <p>*LA Advance Administrator Survey 2016</p> <p>*UPCOS-5 Teacher Interview</p> <p>*Baby FACES Teacher Survey 2018</p> <p>*SCOPE Coach Survey</p> <p>*Teacher Opinion Survey (TOS; Geller and Lynch, 1999)</p> <p>*Teachers' Attitudes About Professional Development (Torff et al. 2005)</p> <p>Center for Epidemiologic Studies Depression Scale (CES-D – short form; Radloff, 1977)</p> <p>Kessler-6 (K-6: Kessler et al. 2003; Kessler et al. 2010)</p> <p>Stages of Change (Peterson and Weber, 2010)</p>	<p>Background survey (Caregiver, PD provider): Sections B, C, D, L and Questions H1, I6</p> <p>Feedback survey (Caregiver, PD provider): Sections A, C, B1 and Question K1</p> <p>Q-CCIIT observational measure</p>

Research questions	Constructs	Measures*	Study Instrument
e. Does the caregiver perceive change in his or her own practice after five months' implementation of We Grow Together? [Secondary]	<ul style="list-style-type: none"> Self-reported change 	Original	<p>Background survey (Caregiver): Question J3</p> <p>Feedback survey (Caregiver): Section E 2, H1</p>
f. Does the caregiver report other changes after participating in We Grow Together? [Secondary–exploratory]	<ul style="list-style-type: none"> Awareness of and access to resources Administrative and collegial support Change in self-efficacy Attitudes about professional development 	<p>Original</p> <p><i>Q-CCIT Caregiver SAQ, 2012</i></p> <p><i>LA Advance Administrator Survey 2016</i></p> <p><i>*Teacher Opinion Survey (Geller and Lynch, 1999)</i></p> <p><i>*Teachers' Attitudes About Professional Development (Torff et al. 2005)</i></p>	<p>Background survey (Caregiver): Sections F, G, L5</p> <p>Feedback survey (Caregiver): Sections B, D, E1, G</p>

Research questions	Constructs	Measures*	Study Instrument
2. What tools and support are required for early childhood professionals to use the responsive caregiving principles covered by We Grow Together to improve caregiver-child interactions? [Primary/Secondary]			
a. How frequently do caregivers and PD providers make use of We Grow Together over the implementation period, and which tools did they access? [Primary]	<ul style="list-style-type: none"> • Frequency of PD tools accessed • Average time spent with practices • Number of times self-video-recorded • Number of meetings • Length of meetings • Dosage: average time spent per week working on PD in and outside of classroom 	Original <i>LA Advance Early Educator Survey 2016</i>	Website user data and implementation data collection (Caregiver, PD provider) Pop-up survey (Caregiver, PD provider) Feedback survey I1-2, G1 (Caregiver); I5, K (PD provider)
b. How do caregivers and PD providers engage with the technological components of We Grow Together (that is, usability of the website, accessing the website and tools within it, using the tablets)? [Primary]	<ul style="list-style-type: none"> • Access to and ease of use of website tools, website, video recording experience 	Original <i>*Administrator Technology Survey (Burris 2014)</i> <i>*Perceived Website Usability Items (Wang and Senecal 2007)</i> <i>*Computer System Usability Questionnaire (CSUQ, Lewis 1995)</i>	Background survey Section K (Caregiver, PD provider) Feedback survey Questions F1, F2, F2a, F3, F4, F4_1 (Caregiver, PD provider) Website user data and implementation data collection (Caregiver, PD provider)
c. Are participants satisfied with We Grow Together (tool types, content)? [Primary]	<ul style="list-style-type: none"> • Satisfaction with website tools, activities, resources, and content 	Original <i>*UPCOS-5 Teacher Interview</i> <i>*LA Advance Early Educator Survey 2016</i> <i>*NCRECE Teacher Interview (Pianta et al. 2016)</i>	Feedback survey Questions F10, F11, F12, F13, F14, F14_1 thru F14_9, F18, and G2 (Caregiver, PD provider)
d. Are participants satisfied with the We Grow Together process (goal setting, action planning, practice and observation, reflection, feedback, trusting relationship)? [Primary]	<ul style="list-style-type: none"> • Caregiver satisfaction with PD process/strategies • PD satisfaction with supports for PD strategies • Relationship satisfaction 	Original <i>*Baby FACES Teacher Survey 2018</i> <i>*SCOPE Coach Survey</i> <i>*UPCOS-5 Teacher Interview</i> <i>**NCRECE Teacher Interview (Pianta et al. 2016)</i>	Feedback survey Questions F5, F6, F7, F8, F9, F12, F15, F16, F17, and H1 (Caregiver, PD provider)

