Overview of the Institutional Review Board Process for Healthy Marriage and Responsible Fatherhood Grantees

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OPRE HMRF HEALTHY MARRIAGE & RESPONSIBLE FATHERHOOD OFFICE OF FAMILY ASSISTANCE An Office of the Administration for Children & Families

Contents

Read this first!

This document provides an overview of the institutional review board (IRB) process for Healthy Marriage and Responsible Fatherhood (HMRF) grantees and answers frequently asked questions about the IRB process. All HMRF grantees are encouraged to review this document to understand ACF's IRB requirements and to access helpful resources on the IRB process.

What is an IRB? IRBs are administrative bodies or committees whose function is to conduct an ethical review of proposed research to determine whether the rights and welfare of human research subjects will be adequately protected. An IRB reviews and monitors research plans including data collection protocols, surveys and other data collection instruments, and consent forms and processes, for risks to human subjects. IRBs ensure data are collected ethically and aim to minimize any potential harm to those involved. Harm is of a particular concern to an IRB when special or vulnerable populations such as children or people with disabilities are involved. IRBs also ensure that an appropriate process for informed consent is in place and data about participants are kept confidential.

What is research?

A systematic investigation designed to develop or contribute to generalizable knowledge. (*HHS Office for Human Research Protections*)

What is IRB approval? When an IRB determines that the research, as designed, will not harm human subjects, the IRB approves the research to begin. Before providing approval, some IRBs will require researchers to demonstrate stronger protections for human research subjects. IRB rules apply whether data are collected through direct interaction with human subjects or through use of subjects' personally identifiable information (PII).

Does my HMRF grant need IRB approval? The Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) requires all HMRF grantees to collect and report standardized performance measures using the nFORM 2.0 (Information, Family Outcomes, Reporting, and Management) system. ACF has determined that this performance measures data collection and reporting is not subject to IRB review. However, HMRF grantees may require IRB approval for other reasons:

- Grantees that are conducting local evaluations as part of their HMRF grants are required to have an IRB review their study plans because they are conducting research in addition to collecting performance measures data from clients. ACF has indicated that year 2 Non-Competing Continuation (NCC) applications will not be approved and local evaluation data collection cannot begin without documentation of IRB review. Grantees must submit materials to the IRBs so that they can determine whether a study is exempt or approved, depending on grantee study plans. Grantees conducting local impact evaluations must have IRB approval or documentation of an exemption before proceeding with their implementation study during the start-up period beginning April 2021.
  - Grantees conducting implementation studies during the start-up period and impact studies in later years can choose to do either of two options:
    1. Seek IRB approval/exemption for their implementation study during the start-up period and seek IRB approval for the impact study later; or
    2. Seek IRB approval/exemption for both the implementation and impact studies during the start-up period, even if the impact study protocol will be refined in the future. (If revisions to the impact study protocol are made in the future, this would require an update to the IRB.)

  - The review of grantees' NCC applications will be on hold until the Office of Grants Management (OGM) receives the required IRB documentation as part of their Restriction Revision amendments. Grantees conducting local evaluations should contact their Evaluation Technical Assistance Partner (ETAP) for further guidance on the start-up period timeline and recommended approaches for obtaining IRB approval.

- Grantees that are participating in rapid cycle learning (RCL) as part of the Strengthening the Implementation of Marriage and Relationship Programs (SIMR) or the Strengthening the Implementation of Responsible Fatherhood (SIRF) research projects should discuss IRB requirements with their SIMR or SIRF study team liaison. The SIMR and SIRF study teams have obtained IRB approval for SIMR and SIRF activities and will confirm with each grantee that their organization will accept approval from the IRBs used by the SIMR or SIRF projects. When engaging in SIMR and SIRF study activities, grantees will need to follow the consent, data collection, and data security procedures and protocols that the SIMR and SIRF IRBs have approved. Grantees can reach out to the SIMR and SIRF study teams for more information.
- Some grantees may be required to have an IRB review their plans to enroll clients and collect performance measures data even if they are not conducting a local evaluation or participating in a SIRF or SIMR RCL. Grantees' governing bodies—such as local governments, schools, or universities—may require IRB review for any data collection activity involving human subjects, especially if the grantee is serving vulnerable populations (see Section C). All grantees should check with their governing bodies to determine appropriate procedures for obtaining consent from their clients to collect data, and whether IRB review is required.

