OBTAINING CONSENT FOR LOCAL EVALUATIONS

Obtaining Consent

Obtaining voluntary informed consent is a legal requirement for all research that involves human subjects. A consent form should inform potential participants about the study, their rights, the study protections in place (such as how privacy is protected), and the benefits and risks of participation. Each grantee must seek approval of its consent form by an Institutional Review Board (IRB) before it is used for collecting performance measures or other local evaluation data. The IRB will review and provide feedback about the consent form to ensure that the language accurately represents the aims of the study, provides the necessary protections, and can be clearly understood by study participants.

Information about the FaMLE Cross-Site Project for Consent Forms

Each grantee's consent form may vary depending on its specific study goals and data collection efforts. Information on the consent form may depend, for instance, on who is collecting data, the timing of collection, and whether consent is being obtained for those participating in the program or also from members of a comparison group (who are not participating in the program being studied). The consent forms also reflect the specific requirements of the grantee's state and their IRB. Among other topics, the consent form must provide information about the aims, purpose, and scope of the local evaluation.

Although the consent forms should be tailored to each grantee's specific situation, they should have the following features:

- Use language that can be easily understood by the people participating in the study
- Be brief and not add an unjustifiable time burden on the participant
- Include information on the Fatherhood and Marriage Local Evaluation (FaMLE) and Cross Site Project

Participants will not be asked to sign a separate consent form to give permission to participate in the FaMLE Cross-site Project. Instead, if the participant consents to the grantee's local study, they also grant permission for the FaMLE Cross-site Project, because it will be explained on the same form.

Below is the information grantees should include in their consent forms about the FaMLE Cross-site Project. Grantees should adapt the language below for their consent forms to meet their own state and IRB requirements.

- Each grantee is conducting an independent local evaluation, but also contributing data to a larger study (the Fatherhood and Marriage Local Evaluation [FaMLE] and Cross-Site Project) sponsored by the U.S. Department of Health and Human Services and conducted by Mathematica Policy Research.
- The FaMLE Cross-Site Project will combine data across grantees to learn more about how the programs work. This will involve analyzing data collected by OFA grantees across the nation to provide information about the services families received and how the families fared.
- Data about participating parents, families and others will be stored in the FaMLE Cross-site database maintained by Mathematica. Any data that could identify a participant will be kept private unless specified or required by law.

- Findings from the FaMLE Cross-site Project will be included in reports to the U.S. Department of Health and Human Services. Findings may also be disseminated at professional conferences, and in journal articles, or other research venues. The FaMLE Cross-site team will follow strict rules to protect the privacy of participants. The study team will never disclose any personal information that would identify participants in any public report written for the project or in other dissemination activities. Reports will use aggregate data only and will never discuss specific individuals.

- Mathematica will destroy the data it has stored on the FaMLE Cross-site Project five years after the conclusion of the project.

More Information about the Protection of Human Subjects

Sources containing additional information about protecting the rights of human subjects:

- U.S. Department of Health & Human Services, Informed Consent – FAQs: http://answers.hhs.gov/ohrp/categories/1566
- U.S. Department of Health & Human Services, Tips on Informed Consent: http://www.hhs.gov/ohrp/policy/ictips.html
- National Science Foundation, Human Subjects: http://www.nsf.gov/bfa/dias/policy/human.jsp

For more information or assistance on informed consent, IRB procedures, or program and study enrollment practices, contact your federal program specialist (FPS) or see the FaMLE cross-site evaluation website (www.famlecross-site.info).