Research questions	Constructs	Measures*	Study Instrument
e. What are challenges and barriers to We Grow Together implementation in infant/toddler settings? [Primary]	<ul style="list-style-type: none"> Challenges and barriers encountered 	<p>Original</p> <p><i>*UPCOS-5 Teacher Interview</i></p> <p><i>*ASPIRE Participant Year-End Survey 2013-2014</i></p> <p><i>*LA Advance Early Educator Survey 2016</i></p>	<p>Feedback survey Section I3, I4, I5 (Caregiver, PD provider)</p> <p>Website user data and implementation data collection (Caregiver, PD provider)</p>
f.1 Do answers to any of these questions differ by subgroups (caregivers and PD providers associated with FCC versus center-based settings) [Primary]	<ul style="list-style-type: none"> Includes all constructs in RQ2 analyzed by respondent type (caregivers and PD providers associated with FCCs or center-based settings) 	<p>Original</p> <p><i>*Q-CCIIT Caregiver SAQ, 2012</i></p> <p><i>*LA Advance Administrator Survey 2016</i></p> <p><i>*UPCOS-5 Teacher Interview</i></p> <p><i>*Baby FACES Teacher Survey 2018</i></p> <p><i>*SCOPE Coach Survey</i></p> <p><i>*TOS (Geller and Lynch, 1999)</i></p> <p><i>*Teachers' Attitudes About Professional Development (Torff et al. 2005)</i></p> <p><i>CES-D – short form; Radloff, 1977)</i></p> <p><i>Kessler-6 (K-6: Kessler et al. 2003; Kessler et al. 2010)</i></p>	<p>Feedback survey Section F, G, H, and I3, I4, I5 (Caregiver, PD provider)</p> <p>Background survey Section K (Caregiver, PD provider)</p> <p>Website user data and implementation data collection (Caregiver, PD provider)</p>

Research questions	Constructs	Measures*	Study Instrument
f.2. How are answers to these primary questions associated with characteristics of caregivers and providers (for example, demographics, FCC/classroom characteristics, caregiver mental health ^c , PD provider experience and beliefs)? [Secondary]	<ul style="list-style-type: none"> Includes all constructs in RQ2 and analyzed in relation to characteristics of caregivers and providers (for example, demographics, FCC/classroom characteristics, caregiver mental health^c, PD provider experience and beliefs)? 	Original *Q-CCIIT Caregiver SAQ, 2012 *LA Advance Administrator Survey 2016 *UPCOS-5 Teacher Interview *Baby FACES Teacher Survey 2018 *SCOPE Coach Survey *TOS (Geller and Lynch, 1999) *Teachers' Attitudes About Professional Development (Torff et al. 2005) CES-D – short form; Radloff, 1977) Kessler-6 (K-6: Kessler et al. 2003; Kessler et al. 2010) Stages of Change (Peterson and Weber, 2010)	Feedback survey Section F, G, H, and I3, I4, I5 (Caregiver, PD provider) Background survey Section C , L (Caregiver); Section H, K (Caregiver, PD provider) Website user data and implementation data collection (Caregiver, PD provider)
3. Does the Q-CCIIT reliably assess improvements in caregiver-child interactions in different types of care settings serving infants and toddlers? [Secondary]			
a. What is the inter-rater reliability of the Q-CCIIT measure? [Secondary]	<ul style="list-style-type: none"> Rater reliability 	Q-CCIIT Observation (Atkins-Burnett et al. 2015)	Q-CCIIT observational measure
b. Does the Q-CCIIT factor structure hold with a new sample? [Secondary]	<ul style="list-style-type: none"> Construct validity 	Q-CCIIT Observation (Atkins-Burnett et al. 2015)	Q-CCIIT observational measure
c. Does the measure demonstrate sensitivity to intervention? [Secondary]	<ul style="list-style-type: none"> Change in observed interaction quality Association with self-reported change 	Q-CCIIT Observation (Atkins-Burnett et al. 2015) Original	Q-CCIIT observational measure(fall 2018 and spring 2019) Feedback survey Section E (Caregiver)

^a Demographics includes cultural and linguistic diversity, education, experience in infant-toddler care, technology literacy

^b FCC/Classroom characteristics include the ages of children, proportion of male children, group size, adult-child ratio, philosophy and curriculum, support from administrators and other staff

^c Caregiver's mental health includes the caregiver's report of self-efficacy, symptoms of anxiety and depression, and openness to change

APPENDIX B

60-DAY FEDERAL REGISTER NOTICE

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ANNUAL BURDEN ESTIMATES

	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Annual burden hours
Guide for Recruitment with PHA and PCWA Administrators	20	7	1	1.00	7
Guide to Develop an Evaluation Plan for PCWA FUP Management	10	4	1	1.00	4
Guide to Develop an Evaluation Plan for PHA FUP Management	10	4	1	1.00	4
Guide for Implementation Study for PCWA Management ..	10	4	1	1.00	4
Guide for Implementation Study for PHA Management	10	4	1	1.00	4
Guide for Implementation Study for Referral Provider Administrators	4	2	1	1.00	2
Guide for Implementation Study with PCWA FUP Management (First)	10	4	1	1.00	4
Guide for Implementation Study for PHA FUP Management	10	4	1	1.00	4
Guide for Implementation Study Focus Groups with Frontline Workers	320	107	1	1.50	161
Guide for Implementation Study Focus Groups with PHA Frontline Workers	30	10	1	1.50	15
Guide for Implementation Study for PCWA FUP Management (Follow Up)	10	4	1	1.00	4
Guide for Implementation Study for Service Provider Management	8	3	1	1.00	3
Referral Form	200	67	6	0.17	68
Randomization Tool	10	4	106	0.02	8
Housing Assistance Questionnaire	200	67	3	0.09	18
Ongoing Services Questionnaire	200	67	3	0.09	18
Dashboard	20	7	27	0.17	32
Administrative Data List	30	10	2	5.00	100

Estimated Total Annual Burden Hours: 460.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,
ACF/OPRE Certifying Officer.
 [FR Doc. 2017-28374 Filed 1-2-18; 8:45 am]
BILLING CODE 4184-25-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Study of We Grow Together: The Q-CCIIT Professional Development System.