What else should I know about IRBs? Take a look at the remaining sections of this document:

- Section A describes the IRB review process.
- Section B describes the purpose and process of obtaining informed consent.
- Section C describes special IRB considerations for grantees serving youth, incarcerated individuals, and other vulnerable populations.
- Section D includes data security considerations for IRB review and information on obtaining a Federalwide Assurance.
- Appendix A provides the IRB letter of exemption that Mathematica received to conduct cross-grantee analyses using the performance measures data that grantees collect in nFORM 2.0. Grantees may be asked to provide this letter for their own IRB reviews.

For more information on IRBs…

DHHS's Office of Human Research Protections (OHRP) provides comprehensive information on IRB requirements with frequently asked questions on a range of IRB-related topics, including Informed Consent FAQs. OHRP's website also provides IRB-related policies and guidance, including Tips on Informed Consent."

A. Overview of the IRB process

How can I find an IRB to work with? IRBs often operate within public or private non-profit institutions, such as universities, state agencies, and hospitals. State or local governments might require their own IRB review (e.g., a school district or tribal community). If grantees are conducting a local evaluation, the local evaluator might have an existing relationship with an IRB. In some cases, it might also be necessary for grantees to secure IRB clearance through the state or local governments' IRB or research review board in addition to the evaluator's IRB. If grantees need 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.

The regulations governing IRB review and the protection of human subjects—known as the Common Rule—are found in the Code of Federal Regulations (CFR), specifically at 45 CFR Part 46.

What type of IRB review should I pursue? When confirming with your governing body, FPS, local evaluator, ETAP, or SIRF or SIMR RCL liaison whether IRB review is needed, also discuss what type of review may be appropriate. Your data collection may be eligible for exemption, qualify for an expedited review, or require a full review depending on yours plans and the populations you serve.

What will I be required to submit to the IRB? Grantees should consult with their IRB about what is required for submission for an exemption, expedited review, or full review. Most IRB applications require the following:

a) **A description of the proposed research,** often called a study protocol, which typically includes descriptions of the scope of work, funding level for the research, use of 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. You may be able to draw on materials already developed, such as your evaluation plan or data collection plan, to complete the description. Your governing body, or local evaluator, may also have templates for you to use. As noted above, grantees participating in SIRF and SIMR should consult directly with their liaisons.

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

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

d) **Information about the proposed research subjects,** including whether they are from vulnerable populations. IRBs consider vulnerable populations to 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. (Section C provides further details.)

Some IRBs also require:

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

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

c) **A data security plan** detailing how the study will protect any PII gathered.

d) **Proof of training in human subjects research** for the principal investigator leading the project. 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 (see https://www.citiprogram.org/). In some cases, training may be incorporated into the grantee's existing training procedures.

B. Obtaining informed consent from human subjects

What is the purpose of informed consent? Informed consent is the process by which appropriate information is provided to a potential research subject so that they can decide whether to take part in the research. Human research subjects must *voluntarily* provide consent in order to participate. Obtaining informed consent is a legal requirement for federally funded research involving human subjects unless the study is exempt[1] from this requirement, or an IRB issues a waiver of informed consent.

Grantees will have different requirements for administering and documenting informed consent depending on IRB requirements, the clients they serve, data to be collected in addition to the HMRF performance measures, and other considerations. Because ACF is not requiring grantees to undergo IRB review for the collection of HMRF performance measures, nFORM 2.0 does not include a process for documenting consent when grantees enroll clients in their programs. Grantees will need to develop their own consent and documentation procedures for data collection conducted outside of nFORM 2.0.

How should consent be obtained and documented? Consent is usually obtained in one of two ways—in writing or verbally. Grantees that are providing virtual services should also explore the option of obtaining electronic consent.

Regardless of the method, the potential research subject's rights and the nature of their participation must be clearly explained in the appropriate language(s) and reading level(s) of the subjects. The potential risks and benefits of participation, the option of declining to participate, and the ability to withdraw from the study at any time should be clear and easy to understand.

Tip: Word includes a built-in feature to help you assess reading level. To access, follow these steps:

- Go to File>Options and select Proofing
- Under "When correcting spelling and grammar," ensure the "Check grammar with spelling button is checked."
- Select "Show readability statistics."
- Then, when you use spell check, Word will display information on reading level.

Written consent is the default form of consent. To document 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 of the consent form is usually retained by study staff, and research subjects are provided with a copy of the information.

