MATHEMATICA
Policy Research

Guidance for Institutional Review Board (IRB) Approval of Healthy Marriage and Responsible Fatherhood Grantee Activities

April 20, 2016

Submitted to:
Administration for Children and Families
7th Fl., 901 D St., SW
Washington, DC 20024
(202) 260-2242
seth.chamberlain@acf.hhs.gov
Project Officer: Seth Chamberlain
Contract Number: HHSP23320095642WC/HHSP23337050T

Submitted by:
Mathematica Policy Research
1100 1st Street, NE
12th Floor
Washington, DC 20002-4221
Telephone: (202) 484-9220
Facsimile: (202) 863-1763
Project Director: Sarah Avellar
Reference Number: 40286.F65

CONTENTS

BACKGROUND: READ THIS FIRST

This guidance provides an overview of the IRB process, informed consent, and data security for grantees who are required to pursue IRB review of their HMRF program activities.

1. Background

What is an IRB? IRBs, or Institutional Review Boards, are administrative bodies or committees whose function is to conduct an ethical review of proposed research to assure the protection of the rights and welfare of human research subjects. They independently review research projects prior to projects beginning. *The purpose of an IRB review is to ensure that human research subjects are not harmed – that is, to protect the rights and welfare of humans*.

What is IRB approval? When an IRB determines that the research, as designed, will not harm human research subjects, the IRB approves the project to begin. In order to obtain approval, some IRBs will require researchers to demonstrate stronger protections for human research subjects.

DHHS IRB determination regarding performance measures. Each Office of Family Assistance (OFA) Healthy Marriage and Responsible Fatherhood (HMRF) grantee is required to collect, store, and report data on standardized performance measures using a management information system called nFORM (Information, Family Outcomes, Reporting, and Management). The Department of Health and Human Services (DHHS) considered whether IRB review was necessary for collecting performance measures using nFORM. Because HMRF grantees will use these performance measures for program management, DHHS determined that the data collection and reporting activities associated with the performance measures are not subject to the federal regulations governing IRB review and approval. DHHS is therefore not requiring HMRF grantees to obtain approval from an IRB for these activities.

Requirement for all grantees to review rules of their governing bodies to determine whether IRB approval is necessary. Even though DHHS has determined that performance measures collected using nFORM do not require IRB review, all HMRF grantees must still review the rules of their governing bodies to determine whether they are otherwise required to obtain IRB approval to enroll clients in their programs and/or to collect client data, including performance measures.

In some cases, governing bodies such as universities or local governments may still require IRB review and approval even though DHHS is not requiring it.[1] In addition, some grantees will be conducting their own local evaluations of their grant programs; these grantees will almost certainly be required to obtain IRB approval for local evaluation activities, including obtaining informed consent from their program clients to participate in the local evaluation.

[1] A subset of HMRF grantees have been selected for participation in one of two federal evaluations; these evaluations are called Building Bridges and Bonds (B3) and Strengthening Relationship Education and Marriage Services (STREAMS). Grantees selected for B3 and STREAMS will still collect performance measures data; those grantees will work with the B3 and STREAMS contractors on IRB review procedures.

IRB approval already obtained for cross-site analyses. As part of a contract directed by ACF, Mathematica Policy Research (Mathematica) will conduct cross-site analyses of the 90 HMRF grantees using the data stored in nFORM for the Fatherhood and Marriage Local Evaluation (FaMLE) and Cross-Site Project. Mathematica has received approval from an IRB, the New England Independent Review Board (NEIRB), to conduct these analyses. There are two other salient points:

- *Waiver of consent*. NEIRB also gave Mathematica a "waiver of consent": this means the IRB has approved Mathematica to access client data in nFORM without client consent.
- *Materials related to this IRB approval are available for grantees*. Mathematica's role and its waiver of consent are described in this document (see section B.4 and Appendix A) so that grantees can incorporate relevant information into their IRB applications, as needed.

The remainder of this document provides guidance for grantees that have determined that they must obtain IRB approval.

2. Organization of this document

This document has the following sections:

- Section A describes the purpose and process of an IRB review.
- Section B describes the purpose and process of obtaining informed consent from research subjects.
- Section C describes the special considerations that grantees serving youth and incarcerated individuals may need to follow.
- Section D includes information about data security measures to protect the privacy of grantee research subjects.
- Section E outlines the process for obtaining a Federalwide Assurance, if applicable.
- Section F lists specific sources that grantees can consult for additional information about IRBs and the consent process.

A. PURPOSE AND PROCESS OF AN IRB REVIEW

The regulations governing research funded or supported by DHHS, including the DHHS Policy for the Protection of Human Research Subjects, are found in the Code of Federal Regulations (CFR), specifically at 45 CFR Part 46 (see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). These regulations, otherwise known as the "Common Rule", require IRB review of all research activities covered by the DHHS policy. As mentioned, DHHS has determined that HMRF grantee collection of performance measures in nFORM is not subject to the Common Rule.