OMB No.: New Collection
Description: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a field test of We Grow Together, a system of professional development supports including web-based resources and exercises to be used by caregivers/teachers, with the help of professional development providers, to

improve the quality of infant and toddler care. The study team has developed We Grow Together: The Q-CCIIT Professional Development System based on the research literature to support caregiver-child interactions in care settings serving infants and toddlers. This field test is designed to (1) examine changes associated with use of the We Grow Together system and (2) examine implementation and participant experiences with the We Grow Together system. As a secondary goal, ACF will also further evaluate the properties of the Q-CCIIT observational measure. Ultimately, findings from the field test will provide information about the experiences of professional development providers (PD providers) and caregivers with the We Grow Together system so that ACF can improve the system to make the resources as accessible as possible for infant-toddler caregivers.

Prior to using the We Grow Together system, PD providers will complete a web-based training survey and all participants will complete a web-based background survey. Periodically during the field test, website users will be asked at log-on to respond to a series of web-based questions. After system implementation, participants will complete a web-based feedback survey.

The study team will also collect classroom rosters from caregivers before and after the field test.

Respondents: Early care and education (ECE) setting representatives (e.g., directors or owners), caregivers (in

center-based and family child care settings), and professional development providers (e.g., coaches).

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ECE setting eligibility screener	745	1	.25	186
Caregiver background survey	300	1	.75	225
PD provider background survey	175	1	.50	88
Caregiver We Grow Together website user data pop-up questions	300	6	.17	306
PD provider We Grow Together website user pop-up questions	175	5	.10	88
Caregiver feedback survey	300	1	1.0	300
PD provider feedback survey	175	1	.75	131
Classroom roster	300	2	.08	48
PD provider training survey	175	1	.17	30

Estimated Total Annual Burden Hours: 1,402.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017-28375 Filed 1-2-18; 8:45 am]

BILLING CODE 4184-22-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6759]

Establishing Effectiveness for Drugs Intended To Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders." This draft guidance provides key design considerations, including recommendations for patient enrollment criteria and efficacy endpoints, for clinical trials to establish effectiveness for drugs intended to treat male hypogonadotropic hypogonadism associated with obesity and other conditions that do not cause intrinsic damage to the hypothalamus or pituitary gland. This draft guidance is consistent with recommendations FDA received at the December 2014 advisory committee meeting on the appropriate indicated population for testosterone replacement therapy, and the December 2016 advisory committee meeting on hypogonadotropic hypogonadism.

DATES: Submit either electronic or written comments on the draft guidance by March 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

APPENDIX C

MATHEMATICA CONFIDENTIALITY PLEDGE

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MATHEMATICA

CONFIDENTIALITY PLEDGE

I understand that the names, and any other identifying facts or information, of individuals, businesses, organizations, and families participating in projects conducted by Mathematica, Inc. or its subsidiaries are confidential information. I agree that I will not reveal such confidential information, regardless of how or where I acquired it, to any person unless such person has been authorized by the cognizant Mathematica Project Director or the Mathematica Project Manager to have access to the information.

I further understand that the unauthorized access to, use, or disclosure of any confidential information is a breach of the terms of my employment, or my consultant agreement with Mathematica and may subject me to court action by any interested party or to other sanctions by Mathematica. I acknowledge that this agreement shall continue to bind me even after the project(s) is (are) completed and/or even though my employment or my consultant agreement with Mathematica has terminated.

In addition, in the course of my employment I may have access to personal information, electronic and otherwise, about fellow employees. I agree that I will treat that information as having the highest confidentiality, and not communicate it to fellow employees or others outside Mathematica. Final determination of whether or not there is a business purpose requiring that I access a fellow employees' records will be made in consultation with the Director of Human Resources. Failure to uphold this standard is a breach of trust and may subject me to disciplinary action, including termination of employment.

Other than in the course of my authorized employment or my consultant agreement, I further agree that I will not use, nor facilitate the use by any third party, in any way any information deemed confidential by the terms of any contract or other written agreement between Mathematica and any other organization, except by written authorization by both parties. It is my understanding that Mathematica and the contracting organization(s) have the exclusive right to all information acquired or developed under such a contract or other written agreement. I acknowledge that I acquire no right, title, or interest in and to any data or information to which I have access by reason of my employment or my consultant agreement and that I may not remove such data from my assigned work location without prior authorization.