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 of written consent because

[1] IRBs may determine that a grantee's plans are exempt from IRB review. Grantees should still consider whether an informed consent process is needed to inform clients about the program and assure them of their rights.

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.

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 participant 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 audio-record the verbal consent.

Electronic consent may be an option if program services are being delivered virtually, if the IRB agrees that electronic signatures are acceptable. When sending consents electronically, grantees could email either an attached consent form (note that Word files may be more accessible than pdf files) or links to programmed forms (for example, using DocuSign or a consent form built into SurveyMonkey). A best practice when using programmed forms is to include a brief quiz at the end of the consent materials which asks research subjects questions about their rights to ensure they understand the content of the consent form (for example, "True/False: I can opt to drop out of this study at any point."). For electronic consent, an IRB may specify security requirements, such as rules related to electronic signatures or transmission of completed consent forms. It is important to understand these requirements in order to assess whether electronic consent forms are a feasible option. For example, an IRB may require completed consent forms to be returned via encrypted emails, which could present a technology barrier for some research subjects.

Written, verbal, and electronic consent are *active* consent processes because they require the research subject to explicitly agree to be part of the research. Alternatively, *implied/passive consent* requires research subjects to explicitly refuse to participate. Research subjects who passively consent have not waived their rights as study participants. Implied/passive consent is usually reserved for studies that are found to be completely innocuous by the IRB. It is often used in schools to obtain parental consent for youth to participate in activities, where parents who do not refuse to allow their child to participate are considered as providing passive consent.

What should be included on a consent form? Grantee consent forms will vary based on each grantee's program and data collection efforts. Information on the consent form will depend, for example, on who is collecting data, the timing of collection, and whether consent is being obtained for research subjects only, for all clients participating in a grant program, or also from members of a comparison group (who are not participating in the program being studied). Consent forms should reflect the specific requirements of the grantee's IRB and applicable laws; your IRB may have a sample consent form to help you get started. Grantees should consult with their governing body, local evaluator, and SIRF or SIMR liaison as appropriate when developing consent forms.

Typically, IRBs require the following elements on consent forms:

a) Name of the study's sponsor.

b) The purpose of the study.

c) Specific information on all data collection activities included under the consent request for the duration of the study, such as surveys, focus groups, interviews, collection of administrative records, and any plans for data archiving.

d) 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.[2]

e) Potential risks, harm, discomfort, or inconvenience caused by participation in the study.

f) Possible benefits of participation.

g) 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.

h) A description of any compensation, such as incentives.

i) 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 subjects to call to obtain more information. It might also include contact information for a local evaluator. Grantees should consult with their IRBs about the specific contacts to include on the consent form.

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

Best practices for obtaining consent

To help ensure that potential participants fully understand the request for consent, IRB requirements are met, and privacy is maintained:

- **Make the consent form clear and concise by using simple, easy to understand wording**. Keep the consent form short; generally, one to two pages.
- **Write the consent form in the primary language and at the reading level of the target population.** Translate the consent forms into the appropriate language(s) for non-English speakers.
- **Describe the study, the sponsor, and expected benefits for participants and the community**. Use only IRB-approved materials when interacting with potential participants, such as a study brochure or FAQ, link to a study website, or statements from community leaders or other stakeholders.
- **Provide participants 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 participants is not revealed to anyone outside the research team**. Ensure that participants' identities are protected when forms are collected and if required, submitted to the IRB at the end of the study.

[2] 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.

When is parental/guardian consent and youth assent needed? For many youth-serving programs, parents or legal guardians must provide *consent* for a youth who has not reached the age of majority to participate, and the youth must provide *assent*.

The age of consent is the age of majority—this can vary but is 18 years old in most states. Grantees should confer with their state child welfare agencies to determine the rules and regulations related to consent on behalf of a child, particularly when working with foster or homeless youth. Grantees should consider:

- **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. Emancipated minors can consent for themselves.
- **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 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; others do not.

When can the consent requirement be waived? 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. For example, waivers of parental consent can 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 (e.g., for studies of homeless youth).
4. Whenever appropriate, the research subjects will be given additional pertinent information after participation.