If grantees determine that their governing body requires them to obtain IRB approval for their HMRF program activities the grantee must work with an IRB that will review its research plans, IRBs often operate within public or private non-profit institutions, such as universities, state agencies, and hospitals. If the HMRF grantee is conducting a local evaluation, the local evaluator might have an existing relationship with an IRB. Grantees should confer with their local evaluators, if applicable, to determine whether a relationship with an IRB is already in place and whether it is possible to work with the local evaluator's IRB. In some cases, it might also be necessary for grantees to secure IRB clearance through the state's IRB or research review board in addition to the evaluator's IRB. If a grantee needs to locate an IRB to work with, they can refer to a national list of registered IRBs online at: http://ohrp.cit.nih.gov/search.

If grantees determine that they are required to obtain IRB approval for their HMRF program activities, they should consult with their IRB to determine what materials must be submitted.

In general, most IRB submissions include:

a) **A description of the proposed research,** which typically includes descriptions of the scope of work, funding level for the research, use of respondent incentives, and ways in which data will be used or reported. Most IRBs have protocol forms that require specific data elements. Consult with your IRB to obtain the necessary forms.

b) **A consent form for research subjects** to sign or affirm explaining what it means to participate in the study (see Section B of this document). The form should contain specific consent language as required by the IRB.

c) **Data collection materials** for data collection activities, such as surveys, interview protocols, and focus group protocols.

d) **Information about the proposed research subjects,** including whether they are from vulnerable populations.[2] For example, some HMRF grantees may provide services to pregnant women, youth, or incarcerated individuals.

[2] Vulnerable populations include children and minors; decisionally-impaired persons; elderly and aged persons; international research subjects; minorities (including women); pregnant women, fetuses, and neonates; incarcerated individuals; students and employees; terminally ill patients; and traumatized and comatose patients.

Some IRBs also require the following:

e) **Resumes or CVs** of staff involved in research activities.

f) **Conflict of interest forms** disclosing potential conflicts of interest among research staff.

g) **A data security plan** detailing how the study will protect any personally identifiable information (PII) gathered.

h) **Proof of training in human subjects research** for the principal investigator leading the project. Free training in human subjects research is available through the National Institutes of Health (see https://phrp.nihtraining.com/users/login.php). Your organization may also be a part of the Collaborative Institutional Training Initiative (CITI), which provides online training materials for a fee (see https://www.citiprogram.org/).

B. OBTAINING INFORMED CONSENT FROM RESEARCH SUBJECTS

"Informed consent" is the process by which appropriate information is provided to a potential research subject so that he or she can decide whether to take part in the research. Human research subjects must *voluntarily* provide consent to be involved in the research. Obtaining informed consent is a legal requirement for federally funded research involving human subjects unless the study is exempt or an IRB issues a waiver of informed consent.

DHHS has determined that collecting performance measures in nFORM is not subject to the Common Rule, but grantee governing bodies may still require IRB approval. Because grantees will have varied requirements, or no requirements, regarding informed consent, nFORM does not include a process for consent or documentation of consent. As applicable, grantees will need to develop their own consent and documentation procedures outside of nFORM.

A consent form explains the nature of the potential research subject's involvement in the study and ensures that his or her rights are explained and respected. It describes the potential risks and benefits of participation, the option of declining to participate, and the ability to withdraw from the study at any time.

The IRB will review the draft consent form as part of the IRB submission package and provide feedback to ensure that the language accurately represents the study procedures, clearly explains what is expected of research subjects, and can be easily understood by potential research subjects.

Consent is usually obtained in one of two ways—in writing or verbally. Written consent is the default form of consent. The IRB may waive the need to obtain a written, signed consent, but may still require study participants to be informed about the study, if: (1) the study presents no more than minimal risk to research subjects *and* involves no procedures for which written consent is normally required outside of the research context; and (2) the study cannot feasibly be carried out without a waiver because extremely sensitive information is collected, and the only paperwork that links the subject to the research study is the consent document. Under these conditions, the research subject receives the same information required in a written consent form, but his or her signature is not required by the IRB.

For written consent, at a minimum, the consent form should contain spaces for the research subject's signature and printed name; it may also have spaces for the research subject's address, phone numbers, and date of birth, if needed. After reading (or being read) the consent form, research subjects fill in the required information and sign their name as an indication of their willingness to participate in the study. The signed portion is usually retained by study staff, and research subjects are given a copy of the information on the consent form.

Verbal consent follows the same requirements as written consent. Verbal consent is often used for data collection by phone, with the interviewer using a computer to enter the potential research subject's data or recording data on a paper form. In these cases, the interviewer reads the consent statement to the potential research subject and asks, "Do you have any questions about anything I just told you?" After answering any questions, the interviewer may say, "Can we start now?" or "Let's get started." Typically, the interviewer records the time and date the

research subject consented, as well as the research subject's name or ID number if that information has not already been collected. Sometimes interviewers will tape record the consent.