I agree to promptly notify the cognizant Mathematica Project Director or Project Manager, the Survey Operations Center Manager or Supervisor for survey work, and the Mathematica Security Officer of any unauthorized disclosure, use, or alteration of confidential information that I observe.

Nothing herein shall be construed to prevent divulgence of information to any court or governmental agency, provided such divulgence is required by law. However, if I am subpoenaed, or if I have reason to believe that I may be called upon to make such divulgence, I agree to notify the President of Mathematica promptly in writing and, upon his request, to cooperate in all lawful efforts to resist such divulgence.

Name: _____ Signature: _____

Date: _____

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APPENDIX D

STUDY RECRUITMENT MATERIALS

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ADMINISTRATION FOR
CHILDREN & FAMILIES

330 C Street, S.W., Washington, DC 20201 | www.acf.hhs.gov

[DATE]

Dear [STATE/NETWORK CONTACT NAME],

Your assistance is requested for an important study of We Grow Together: The Q-CCIIT Professional Development System. The We Grow Together study is sponsored by the Administration for Children and Families in the U.S. Department of Health and Human Services and is being conducted by Mathematica Policy Research, a nationally recognized, nonpartisan research organization. We Grow Together includes a website that houses various materials, videos, classroom exercises and aids that are designed to support individual child care providers who work with infants and toddlers. It also includes supports for professional development providers (e.g., coaches, technical assistance specialists, mentors) who work with caregivers (teachers of infants and toddlers in center-based care or in family child care homes). Findings from the study will inform improvements to the professional development tools to help caregivers support infant and toddler development.

To ensure that these professional development resources are tested across the full range of care settings, we are hoping to recruit a diverse set of child care providers serving infants and toddlers in centers and family child care homes to participate in this field test. I am hoping you can help us identify potential providers in [FILL AREA] that Mathematica could invite to participate. This contact information will only be used for recruitment efforts for We Grow Together, and participation in the study is completely voluntary and all information you share will remain private to the extent permitted by law. The Administration for Children and Families, including the Office of Child Care and the Office of Head Start, fully supports this endeavor and encourages the participation of early child care programs and their local PD providers. Mathematica will contact you to provide more details on the project and to answer any questions you might have.

On behalf of the Administration for Children and Families, I thank you in advance for your help. Should you have any concerns regarding the study, please feel free to contact me 202-401-5506 at the Office of Planning, Research, and Evaluation; Administration for Children and Families; U.S. Department of Health and Human Services.

Sincerely,

Ann Rivera, Project Officer

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-XXXX and the expiration date is XX/XX/XXXX.

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WE GROW TOGETHER: THE Q-CCIIT PROFESSIONAL DEVELOPMENT SYSTEM

STATE OR NETWORK INFORMANT EMAIL

Subject Line: ACF study of We Grow Together: The Q-CCIIT Professional Development System

Dear [STATE/NETWORK CONTACT NAME],

Your assistance is requested for an important study of We Grow Together: The Q-CCIIT Professional Development System. The We Grow Together study is sponsored by the Administration for Children and Families in the U.S. Department of Health and Human Services and is being conducted by Mathematica Policy Research, a nationally recognized, nonpartisan research organization. We Grow Together includes a website that houses various materials, videos, classroom exercises and aids that are designed to support individual caregivers (teachers and child care providers) who work with infants and toddlers. We Grow Together also provides supports for the professional development providers (e.g., coaches, technical assistance specialists, mentors) who work with infant-toddler caregivers in center-based care or in family child care homes. Findings from the study will inform improvements to We Grow Together and related efforts to help caregivers support infant and toddler development.

Mathematica will be recruiting caregivers serving infants and toddlers in centers and family child care homes nationwide to use We Grow Together over the 2018/2019 program year. Additional information about the study is attached to this email.

We would greatly appreciate your help to identify potential early child care providers in your area that Mathematica could contact to see if they are interested in participating in this study. This list will only be used for recruitment in the We Grow Together study, and participation in the study is completely voluntary. All information you share will remain private to the extent permitted by law.

Mathematica will contact you in a few days to provide more details about We Grow Together and to answer any questions you might have. If you would like to speak with someone before then, please contact us by phone toll-free at 844-934-7692 (844-WEGROW2) or by email at wegrowtogetherstudy@mathematica-mpr.com.

Thanks in advance for your help with this important study!

Sincerely,

FILL NAME

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-XXXX and the expiration date is XX/XX/XXXX.
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Timothy Bruursema
Survey Director

Mathematica Policy Research
1100 1st Street, NE 12th Floor
Washington, DC 20002-4221
Telephone (202) 484-9220
Fax (202) 863-1763
www.mathematica-mpr.com

Dear [CAREGIVER NAME] or / Early Childhood Caregiver],

I am pleased to invite you to be part of an important study of We Grow Together: The Q-CCIIT Professional Development System. We Grow Together includes resources that are designed to help caregivers (teachers in center-based care or in family child care homes) like you serving infants and toddlers.