Helpful tips for developing a youth assent form

- **Use age-appropriate language** that clearly conveys the major elements of consent.
- **Ask youth to assent actively** to help them understand what they are agreeing to. Let them know they can skip any questions they do not wish to answer, and they can stop participating at any time if they feel uncomfortable.
- **Request contact information** when youth are filling out the assent form so they can be located for subsequent data collection efforts.
- **Assure youth that their identity and their responses will be kept confidential.**

Grantees that believe they may be eligible for a waiver of consent must apply for it from their IRB. Grantees should consult with their IRB and local evaluators to determine whether a waiver is an option.

C. Special considerations for vulnerable populations

The Common Rule regulations detail special considerations for research involving vulnerable populations, including youth, pregnant women, and incarcerated individuals. 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 how to protect the rights and welfare of these clients in accordance with Common Rule requirements. Several considerations for working with vulnerable populations follow; grantees should consult with their governing bodies, ETAPs, Family Assistance Program Specialists (FPSs), IRBs, and OHRP's website for further information on these and other considerations.

What is PII?

Information that can be used to distinguish an individual, either alone or when combined with other personal or identifying information that is linked to a specific individual (*OMB M-07-1616).* PII collected in nFORM includes client contact information and information about clients' involvement in the program.

Ensuring that participation is not coerced by making sure human subjects understand that their participation is voluntary. Coercion can take many forms. For example, incentives can be too high; this could lead potential subjects to agree to participate even if they do not want to otherwise. The environment could also be coercive, such as if potential subjects are asked to participate in front of other people and are not allowed to decline privately.

Protecting research subjects' confidentiality is one of the most vital components of any study. Grantees must protect their clients' PII unless disclosure is required by law. Grantees/local evaluators must thoroughly review their disclosure obligations and specify on the consent form any circumstances in which the grantees/local evaluators would be required to disclose subjects' PII.

Considering whether a waiver of parental consent is necessary. As noted above, youth are considered a vulnerable population and IRBs typically require parents or guardians to provide consent for youth to participate in research. Some youth may not be able to identify an adult who can provide this consent. 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 clients that adhere to prison and jail regulations. Prisons and jails may restrict incarcerated individuals' participation in a study and collection of data from them. 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 develop 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

IRBs may require grantees to describe their processes for ensuring that data collected from human subjects is secure and kept confidential. Best practices for securing client PII are described in the Performance Measures and Data Collection Logistics Manual on the nFORM 2.0 help page. Grantees are encouraged to review these procedures and document how they will ensure data security in their HMRF grant data collection plans. Grantees should be sure to abide by the requirements of their IRB and keep data secure until it can be destroyed.

Some IRBs may also require grantees to describe the security of the nFORM 2.0 system that grantees will use for collecting, storing, and reporting performance measures and service data. The 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. If appropriate, the language in the data sharing agreement may be adapted for the grantee's IRB application. As described in the data sharing agreement, Mathematica has deployed the nFORM 2.0 system to the Amazon Web Services (AWS) cloud which is FedRAMP-certified to ensure effective, repeatable cloud security. Safeguards that will be used to protect sensitive data stored within the nFORM 2.0 system are consistent with the Privacy Act, the Health Insurance Portability and Accountability Act, the Federal Information Security Management Act (FISMA), 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.

Federalwide Assurance

HMRF grantees conducting local evaluations must obtain a Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP) to document their commitment to complying with the Common Rule. An FWA through OHRP is required for all research that HHS 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. Please contact your ETAP and consult OHRP's website for more information.

Appendix

Mathematica's IRB exemption letter

29 January 2021

Grace Roemer, M.S.
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RE: Exempted research ethics review findings for: *Building Usage, Improvement, and Learning with Data in Healthy Marriage and Responsible Fatherhood Programs (BUILD HMRF)*
(HML IRB review #837MATH21x)

Dear Grace Roemer,

Protocols for the protection of human subjects in the above study were assessed through an exemption from on-going review by HML Institutional Review Board on 28 -- 29 January 2021.

This study's human subjects' protection protocols, as stated in the materials submitted, received **IRB exemption** from ongoing review in accordance with the requirements of the US Code of Federal Regulations for the Protection of Human Subjects, 45 CFR 46.104.

To be in compliance with 45 CFR 46, please notify this IRB of any changes in this study's human protection protocols.

HML IRB is authorized by the U.S. Department of Health and Human Services, Office of Human Research Protections (IRB #00001211, IORG #0000850), and has DHHS Federal-Wide Assurance approval (FWA #00001102).

Sincerely,

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cc: Annie Buonaspina, Sarah Avellar, Mathew Stange, Penelope A. Lantz, JD

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