Both written and verbal consent are *active* consent processes because they require the research subject to explicitly agree to be part of the research. But sometimes researchers use *implied/passive consent*, requiring research subjects to explicitly refuse to be a part of the study rather than actively give their consent. Implied/passive consent means that the research subject agrees to participate, if he or she does not explicitly refuse to participate, but does not waive any of his or her rights as a research subject. This type of consent is usually reserved for studies that are found to be completely innocuous by the IRB. It is often used in schools that send forms to parents asking them to allow their students to participate in various activities. Typically these are consent processes where parents who do not respond are considered as consenting.

1. Elements of a consent form

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 from members of a comparison group (who are not participating in the program being studied). Consent forms should also reflect the specific requirements of the grantee's IRB and applicable state laws.

Typically, IRBs require the following elements on consent forms:

- Name of the study's sponsor.
- The purpose of the study.
- Specific information on all activities included under the consent request for the duration of the study, such as surveys, focus groups, and interviews; the collection of administrative records; and any other data collection activities.
- A confidentiality statement and explanation of how the research subject's personally identifiable information will be protected. This would include a description of the federal Certificate of Confidentiality, if one has been obtained by the researchers.[3]
- Potential risks, harm, discomfort, or inconvenience caused by participation in the study.
- Possible benefits of participation.
- A description of the voluntary nature of the study and the right of the research subject to withdraw at any time. This description should indicate that research subject data provided prior to withdrawal can still be used by the study.
- A description of any compensation, such as incentives.
- The information for a contact person or people who can answer questions about the study or the rights of research subjects; ideally, this would include a toll-free number for research

[3] The Certificate of Confidentiality prevents researchers from being compelled to disclose confidential information about research subjects. For more information please see http://www.hhs.gov/ohrp/policy/certconf.html.

subjects to call to obtain more information. A contact person from the local evaluator might also be listed. Grantees should consult with their IRBs about the specific contacts to include on the consent form.

- Documentation that consent was given; for example, space for the research subject's printed name, signature, and the date that consent was obtained.

An example of a consent form from a recent Mathematica study is attached in Appendix A.

2. Best practices for obtaining consent

The following best practices can help ensure that the research subject fully understands the request for consent, IRB requirements are followed, and privacy is maintained:

- **Make the document clear and concise** by using simple, clear wording that research subjects will be able to understand. Use informative language to describe the study, and aim to minimize the burden on research subjects by keeping the consent form short, generally one to two pages.
- **Write the document in the primary language and reading level of the target population.** In cases where grantees are serving non-English speaking research subjects, grantees will need to translate the consent forms into the necessary language(s). Grantees can also use the Flesch Kincaid scale, which is included as a component of Microsoft Word, to assess the reading level of the consent forms.
- **Describe the study, the sponsor, and how the research is expected to help the research subjects and community.** Examples include:
  - A frequently asked questions document
  - The link to a study website
  - A study-specific brochure
  - Supporting statements from key stakeholders or community leaders
- **Use only IRB-approved materials** when interacting with study research subjects.
- **Provide research subjects with a copy of the consent form** for their own records.
- **Store completed consent forms in a locked and secure location** so that the identity of research subjects is not revealed to anyone outside the research team; ensure that research subjects' identities are protected when forms are collected and/or transmitted. Appropriate storage of completed consent forms is important if IRBs require submitting completed consent forms at the conclusion of the study.

3. Parental/guardian consent and youth assent

For many youth-serving programs, parents/legal guardians must provide *consent*, and youth must provide *assent*.

The age of consent is the age of majority, which is 18 years old in most states, but can vary. Grantees should follow the guidance provided by their state. When working with youth who cannot provide consent because they have not yet reached the age of majority, parents or legal guardians must typically provide consent for them. Which adults may consent on behalf of a child is also a matter of state and child welfare agency policy and varies across states. The process of obtaining consent may be simple in some states, but very complicated in others. Grantees should confer with their state child welfare agencies to determine the rules and regulations related to consent, specifically:

- **Who can provide consent for the minor?** It depends on who has legal authority for the youth. It could be a parent, a caregiver, a casework supervisor or area manager, a legal guardian, or a judge. Foster parents often are not able to provide consent for youth in their care; however; their ability to do so varies based on the state and specific circumstances of the request.
- **Does the court need to be involved in the consent process?** Some states require judicial involvement for youth in state care.
- **Do the rules for consent change depending on whether or not the youth is currently in state custody?** Some states and IRBs have special precautions in place for youth with an open child welfare case, even if the youth is over age 18.
- **Are homeless minors allowed to provide their own consent?** Some states allow homeless minors to provide their own consent under some circumstances, while others do not.

After appropriate consent is obtained for a youth to participate in the study, the minor must also provide assent, or agreement, to participate in the study. Simply securing parental or guardian consent is not sufficient for youth participation in the study. Likewise, securing youth assent without having parental or guardian consent does not grant the youth permission to participate in the study.

Consider the following tips when developing a youth assent form:

- **Use age-appropriate language** that clearly conveys the major elements of consent described above and is written at an appropriate reading level.
- **Ask youth to assent actively** to help them understand the research and make an active decision to agree to participate.
- **Request contact information for tracking** when the youth are filling out the assent form so they can be located for subsequent data collection efforts, if this will be needed for the grantee's local evaluation.
- **Assure confidentiality of their identity and their responses** and remind youth that they can skip questions in the data collection as they wish. Indicate that they can stop their participation in the study at any time if they feel uncomfortable.