We would like to invite you to use We Grow Together with your professional development provider (for example, coach, technical assistance specialist, mentor) and participate in an important study sponsored by the Administration for Children and Families in the U.S. Department of Health and Human Services. Mathematica Policy Research, a nationally recognized research organization is conducting the study. Findings will inform improvements to We Grow Together and related efforts to help caregivers support infant and toddler development. Additional information about We Grow Together can be found on the other side of this letter.

Participating in this study includes:

1. Allowing observers to conduct two observations in your classroom (center-based classroom or family child care home). One observation will be conducted in fall 2018 and one in spring 2019. On the day of the observation, we will ask you to fill out a 5-minute questionnaire about your classroom.
2. Working with your own professional development provider to use We Grow Together for approximately five months. All materials are available online and the study will provide you with an iPad mini, tripod, and case so you can access the resources and also video-record and reflect on your interactions with children as you implement key practices (see the next page for more details).
3. Completing a 30-minute web-based survey about your background (for example, education and experience, knowledge about child development and caregiving, and professional development beliefs and experiences) in fall 2018.
4. Complete a 60-minute web-based survey about your experiences using We Grow Together.

If you wish to participate or if you have any questions, please feel free to call Timothy Bruursema by phone at 800-XXX-XXXX or by email at xxxxxxxx@mathematica-mpr.com. Thank you in advance for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Timothy Bruursema".

The We Grow Together modules are research-based and focus on supporting children’s language development, social-emotional development, or cognitive development. Each module explores several key practices.

We Grow Together includes the following:



- **Brief presentations:** Short narrated presentations will introduce the key practices that caregivers can use when interacting with infants and toddlers to support their development.



- **Handouts:** The handouts are 1- to 2-page documents that provide a summary of key practices. You could share these with colleagues or families to help the entire caregiving team work together in supporting children with these practices.



- **Step-by-step guides and checklists:** These guides and checklists can be used to help you track how you are using a new practice or changing a current practice.



- **Brief videos of caregivers implementing practices:** Our video library shows caregivers using these practices in their everyday care to support children’s development. We encourage you to think about how the caregivers implement these practices and how you can apply the strategies to your practice.



- **Activities and self-reflection exercises:** These exercises encourage you to think about the key practices and consider ways to change or improve practice.



- **Classroom supports:** These supports include handouts, posters, and key rings that provide ongoing reminders of new practices.



- **Progress chart:** These visuals help you track children’s progress in response to the practices.

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Timothy Bruursema
Survey Director

Mathematica Policy Research
1100 1st Street, NE 12th Floor
Washington, DC 20002-4221
Telephone (202) 484-9220
Fax (202) 863-1763
www.mathematica-mpr.com

[MONTH, YEAR]

[Center's Name]

[Address 1]

Address 2]

[City, State Zip]

Dear [CENTER DIRECTOR NAME/ Center Director]:

I am pleased to invite your child care setting (center-based early care and education settings or family child care homes) to be part of an important study of We Grow Together: The Q-CCIIT Professional Development System. We Grow Together is a website that houses a collection of materials, videos, classroom exercises, and aids that are designed to support caregivers (teachers of infants and toddlers in center-based care or in family child care homes) and their professional development providers (e.g., coaches, technical assistance providers, mentors) improve care provided to infants and toddlers.

Study participants will access We Grow Together on a website during the 2018/2019 program year. Training will be provided for professional development providers to use We Grow Together in their work with participating caregivers. We will also provide caregivers with an iPad mini so they can easily access We Grow Together online and use the iPad to video-record and reflect on their interactions with children. Additional information about the study is provided in the brochure included with this letter.

The study of We Grow Together is sponsored by the Administration for Children and Families in the U.S. Department of Health and Human Services and is being conducted by Mathematica Policy Research, an independent policy research organization. Findings from this study will inform improvements to We Grow Together and related efforts to help caregivers support infant and toddler development. Additional information about We Grow Together can be found on the other side of this letter.

A We Grow Together site coordinator will call you soon to discuss the project, answer any questions you might have, and assess whether you have a caregiver and professional development provider who may be interested and eligible to participate. Participation in the study is completely voluntary and all information you share will remain private to the extent permitted by law. If you have any questions in the meantime, please feel free to contact me, either by email at wegrowtogetherstudy@mathematica-mpr.com or by phone toll-free at 844-934-7692 (844-WEGROW2). For more information about Mathematica Policy Research, please visit our website at <http://www.mathematica-mpr.com>. I thank you in advance for your role in this important study.

Sincerely,

The We Grow Together modules are research-based and focus on supporting children’s language development, cognitive development, or social-emotional development. Each module focuses on several key practices. We Grow Together allows for individualization of the professional development for each caregiver, with different materials in the module available for each key practice. Caregivers and professional development providers select a key practice goal and prepare a plan for how to work toward that key practice goal. As caregivers make progress, additional key practices might be added and plans updated.

We Grow Together includes the following:



- **Brief presentations:** Short narrated presentations will introduce the key practices that caregivers can use when interacting with infants and toddlers to support their development.



- **Handouts:** The handouts are 1- to 2-page documents that provide a summary of key practices. Caregivers could share these handouts with colleagues or families to help the entire caregiving team work together in supporting children with these practices.



