Appendix C: Informed Consent Form

Local Implementing Agency Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Family Level Assessment and State of Home Visiting – Local Implementing Agency Interview

TITLE:	Family Level Assessment and State of Home Visiting: Phase One Interviews
PROTOCOL NO.:	None
SPONSOR:	Office of Planning, Research, & Evaluation Administration for Children and Families U.S. Department of Health and Human Services
INVESTIGATOR:	Jill Filene, MPH 3033 Wilson Blvd., Suite 650 Arlington, VA 22201 United States
STUDY-RELATED PHONE NUMBER(S):	Jill Filene Melanie Estarziau 1-800-546-3230 (703) 528-3230
SUB-INVESTIGATOR(S):	Melanie Estarziau (703) 528-3230

SUMMARY

This is a research study in collaboration with the Administration for Children and Families, Office of Planning Research and Evaluation (OPRE), and James Bell Associates, an independent research firm. OPRE, in collaboration with the Health Resources and Services Administration (HRSA), has contracted with James Bell Associates to learn more about how families are selected for Maternal, Infant, and Early Childhood Home Visiting (MIECHV) services.

You are being asked to take part in the research study because your program typically has a higher number of families interested in services than it has the capacity to serve. Your participation in the study will include completion of a 60-minute telephone interview. I am going to read the information below before asking for your verbal consent. Please note that you may ask me any questions that you have, or you may contact the individuals I name under 'Questions' to ask any questions you have before deciding to participate in the study.

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to participate.

You should not join this research study until all of your questions are answered. Your verbal agreement to take part in the interview constitutes your consent and agreement to participate in the study.

PURPOSE OF THE STUDY

An important part of the FLASH-V project is talking to MIECHV funded home visiting programs, like yours, to learn about recruitment and enrollment practices. The purpose of the interview is to understand how your home visiting program recruits and enrolls families. In addition, the proposed study will review what the literature says about family characteristics that may relate to prioritization processes in the field.

PROCEDURES

The research team is conducting telephone interviews with a sample of local implementing agencies and centralized intake agencies. If you agree to participate in the study, you will be asked to participate in a telephone interview lasting approximately 60 minutes. During the interview, you will be asked questions about your home visiting program's capacity, incoming referral processes, eligibility assessment practices, and the prioritization of eligible families. If you agree, the phone interview will be audio taped for later review by the research team.

RISKS AND DISCOMFORTS

There are no foreseeable risks involved in participating in this research beyond those experienced in everyday life. You will be asked to respond to questions about your program's processes for receiving incoming referrals, determining program eligibility, and offering enrollment to families. Your decision to participate or not participate will not impact your employment or your program's funding through the Maternal, Infant, and Early Childhood Home Visiting Program. Should you decide to participate, your responses will not impact your employment or your program's funding through the Maternal, Infant, and Early Childhood Home Visiting Program.

BENEFITS

There are no direct benefits to you from participation; however, the research study may provide valuable information to help target services to those who need them most and can benefit most.

PAYMENT FOR PARTICIPATION
You will not be paid for being in this study.

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study.

Privacy
Privacy will be maintained to the degree permitted by the technology used. Your participation in the phone interview involves risks similar to a person's everyday use of the telephone. All information and responses from the interview will be held in strictest privacy. Your data will be stored using private ID numbers. When you complete this interview, your name and contact information will be visible to select members of the research team but will be replaced with a private ID number. The research team will not divulge names or any other identifying information about you to anyone, unless we have received your permission to do so.

If requested, information from this study will be given to the sponsor. This information would not be attributed directly to you. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

The information that the study team collects during the interview and the consent form signed by you may be looked at and/or copied for research or regulatory purposes by:

- the sponsor,

and may be looked at and/or copied for research or regulatory purposes by:

- Western Institutional Review Board® (WIRB®).
- Food and Drug Administration (FDA)

Absolute privacy cannot be guaranteed because of the need to give information to these parties. Information learned in this study may be shared. Your identity will not be disclosed in those presentations. The identity of your program will not be disclosed without prior consent. Presentations may disclose the states and HRSA regions that participated in the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may end your participation at any time by asking to stop the interview. You may also skip any question you do not wish to answer. Your decision will not result in any penalty or loss of benefits to which you or your program are entitled.

SOURCE OF FUNDING FOR THE STUDY
This research study is sponsored by the Administration for Children and Families (ACF), Office of Planning, Research, and Evaluation, Office of Planning, Research, and Evaluation (OPRE) in collaboration with the Health Resources and Services Administration (HRSA).

QUESTIONS
Contact Jill Filene, Principal Investigator, or Melanie Estarziau, Sub-Investigator, at 1-800-546-3230 or (703) 528-3230 for any of the following reasons:

- if you have any questions about your participation in this study,
- if you have questions, concerns or complaints about the research,
- if at any time you feel you have had a research-related problem.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not agree to participate in the study unless you have had a chance to ask questions and have gotten satisfactory answers. By verbally agreeing to complete the interview, you give your consent to join this study.