4. Waivers of consent

IRBs can waive informed consent requirements if the research meets four conditions:

1. It involves no more than minimal risk to the research subjects.
2. The waiver will not adversely affect the rights and welfare of the research subjects.
3. The research could not practicably be carried out without the waiver or alteration of consent.
4. Whenever appropriate, the research subjects will be given additional pertinent information after participation.

Grantees who would like to receive a waiver of consent must apply for it from the IRB; waivers are not automatically granted by IRBs. The likelihood of being granted a waiver depends on the research protocol and the requirements of the IRB. Grantees should consult with their IRB and local evaluators to determine whether a waiver is an option.

Waivers of parental consent can in some circumstances be granted if the IRB determines that, due to the study conditions or target population, permission is not a reasonable requirement to protect the research subjects—for example, for studies of homeless youth. In these rare circumstances, parental consent may be waived.

As noted, Mathematica received a waiver of informed consent from NEIRB for the FaMLE Cross-Site Project. This waiver means that Mathematica can access each grantee's client data in nFORM without consent from the grantee's clients. A copy of the NEIRB approval letter is attached in Appendix B.

C. SPECIAL CONSIDERATIONS FOR WORKING WITH VULNERABLE POPULATIONS

The Common Rule regulations on human subjects research, specified at 45 CFR Part 46, require special considerations when working with vulnerable populations. Vulnerable populations are defined in the Common Rule as children and minors; decisionally-impaired persons; elderly and aged persons; international research subjects; minorities (including women); pregnant women, fetuses, and neonates; incarcerated individuals; students and employees; terminally ill patients; and traumatized and comatose patients. Because many HMRF grantees will serve clients from vulnerable populations, and may conduct research involving these clients, grantees and their local evaluators should carefully consider whether and how research would need to be designed to protect the rights and welfare of these vulnerable populations. Grantees need to consider the following issues:

- **Ensure that participation is not coerced** by making sure potential research subjects understand that taking part in the study is voluntary. Further, it is important to understand that coercion can take many forms. For example, incentives can be too high, thus incentivizing potential research subjects to say yes to the study not because they want to participate, but because the cost of not participating is too high. The environment could also be coercive. For example, if potential research subjects are not allowed to decline to participate privately, and instead are asked to do so in front of other people, that environment may be coercive.
- **Protect research subjects' confidentiality,** which is perhaps one of the most vital requirements of any study. Researchers must protect research subjects' personally-identifiable information (PII) unless disclosure is required by law. For example, state laws regarding the mandatory reporting of child abuse vary. Grantees/local evaluators must notify research subjects in the consent form about any circumstance in which the grantees/local evaluators would be required to disclose their research subjects' PII. Grantees should be aware of all applicable local and state regulations regarding any mandatory reporting obligations that so that these do not conflict with the confidentiality assurances given to study subjects.
- **Consider whether waivers of parental consent are necessary**. Some youth may not be able to identify an adult who can provide consent for their participation in the study. In this case, grantees should work closely with their IRB and local evaluator (if applicable) to determine if parental consent can be waived or if nonparental adults, such as foster parents or other relatives, can provide consent. Youth may also identify themselves as emancipated minors who can lawfully consent for themselves. Grantees should develop a plan for documenting emancipation and seek guidance from their IRBs on the documentation an emancipated youth is required to provide.
- **Develop data collection protocols for incarcerated research subjects** that adhere to prison regulations. Prisons may restrict the way incarcerated individuals can participate in a study. For example, it may not be possible to bring written materials or electronic devices (laptops or tablets) into a prison facility. In such a situation, the grantee and its local evaluator must devise alternative options for obtaining consent and collecting data from incarcerated individuals. These might include allowing incarcerated individuals to consent to

participate and provide data by telephone with a grantee staff person. Further, the IRB may require that the consent language clearly indicate that study participation will not affect the treatment or parole of incarcerated individuals. Grantees serving incarcerated individuals should consult with their IRBs about the specific requirements for obtaining consent and collecting data from incarcerated individuals.

D. DATA SECURITY

Some IRBs may also require grantees to describe the security of the nFORM system which grantees will use for collecting, storing, and reporting on performance measures and service data. A formal data sharing and user agreement established between each grantee and Mathematica describes the data that grantees will capture in nFORM and provide to Mathematica for cross-site analysis, as well as how Mathematica will protect the grantee data in nFORM throughout the grant.

Grantees should consider when and how information will be collected, and ensure that no one outside their own HMRF grant team can access personally-identifiable information (PII) in any form. All authorized grantee and/or local evaluator staff should receive training on data security best practices before collecting client data.

Grantees should store all study materials, including paper records and computer systems, in a locked office or room that only authorized staff are able to access. Paper materials containing PII should be stored in locked filing cabinets. Likewise, laptops, tablets, and desktop computers used to collect and store information about clients should be password protected and stored in locked locations.

Please also see Appendix C in this document for further ways to protect PII.