- **Step-by-step guides and checklists:** These guides and checklists can be used to help caregivers track how they are using a new practice or changing a practice.



- **Brief videos of caregivers implementing practices:** Our video library shows caregivers using these practices in their everyday care to support children’s development.



- **Activities and self-reflection exercises:** These exercises encourage caregivers to think about the key practices and consider ways to change or improve practice.



- **Classroom supports:** These supports include handouts, posters, and key rings that serve as ongoing reminders of new practices that caregivers can try throughout the day.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-XXXX and the expiration date is XX/XX/XXXX.



Timothy Bruursema
Survey Director

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Fax (202) 863-1763
www.mathematica-mpr.com

Dear [PD PROVIDER NAME/ Professional Development Provider],

I am pleased to invite you to be part of an important study of We Grow Together: The Q-CCIIT Professional Development System. We Grow Together is a website that houses various materials, videos, classroom exercises and aids that are designed to support professional development providers (e.g., coaches, technical assistance specialists, mentors) like you who work with caregivers (teachers in center-based care or in family child care homes) serving infants and toddlers.

We would like to invite you to use We Grow Together with one or two of the caregivers you work with and participate in an important study sponsored by the Administration for Children and Families in the U.S. Department of Health and Human Services. Mathematica Policy Research, a nationally recognized, nonpartisan research organization, is conducting the study. Findings will inform improvements to We Grow Together and related efforts to help caregivers support infant and toddler development. Additional information about We Grow Together can be found on the other side of this letter.

All participating professional development providers will:

1. Receive training to learn about We Grow Together in fall 2018. Training modules will be available on the We Grow Together website. The training will take approximately 3 hours a week over four weeks (12 hours total), and will include three webinars to allow for discussion of the training materials. Each training module can be completed at a flexible time and pace over the course of a given week.
2. Complete a 30-minute web-based survey about your background (for example, education and experience, knowledge about child development and caregiving, and professional development beliefs and experiences) in fall 2018.
3. Work with 1 or 2 caregivers using the We Grow Together for approximately five months;
4. Complete a 45-minute web-based survey about your experiences with We Grow Together.

Participation in the study is completely voluntary and all information you share will remain private to the extent permitted by law. If you would like to participate or if you have any questions, please feel free to contact Tim Bruursema by phone toll-free at 844-934-7692 (844-WEGROW2) or by email at wegrowtogetherstudy@mathematica-mpr.com. Thank you in advance for your time and consideration.

Sincerely,

The We Grow Together modules are research-based and focus on supporting children’s language development, cognitive development, or social-emotional development. Each module focuses on several key practices. We Grow Together allows for individualization of the professional development for each caregiver, with different materials in the module available for each key practice. Caregivers and professional development providers select a key practice goal and develop a plan for how to work toward that key practice goal. As caregivers make progress, additional key practices may be added and plans updated.

We Grow Together includes:



- **Brief presentations:** Short narrated presentations will introduce the key practices that caregivers can use when interacting with infants and toddlers to support their development.



- **Handouts:** The handouts are 1- to 2-page documents that provide a summary of key practices. Caregivers could share these handouts with colleagues or families to help the entire caregiving team work together in supporting children with these practices.



- **Step-by-step guides and checklists:** These guides and checklists can be used to help caregivers track how they are using a new practice or changing a practice.



- **Brief videos of caregivers implementing practices:** Our video library shows caregivers using these practices in their everyday care to support children’s development. We encourage caregivers to consider how other caregivers implement these practices and how caregivers might apply these strategies to their own practice.



- **Activities and self-reflection exercises:** These exercises encourage caregivers to think about the key practices and consider ways to change or improve practice.



- **Classroom supports:** These supports include handouts, posters, and key rings that serve as ongoing reminders of new practices that caregivers can use throughout the day.

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We Grow Together:
Q-CCIIT Professional
Development System



Participate in the study of We Grow Together

We Grow Together helps early childhood caregivers (teachers working in center-based care or in family child care homes) support infant and toddler cognitive, language, and socio-emotional development. Caregivers work with their professional development providers (e.g., coaches, technical assistance providers, or mentors) on web-based materials that include brief presentations, handouts, step-by-step guides, checklists, self-reflection exercises, and a variety of other supports.

We are looking for early childhood caregivers of infants and toddlers (less than 36 months old) and their professional development providers to use We Grow Together over the 2018/2019 program year. Participating caregivers will be provided with an iPad mini to access and use the online resources.

Participation in We Grow Together involves:

- Use of We Grow Together for about five months during the 2018/2019 program year for approximately 1.5 hours a week
- Two online surveys: once in fall 2018 and once in spring 2019
- Caregivers will be observed at the early childhood classroom (center-based classroom or family child care home) once in fall 2018 and once in spring 2019.
- Professional development providers will attend an online training (approximately 12 hours) over four weeks to learn how to support caregivers' use of the We Grow Together online resources.

- Caregivers will be provided with an iPad mini, tripod and iPad case to facilitate participation.

What are the benefits of participating?