Centralized Intake Agency Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Family Level Assessment and State of Home Visiting – Centralized Intake Agency Interview

TITLE:	Family Level Assessment and State of Home Visiting: Phase One Interviews
PROTOCOL NO.:	None
SPONSOR:	Office of Planning, Research, & Evaluation Administration for Children and Families U.S. Department of Health and Human Services
INVESTIGATOR:	Jill Filene, MPH 3033 Wilson Blvd., Suite 650 Arlington, VA 22201 United States
STUDY-RELATED PHONE NUMBER(S):	Jill Filene Melanie Estarziau 1-800-546-3230 (703) 528-3230
SUB-INVESTIGATOR(S):	Melanie Estarziau (703) 528-3230

SUMMARY

This is a research study in collaboration with the Administration for Children and Families, Office of Planning Research and Evaluation (OPRE), and James Bell Associates, an independent research firm. OPRE, in collaboration with the Health Resources and Services Administration (HRSA), has contracted with James Bell Associates to learn more about how families are selected for Maternal, Infant, and Early Childhood Home Visiting (MIECHV) services.

You are being asked to take part in the research study because your agency implements a centralized intake that refers families to one or more MIECHV-funded home visiting

programs. Your participation in the study will include completion of a 60-minute telephone interview. I am going to read the information below before asking for your verbal consent. Please note that you may ask me any questions that you have, or you may contact the individuals I name under 'Questions' to ask any questions you have before deciding to participate in the study.

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to participate.

You should not join this research study until all of your questions are answered. Your verbal agreement to take part in the interview constitutes your consent and agreement to participate in the study.

PURPOSE OF THE STUDY
An important part of the FLASH-V project is talking to centralized intake systems that refer families to MIECHV funded home visiting programs, like yours, to learn about recruitment and referral practices. The purpose of this interview is to understand how your centralized intake system recruits and refers families to home visiting programs. In addition, the proposed study will review what the literature says about family characteristics that may relate to prioritization processes in the field.

PROCEDURES
The research team is conducting telephone interviews with a sample of local implementing agencies and centralized intake agencies. If you agree to participate in the study, you will be asked to participate in a telephone interview lasting approximately 60 minutes. During the interview, you will be asked questions about your centralized intake system's resources for families, incoming referral sources, referral assessment practices, and outgoing referral protocols. If you agree, the phone interview will be audio taped for later review by the research team.

RISKS AND DISCOMFORTS
There are no foreseeable risks involved in participating in this research beyond those experienced in everyday life. You will be asked to respond to questions about your centralized intake system's resources for families, incoming referral sources, referral assessment practices, and outgoing referral protocols. Your decision to participate or not participate will not impact your employment or your agency's funding through the Maternal, Infant, and Early Childhood Home Visiting Program. Should you decide to participate, your responses will not impact your employment or your program's funding through the Maternal, Infant, and Early Childhood Home Visiting Program.

BENEFITS
There are no direct benefits to you from participation; however, the research study may provide valuable information to help target services to those who need them most and can benefit most.

PAYMENT FOR PARTICIPATION
You will not be paid for being in this study.

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to be in this study.

Privacy
Privacy will be maintained to the degree permitted by the technology used. Your participation in the phone interview involves risks similar to a person's everyday use of the telephone. All information and responses from the interview will be held in strictest privacy. Your data will be stored using private ID numbers. When you complete this interview, your name and contact information will be visible to select members of the research team but will be replaced with a private ID number. The research team will not divulge names or any other identifying information about you to anyone, unless we have received your permission to do so.

If requested, information from this study will be given to the sponsor. This information would not be attributed directly to you. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study.

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and may be looked at and/or copied for research or regulatory purposes by:

- Western Institutional Review Board® (WIRB®).
- Food and Drug Administration (FDA)

Absolute privacy cannot be guaranteed because of the need to give information to these parties. Information learned in this study may be shared. Your identity will not be disclosed in those presentations. The identity of your agency will not be disclosed without prior consent. Presentations may disclose the states and HRSA regions that participated in the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may end your participation at any time by asking to stop the interview. You may also skip any question you do not wish to answer. Your decision will not result in any penalty or loss of benefits to which you or your program are entitled.

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- if you have any questions about your participation in this study,
- if you have questions, concerns or complaints about the research,
- if at any time you feel you have had a research-related problem.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

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WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not agree to participate in the study unless you have had a chance to ask questions and have gotten satisfactory answers. By verbally agreeing to complete the interview, you give your consent to join this study.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for this information collection is 0970-0356 and the expiration date is 03/31/2018.