After all data collection and analysis under the HMRF grants is complete, grantees should cross-shred all paper documents containing PII. All electronic documents should be deleted using a security tool such as Eraser, which completely removes sensitive data from the user's hard drive. Some IRBs might mandate a specific amount of time for which data collection materials should be kept. Grantees should be sure to abide by the requirements of their IRB and keep data secure until it can be destroyed.

To protect data security, nFORM is hosted and maintained by Mathematica and all data are stored on secure servers behind Mathematica's firewalls. Safeguards used to protect sensitive data stored within the nFORM system are consistent with the Privacy Act, the Health Insurance Portability and Accountability Act, the Federal Information Security Management Act, and National Institute of Standards and Technology security and privacy standards. Identifiable data will be encrypted at all times (in transit and at rest) using cryptographic modules that are compliant with Federal Information Processing Standard 140-2, and will be securely deleted from the system when no longer needed. Access to the nFORM system will be controlled via multifactor authentication mechanisms and will be limited for both grantee and Mathematica staff. A grantee will only be able to view and report data for its own program.

E. FEDERALWIDE ASSURANCE

Grantees may determine that they must obtain a Federalwide Assurance (FWA). Through an FWA, an institution commits that it will comply with the Common Rule. An FWA through the Office for Human Research Protections (OHRP) is required for all research that DHHS conducts or supports.

After completing the process to obtain an FWA, an organization will receive a unique FWA number from OHRP. IRBs may require the FWA number for their review process. More information is available online at http://www.hhs.gov/ohrp/assurances/assurances/index.html#.

F. ADDITIONAL INFORMATION ABOUT IRBS AND THE CONSENT PROCESS

For more information on IRB procedures and informed consent, grantees may refer to the following sources:

- The U.S. Department of Health and Human Services (DHHS). "Informed Consent FAQs." This site provides answers to frequently asked questions about informed consent. (http://www.hhs.gov/ohrp/policy/faq/informed-consent/index.html).
- The U.S. Department of Health and Human Services (DHHS). "Tips on Informed Consent." This site also provides tips on obtaining informed consent. (http://www.hhs.gov/ohrp/policy/ictips.html).
- The National Science Foundation. "Human Subjects." This website provides information about human subjects protection and IRB review. (http://www.nsf.gov/bfa/dias/policy/human.jsp).
- Social Innovation Fund. "Working with Institutional Review Boards" includes tips for selecting an IRB, when to consult with one, and suggestions for working together. (http://www.famlecross-site.info/pdfs/SIF_IRB_Tips.pdf).
- National Healthy Marriage Resource Center. "Marriage and Relationship Education Program Development and Management Manual." August 2013. Chapter 12 of this manual ("Evaluation") briefly discusses the need for IRB approval and the role of IRBs in ensuring research subject protections. (http://www.healthymarriageinfo.org/resource-detail/index.aspx?rid=4025).
- San Diego State University. This website provides a tutorial and case study examples about maintaining confidentiality of data. The "Handling Information" section of the tutorial briefly discusses important issues such as proper documentation of the consent process, secure storage, informed consent, and other precautions that should be taken when conducting research with human subjects. (http://ori.hhs.gov/education/products/sdsu/handling.htm).

APPENDIX A

EXAMPLE CONSENT FORM

MATHEMATICA
Policy Research, Inc.

OMB Control No: 0970-0273
Expiration Date: 03/31/2008

BUILDING STRONG FAMILIES STUDY

THE BUILDING STRONG FAMILIES PROGRAM

Building Strong Families helps unmarried couples with a new baby learn how to get along better with each other and be better parents for their children. Couples will learn about marriage, communication, trust, affection, dealing with stress, and relating to their baby. They also can get referrals to employment assistance, health care and mental health services, and other needed services.

WHAT IS THE STUDY ABOUT?

Building Strong Families is part of a national study being conducted by a research team from Mathematica Policy Research, Inc. based in Princeton, New Jersey. The study is sponsored by the U.S. Department of Health and Human Services. The study is being done to learn more about which services help couples build better relationships and healthy marriages.

If you participate in this study, we will ask you some questions about yourself, the baby you are expecting or have just had, your living arrangements, your employment, how you are feeling about yourself, and how you are feeling about your relationship with the other parent of your child. Later, the research team will interview both of you two or three times. The researchers may also ask you for permission to do some activities with your child to see how your child is growing up. The interviews will be about how things have gone for you as a couple and as parents. Your answers could help in providing services in the future to other parents like you, who want to learn more about relationships, marriage, and being parents.

If you agree to be part of the study, it means you are giving permission for the Building Strong Families program to share information with the research team about services you received, and for state and local agencies to release information to the research team about earnings and benefits you might get from government programs.

The Building Strong Families program will not have room for all couples who might be eligible. If you want to be in the program and agree to be in the study, a lottery will decide whether you can be in the program. You can go through this lottery and have a chance to be in the program only if both parents agree. Whether you are selected or not, you will still be part of the study. If you are not selected for Building Strong Families, you can still receive other services in your community.