- The opportunity to learn about evidence-based practices for supporting infants' and toddlers' development and improve caregiving practices.
- Participation will help us improve We Grow Together and help caregivers support the development of infants and toddlers in the future.

The We Grow Together study will give us important information on how to help programs and staff deliver high-quality services that promote positive outcomes for young children.

Mathematica Policy Research and its partners are conducting the We Grow Together study for the Administration for Children and Families in the U.S. Department of Health and Human Services. Mathematica is a nationally recognized, nonpartisan policy research organization that conducts studies in early childhood care and education and other public policy areas.

For information about participating in this study, please contact:

Tim Bruursema
Mathematica Policy Research
wegrowtogetherstudy@mathematica-mpr.com
1-844-934-7692 (844-WEGROW2)

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What is We Grow Together?

We Grow Together is a set of professional development materials that help early childhood caregivers support infant and toddler cognitive, language, and socio-emotional development. Caregivers (teachers of infants and toddlers in center-based care or in family child care homes) work with their professional development providers (e.g., coaches, technical assistance providers, or mentors) on web-based materials that include brief presentations, handouts, step-by-step guides, checklists, self-reflection exercises, and a variety of other supports. The We Grow Together study will give us important information on how to help programs and staff deliver high-quality services that promote positive outcomes for young children.



We Grow Together:
Q-CCIIT Professional
Development System

Who is conducting the Q-CCIIT PD Tools Study?

Mathematica Policy Research is conducting the study under contract to the Administration for Children and Families, U.S. Department of Health and Human Services. Staff members working on the Q-CCIIT PD Tools study have a great deal of experience conducting research in child care and Early Head Start settings and have been fully trained for this study.

If you would like more information about We Grow Together, please contact the survey director, Timothy Bruursema, at Mathematica, by phone at 1-844-934-7692 (844-WEGROW2) or by email at wegrowtogetherstudy@mathematica-mpr.com.



**A Study of We
Grow Together:
The Q-CCIIT
Professional
Development
System**

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Who will participate in We Grow Together?

About 300 early childhood caregivers serving infants and toddlers and their professional development providers will be invited to participate. Participation in the study is completely voluntary.

What do caregivers and professional development providers need to do?

- Use We Grow Together for about five months during the 2018/2019 program year for approximately 1.5 hours a week
- Two online surveys: once in fall 2018 and once in spring 2019
- Caregivers will be observed in their early childhood classroom (center-based classroom or family child care home) once in fall 2018 and once in spring 2019.
- Professional development providers will attend an online training (approximately 12 hours) over four weeks to learn how to support caregivers' use of the We Grow Together online resources.
- Caregivers will be provided with an iPad mini, tripod and iPad case to facilitate participation.

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What kind of information will be collected?

- Information on caregiver-child interactions will be collected during the observations.
- The first survey will ask about participants' background (for example, education and experience, knowledge about child development and caregiving, and professional development beliefs and experiences).
- The second survey will ask about participants' experiences using We Grow Together.
- Information you share will remain private to the extent permitted by law. Individual responses and names will never be associated with or identified in study reports.

What are the benefits of participating?

- The opportunity to learn about evidence-based practices for supporting infants' and toddlers' development and improve caregiving practices.
- Participation will help us improve We Grow Together and help caregivers support the development of infants and toddlers in the future.



APPENDIX E

STUDY PARTICIPANT CONSENT FORMS

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A STUDY OF WE GROW TOGETHER: THE Q-CCIIT PROFESSIONAL DEVELOPMENT SYSTEM
CAREGIVER CONSENT FORM

What is the purpose of the research study?	We Grow Together helps early childhood caregivers (teachers of infants and toddlers in center-based care or in family child care homes) support the development of children between birth and age three. This study will help us to improve We Grow Together in its effort to support caregivers in their interactions with infants and toddlers.
Who is being invited to participate in the research study?	This study will involve 300 pairs of early childhood caregivers and their local professional development providers. Participation is voluntary; refusal to participate in the study will not negatively affect your relationship with your program. Even if you agree to participate in the study, you may withdraw at any time.
When will the research study be conducted?	The study activities will take place between summer 2018 and spring 2019.
What will be asked of staff who agree to participate?	If you agree to participate, we will ask you to (1) allow us to observe your classroom (center-based classroom or family child care home) for approximately 3 hours and complete a brief paper-and-pencil classroom roster in fall 2018 and spring 2019. The observation will help personalize your experience with We Grow Together by suggesting modules that will help you the most; (2) complete a 45-minute web-based survey about your background in fall 2018; (3) work with your professional development provider and use We Grow Together materials for approximately 1.5 hours per week for about five months (the materials are available online). You will also be provided with an iPad mini, tripod and iPad case to facilitate participation; and (4) complete a 60-minute web-based survey about your experiences using We Grow Together in spring 2019. All the information we collect will be used for research and educational purposes only.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-XXXX and the expiration date is XX/XX/XXXX.