YOUR ANSWERS WILL BE KEPT PRIVATE

Everything you tell the research team will be kept strictly confidential and will not be shared with any agency. Only the researchers will be able to see information you give them and nothing will ever be said about you as an individual. Instead, information about you will be combined with information about everybody else in the study, so the researchers can say things like “30 percent of couples in the program have two children.”

YOUR PARTICIPATION IS VOLUNTARY

We hope that you will want to be in the Building Strong Families study, but you only have to be in the study if you want to. However, if you do not want to participate in the study, you and the other parent of your baby cannot receive Building Strong Families services.

Consent to Participate in Building Strong Families Study

I have read the information on the reverse side.

- β *I understand that the Building Strong Families program will not have space for all couples, and I agree to participate in a lottery to determine whether we can receive services. I understand that if we cannot receive Building Strong Families services, we can still get other program services in my community.*

- β *I agree to complete an information form now, and to participate in later interviews. I understand that I may be asked some questions about personal things, but I will not have to answer any questions that make me feel uncomfortable. I understand that later I may be asked permission for researchers to include my child in the study as well.*

- β *I give permission for the study team to collect information on Building Strong Families services I receive. I give permission for state and local agencies to release information to the study team about earnings and benefits I may receive from government programs*

- β ***I understand that all information will be kept strictly confidential**, except as required by law or I request otherwise in writing. Only the research team will be able to look at the information I give. The information will be used only for the study. However, I do understand that if a person on the study team observes child abuse, it must be reported.*

- β *I can call [redacted] collect at [redacted] at Mathematica Policy Research, Inc. to get an answer about any questions I may have.*

Name of Participant *(Printed)*

Signature of Participant | Date

Name of Person Administering this Form *(Printed)*

Signature of Person Administering this Form | Date

APPENDIX B

NEIRB APPROVAL OF FAMLE CROSS-SITE PROJECT

A WIRB-Copernicus Group Company

October 14, 2015

Sarah Avellar, PhD
Mathematica Policy Research
1100 First Street NE #1200
Washington, DC 20002

IRB#: 15-369
Sponsor Protocol Number: HHSP23320095642WC/HHSP23337050T
Study Title: "Fatherhood and Marriage Local Evaluation (FaMLE) and Cross-Site Project"

Notification of Study Approval

This is to inform you that New England Independent Review Board (NEIRB) has approved the above-referenced research protocol and the participation of the above-referenced investigative site in the research.

Reviewed by: Expedited Review (Thursday Board)
Date(s) of Review: 10/14/2015
Expedited Review Category: (**5**) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Action Date (first day of study approval period): **10/14/2015**
End Approval Date (last day that the study is approved): **10/13/2016**

Waiver of Consent Approval: NEIRB has approved a Waiver of Informed Consent, in accordance with NEIRB's standard operating procedures.

Continued approval is conditional upon your compliance with the following requirements:

- Compliance with all aspects of NEIRB's Investigator Responsibilities (available at www.neirb.com).
- The study cannot continue after the End Approval Date unless re-approved by NEIRB. A Study Continuing Review Report must be completed and returned to NEIRB prior to the end date of the approval period.
- Compliance with all federal, state and local laws pertaining to this research.
- Any and all necessary FDA approvals must be received prior to your initiation of the trial.

Please contact NEIRB with any questions about this determination.

Copy: NEIRB study file

APPENDIX C

PERFORMANCE MEASURE AND DATA COLLECTION LOGISTICS

2015 RFHM Grantees
Performance Measure and Data Collection Logistics

Purpose of this document. This is a guidance document which provides best practice approaches to logistics around collecting performance measure data. This document is in development and will be updated. ***Not every RFHM situation is addressed in this document. In all situations, we suggest developing a comprehensive plan for your specific programming context along with your FPS.***

General principles:

1. **Privacy: client privacy is paramount**. Use every effort to protect your clients' privacy:
    a. Identify places in your data collection processes (or your partners') where privacy could be compromised. For example: Will clients tell you private information in a place where they could be overheard? Will you use any paper files, even just attendance rosters, and is that paper quickly locked safely or destroyed? When you go onto nFORM, will anyone be able to look over your shoulders?
    b. Strategize on ways to eliminate and/or reduce risk.
    c. Create a plan for what you will do if client privacy is compromised.
    - ***Please see the Appendix for important approaches to protecting personally identifiable information (PII).***
2. **Consistency: data should be collected the same way every time**. Think about how you will do intake, distribute tablets/computers for client surveys, and enter participation information. Create a process, and then follow it every time.
3. **Completeness: every question should be answered**. Grantee staff should complete all data fields in nFORM. Clients can refuse to answer questions or entire surveys, but they should be encouraged to complete them.

Establishing data collection processes. Consider undertaking these steps:

1. **Use your resources (funding, staff) to create a comprehensive data collection process**. Working with your performance measure and/or local evaluation staff, think about every step of your data collection efforts. Identify ways to ensure the three principles (privacy, consistency, and complete data collection). Think of complications that could arise, and identify ways to address them.
2. **Write down the plan**. That way, others will quickly understand your procedures, and later you can review your plan and make changes.
3. **Test-run the data collection process with staff**. Walk through each step of the plan to fine-tune it.
4. **Train all staff on their roles**. Grantee staff, even those who won't use nFORM, should be trained to understand their roles and expectations for privacy, consistency, and completeness. Ask staff to test-run processes, too.
5. **Check data collected, and check-in with staff, at least quarterly and more frequently until your data collection process is running smoothly**. Analyze data frequently to identify whether specific questions or even whole surveys are not being completed, or are being competed in an odd way. (You may need to use the export

function to check on entrance and exit surveys.) Check-in with staff about how data collection is going: Have they run into any problems? Do they have any suggestions on improvements to the processes?

6. **Make changes when needed, communicate changes to team, and update written plan**. Continue checking your data and coordinating with staff to make sure changes are implemented and effective.

Standard Approach
(Applicable in Most RFHM Contexts)

The nFORM User Manual provides detailed procedures for data collection, case management, and reporting using the nFORM system. Following are additional recommended practices to incorporate into your grant's data collection plan:

A. Conducting intake for applicants using nFORM:

1. Add the client to nFORM:
    - Take client to quiet area where your discussion will not be overheard.
2. Ask the client for information to complete the Application Form. Type answers directly into nFORM (avoid writing them down on paper, if possible).
3. Have client complete Applicant Characteristics Survey:
    - Set up survey on separate tablet/computer for client use.
    - Hand the tablet/computer to client.
    - Have client sit in quiet place where the answers won't be seen by others.
    - Offer earbuds/headphones to client so that they can hear the survey questions, if they wish. Show the client how to adjust the volume on the device. If the client does not want to listen to the questions, show them how to mute the audio.
    - Tell client that if they have questions to let you know; stay visible to the client so that if they have questions they can ask you.
    - When the client is done, ask whether they have clicked "Submit." Confirm submission by going into nFORM (on staff computer) and confirming that Status is "Complete."

B. Conducting entrance/exit surveys using nFORM:

Conduct the entrance survey at the beginning of the first class, before any instruction occurs (perhaps right after introductions). Conduct the exit survey at the end of the last class, after all instruction is finished.

1. Set up surveys ahead of time using a separate tablet/computer for each client.
2. Hand the tablet/computer to each client.
3. Have the client(s) sit in a quiet place where the answers won't be seen by others.
4. Offer earbuds/headphones to (each) client so that they can hear the survey questions, if they wish. Show the client how to adjust the volume on the device. If the client does not want to listen to the questions, show them how to mute the audio.
5. Tell client(s) that if they have questions to let you know; stay visible to the client so that if they have questions they can ask you.

6. When the client(s) is done, ask whether they have clicked "Submit." Confirm submission by going into nFORM (on staff member's computer) and confirming that Status is "Complete."
7. Wait to begin instruction until (all) client(s) have completed the survey.

C. Entering Case Management and Workshop Participation Information in nFORM:

- Enter this information as soon as possible into nFORM - within an hour if possible, and no later than 24 hours after session.
- If you have written anything down (e.g. case notes, e.g. attendance log), after entering into nFORM either shred the paper or keep it in a locked cabinet.

Special Scenarios

School-based programs - conducting intake and entrance surveys. For school-based programs, it may be possible to ask students to complete the Applicant Characteristics Survey and the Entrance Survey in one sitting. We suggest using multiple staff members to facilitate this, depending on the number of students to be surveyed:

- Prior to First Class:
    - Enter basic information on all students in nFORM, so that each student has an nFORM ID.
    - Bookmark the survey URL in each tablet/computer (a separate tablet/computer for each student) so the survey is ready to launch.
    - Generate a passcode for each student, and document the student's ID and passcode on an index card or other method.
    - Passcodes for each survey are valid for one hour—clients must begin the survey within one hour of grantee staff generating the student's passcode. Staff should plan accordingly based on the number of students who will be taking the survey and the class setting.
- During First Class:
    - Applicant Characteristics Survey:
        - When class begins, make brief introductory remarks.
        - Hand out the tablets/computers to students. Hand out the index cards to each student by name with the student's ID and passcode to each student. Ask students to insert their earbuds, click on the bookmark to navigate to the **applicant characteristics** survey log-in screen, and then enter the information on the index card.
        - Ask students to confirm after log-in that their identity appears correctly. If there are any mix-ups, it may be necessary to regenerate passcodes.
        - Ask students to complete the Applicant Characteristics Survey.
        - After logging-in to the survey, a student may be logged out after 30 minutes of inactivity.
        - Instruct students that, when they have finished the Applicant Characteristics Survey, they should click "Submit" and bring the device back to the instructor.

        - At the front of the room, with each individual student, take the tablet/computer, and confirm in nFORM on staff computer that the student has completed the Applicant Characteristics Survey. (Reassure the students that you are not checking their responses, just that the previous survey was submitted, so that they can begin the next part.)
    - Entrance Survey
        - In nFORM, obtain the student's passcode for the Entrance Survey (different from the Applicant Characteristics Survey passcode), and write it on the index card.
        - Hand the tablet/computer back to the student with the index card. Ask student to return to their desk and insert their earbuds, click on the bookmark to navigate to the **entrance** survey log-in screen, and then enter the information on the index card.
- During Last Class:
    - Follow the same process described for the Applicant Characteristics Survey, but instead generate the student's passcode for the Exit Survey (different from the Applicant Characteristics and Entrance Survey passcodes).