Who is conducting the research study?	<p>Mathematica Policy Research and its partners are conducting the study for the Administration for Children and Families in the U.S. Department of Health and Human Services. Mathematica is a nationally recognized, nonpartisan policy research organization that conducts studies in early childhood education and other public policy areas.</p> <p>Additional information about Mathematica is available online at http://www.mathematica-mpr.com.</p>
How will Mathematica protect the privacy of research study participants?	<p>Mathematica is committed to respecting the privacy of everyone who contributes to this study. A code number will be used on all information we collect from you so that you cannot be identified. If you agree to take part in the study, all information you share will remain private to the extent permitted by law. No one from your program will see or hear your individual responses, and your name will never be associated with or identified in study reports. The information we get will be used for research and educational purposes to make We Grow Together better.</p> <p>We have a Certificate of Confidentiality from the National Institutes of Health. The Certificate helps us protect your privacy. This means no one can force the study team to give out information that identifies you, even in court. However, we may need to share your information if it shows a serious threat to you or to others, including reporting to authorities when required by law. The United States government may still request information for an audit.</p>
How can I get more information about the research study?	<p>If you have any questions or would like more information about the study, please contact Tim Bruursema at Mathematica by phone toll-free at 844-934-7692 (844-WEGROW2) or by email at wegrowtogetherstudy@mathematica-mpr.com.</p>

Please read the following statements, check the appropriate box, and complete the bottom section.

- Yes, I wish to participate in this study.** I agree to allow an observer to observe my classroom once in fall 2018 and again in spring 2019. As part of each observation, I will complete a short classroom roster form. I will work with my professional development provider and use We Grow Together tools and materials for approximately five months. I will complete a background survey at the start of the study and a feedback survey at the end of the study. I may withdraw this consent at any time.

I have read this form and have received a copy for my records.

- No, I do not wish to participate in this study.**

I have read this form and have received a copy for my records.

Printed Name _____

Signature _____

Date _____

A STUDY OF WE GROW TOGETHER: THE Q-CCIIT PROFESSIONAL DEVELOPMENT SYSTEM
PROFESSIONAL DEVELOPMENT PROVIDER CONSENT FORM

<p>What is the purpose of the research study?</p>	<p>We Grow Together helps early childhood caregivers (teachers of infants and toddlers in center-based care or in family child care homes) support the development of children between birth and age three. This study will help us to improve We Grow Together in its effort to support caregivers in their interactions with infants and toddlers.</p>
<p>Who is being invited to participate in the research study?</p>	<p>This study will involve 300 pairs of early childhood caregivers and local professional development providers. Participation is voluntary; refusal to participate in the study will not negatively affect your relationship with your program. Even if you agree to participate in the study, you may withdraw at any time.</p>
<p>When will the research study be conducted?</p>	<p>The study activities will take place between summer 2018 and spring 2019.</p>
<p>What will be asked of staff who agree to participate?</p>	<p>If you agree to participate, we will ask you to (1) participate in a professional development provider training to learn about We Grow Together and to support caregivers' use of the system. The training will take place in fall 2018 and will include online modules and webinars; (2) complete a 30-minute web-based survey about your background in fall 2018; (3) work with one or two caregivers and support their use of We Grow Together materials for approximately five months (the materials are available online); and (4) complete a 45-minute web-based survey about your experiences working with the system. All the information we collect will be used for research and educational purposes only.</p>
<p>Who is conducting the research study?</p>	<p>Mathematica Policy Research and its partners are conducting the study for the Administration for Children and Families in the U.S. Department of Health and Human Services. Mathematica is a nationally recognized, nonpartisan policy research organization that conducts studies in early childhood education and other public policy areas. Additional information about Mathematica is available online at http://www.mathematica-mpr.com.</p>

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-XXXX and the expiration date is XX/XX/XXXX.

<p>How will Mathematica protect the privacy of research study participants?</p>	<p>Mathematica is committed to respecting the privacy of everyone who contributes to this study. A code number will be used on all information we collect from you so that you cannot be identified. If you agree to take part in the study, all information you share will remain private to the extent permitted by law. No one from your program will see or hear your individual responses, and your name will never be associated with or identified in study reports. The information we get will be used for research and educational purposes to make We Grow Together better.</p> <p>We have a Certificate of Confidentiality from the National Institutes of Health. The Certificate helps us protect your privacy. This means no one can force the study team to give out information that identifies you, even in court. However, we may need to share your information if it shows a serious threat to you or to others, including reporting to authorities when required by law. The United States government may still request information for an audit.</p>
<p>How can I get more information about the research study?</p>	<p>If you have any questions or would like more information about the study, please contact Tim Bruursema at Mathematica by phone toll-free at 844-934-7692 (844-WEGROW2) or by email at wegrowtogetherstudy@mathematica-mpr.com.</p>

Please read the following statements, check the appropriate box, and complete the bottom section.

- Yes, I wish to participate in this study.** I agree to complete the online professional development provider training. I will work with an early childhood caregiver(s) to support their use of the Q-CCIIT PD Tools and materials for approximately five months. I will complete a survey at the start of the study and at the end of the study. I may withdraw this consent at any time.

I have read this form and have received a copy for my records.

- No, I do not wish to participate in this study.**

I have read this form and have received a copy for my records.

Printed Name _____

Signature _____

Date _____