Programs without internet access. In some places internet is not accessible. There are two options for administering surveys (the Applicant Characteristics Survey, the Entrance Survey, and the Exit Survey) without internet access.

- **Applicants/clients can complete paper surveys, and grantee staff can enter the information into nFORM later**. If you use this option, you will need to think through how to help applicants/clients navigate the paper surveys (there are "skip patterns" that are seamless in nFORM but that may be hard to follow on paper.) Also, carefully guard any paper copies with client information following your organization's best practices for data security; for example, secure the copies in locked cabinets and shred them when specified by your organization or, if applicable, your designated institutional review board.
- **Via a phone conversation, grantee staff can ask the questions of applicants/clients, and record the information as they go**. Grantee staff should take measures to ensure that the applicant/client is in quiet location where answers cannot be easily overheard. Also, make plans for how to reconnect if the phone service cuts out.

Programs with differently-abled applicants/clients who cannot respond to a tablet/computer survey, even with the audio assistance. In this instance, grantee staff can ask clients the questions, and input the data as the client provides answers.

Programs with clients who cannot speak English or Spanish. There are two related options:

- **Grantees should create paper versions of the surveys in other languages**. The grantee should work closely with a professional translation service to ensure that all translations are accurate and appropriate for the grantee's population.

- **As needed, grantee staff can sit with clients and ask the questions from these translated paper surveys question-by-question.** This will allow clients with literacy issues to complete the surveys.

Two methods of survey administration are *not* permitted due to security requirements:

- **Grantees cannot send the nFORM ID and passcode to clients to complete the surveys off-site**.
- **Grantees cannot reproduce the surveys in another system (e.g. surveymonkey) in order to transfer the questions later**.

Appendix: Protecting Personally Identifiable Information (PII)

Over the course of working with clients, you will ask for and have access to confidential personal information. The confidentiality of this information—called "personally identifiable information" or "PII" for short—must be preserved. While you are working within nFORM or in any other capacity, be sure to safeguard applicants' personally identifiable information (PII). The nFORM system is being developed as a "FISMA moderate" system: this means that several security safeguards are built into the system. These safeguards are described in the nFORM User Manual. <u>However, grantees will need to build additional safeguards into their processes as described in this appendix.</u>

The Federal Office of Management and Budget (OMB) defines PII as "information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc." The most common forms of PII are social security number, name, address, phone, and date of birth, but PII can also involve other information. You must use your judgment in deciding whether information you work with is confidential; some information that would not appear to be PII on its own, may in fact be PII when combined with additional information. For example, a first name, when combined with a last name and home address or a date of birth, could be considered PII. If you have any questions about whether information you work with is considered confidential PII, please contact your program director or FPS.

To safeguard PII and other sensitive information, you should control access to these data. There are many ways to maintain the confidentiality of personally identifiable information (PII) and you probably already use some of these methods.

- Discussions, including phone calls, about individuals must remain confidential. When discussing individuals with other staff or evaluation team members, please do so in a private room, if possible, or a restricted area out of earshot of unauthorized people.
- ***<u>Under no circumstances should you email PII to anyone, including other program staff</u>***.
- Keep all project materials such as the letters, printouts, and other documents with PII out of sight and locked up in appropriate locking storage (such as a file cabinet) when not in use.
- Keep all work surfaces and open storage areas (such as bookcases) clear of information containing PII. Never leave paper documents containing PII and other sensitive information unattended.
- When displaying screens with PII on your computer monitor, ensure that unauthorized persons cannot see the information (for example, by looking over your shoulder from a hallway or through a window). When possible, shut office doors, close window blinds, or position your computer monitor so that it is not visible to others.
- Activate your screen saver whenever you leave your computer. Usually, this is accomplished by pressing CTRL+ALT+DELETE, then ENTER. If possible, set your screen saver to auto-activate after a short time period of inactivity on your computer.

- Do not allow any other person to use your computer accounts, and always keep your passwords secure. Note that this is intended to prevent unauthorized users from having access to restricted files by using your account.
- PII should not appear on any unencrypted device including shared network drives or unencrypted portable media such as CDs, flash/thumb drives, or a laptop.

General guidance on human subjects protections can be found in the 12-page document found in the human subjects training we recommended for applicable staff (http://www.neirb.com/Investigator_Training). Be sure to consult with your governing organization and, if applicable, your local evaluator, to determine if you need to seek institutional review board exemption or approval. This process will involve review of your grant's specific procedures for protecting client confidentiality.

www.mathematica-mpr.com

Improving public well-being by conducting high quality, objective research and data collection

PRINCETON, NJ ■ ANN ARBOR, MI ■ CAMBRIDGE, MA ■ CHICAGO, IL ■ OAKLAND, CA ■ WASHINGTON, DC

MATHEMATICA
Policy Research