

Enhancing the informed consent process and enrolling participants in a program evaluation

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The success of a Healthy Marriage and Relationship Education (HMRE) program evaluation begins with clearly describing the evaluation to potential participants, obtaining their informed consent, and enrolling them in the study (Box 1.1). Describing the study accurately—including its purpose, procedures, risks, and benefits—and obtaining informed consent is both a legal and ethical requirement.¹ However, research and evaluation concepts and terminology may be unfamiliar to potential participants, participants may have had negative experiences with research, and/or participants may not fully understand what they are signing up for. HMRE program staff and evaluators' early interactions with potential participants are important for addressing these issues and fully informing and encouraging them to enroll in the study. This brief contains five tips that HMRE program staff and local evaluators can use to improve procedures for obtaining informed consent and enrolling participants in evaluations.

Box 1.1. Key terms

Informed consent. The process in which staff explain to potential participants the purpose, risks, benefits, and voluntary nature of the evaluation. Staff must properly inform participants of all possible risks and benefits so that they can make a voluntary decision about whether to participate in the evaluation. If the evaluation involves youth, a parent's or guardian's consent needs to be obtained first, followed by the youth's assent, or agreement, to participate (Shah et al. 2023).

Enrollment. Enrolled participants are those who are eligible to participate (they meet the study's inclusion criteria) and who consent to participate. Enrollment in an evaluation means the participant plans to participate in the program and the evaluation activities for their study group (for example, by attending workshops or participating in data collection activities), as appropriate (Bruursema 2015).



Tip 1: Develop a consent form that is concise and easy to understand

A consent form is a document that briefly describes the evaluation's purpose and procedures as well as the risks and benefits of participation. An effective consent form presents the potential participant with enough information to understand the evaluation and to make an informed decision about whether to participate.

¹ HMRE evaluators must obtain approval from their local Institutional Review Board (IRB) on all consent procedures and forms.

The Administration for Children and Families (ACF) provides grants to fund healthy marriage and relationship education (HMRE) programs to strengthen and improve the quality of relationships. The programs offer a range of services from relationship education for high school students to marriage and relationship skills building for adult couples. Grant recipients may be funded to also conduct descriptive or impact evaluations of their funded programs. Independent local evaluators support grant recipients in conducting their local evaluations. This brief is part of a larger evaluation technical assistance (TA) toolkit developed by Mathematica to help HMRE local evaluators understand key program evaluation concepts, common evaluation challenges, and strategies to prevent or overcome challenges. The briefs are standalone documents that can be read in any order. The TA toolkit was developed with HMRE program staff, their local evaluators, and other partners in mind, but it is also relevant to other program areas and organizations.

Box 1.2. Common elements of a consent form

- Purpose of the evaluation
- Eligibility criteria
- Description of the evaluation procedures and expected duration of participation
- Benefits and risk of participating
- How confidentiality will be protected and limits to those protections, if any
- Data protection procedures
- Compensation, if any
- A statement that participation is voluntary
- Evaluation team contact information
- Any specific IRB requirements

Source: U.S. Department of Health and Human Services (2016).

Although consent forms must be thorough (Box 1.2), they should also be brief and easy to understand (Grant 2021; Kadam 2017). HMRE evaluators should distill the form to the essential elements that a potential participant would need to make an informed decision. Keep sentences and paragraphs on the form concise—for example, less than seven lines per paragraph and less than 12 words per sentence.

Consider using bulleted lists rather than paragraphs to keep information brief and consumable. Providing succinct information and using accessible language will help potential participants understand the evaluation and their role in it.

Developing the right language for participant audiences may be challenging when describing more complicated research and evaluation processes and procedures. It may be hard to avoid using certain evaluation terms that participants might not be familiar with—for example, randomization, intervention, or comparison group. In general, consent forms should avoid technical terminology when possible or provide definitions and examples when introducing new or complicated concepts.

After crafting the consent form, consider obtaining feedback on its overall readability and comprehension from program

participants not enrolled in the evaluation or from other community members. Including input from community members can increase enrollment of underrepresented groups in research studies (Markman et al. 2023).

In addition, HMRE programs and local evaluators should think carefully about the participants they want to enroll in the evaluation and tailor the form to them. Identify key characteristics that might influence a participant's ability to understand the consent form, such as education level and primary language. For example, if participants generally have lower educational attainment, make sure the consent form is tailored to a sixth- to eighth-grade reading level using Microsoft Word's accessibility functions. Or, if the HMRE program is primarily recruiting from a community with high rates of Spanish speakers, make sure the Spanish-language version of the consent form is translated to fit the words and phrases used by the local population by having multiple team members or other native Spanish speakers review it.



Tip 2: Assess intake procedures to incorporate evaluation consent and enrollment

Because HMRE programs typically have a centralized intake process for enrolling participants, the processes of engaging participants in the program and in the evaluation can be linked. Typically, programs recruit people who are eligible for and interested in program services, then they obtain consent for participating in an evaluation of the program (Avellar et al. 2017). HMRE program staff and local evaluators should work together to identify the best point in the intake process for evaluation consent and enrollment to occur (Box 1.3).

Box 1.3. Methods for assessing existing procedures

- Use customer journey mapping (also called [experience diagramming](https://www.luma-institute.com/experience-diagramming/))² to map a participant's journey through the intake and enrollment processes. Illustrating their experiences may help reveal existing processes or steps to simplify or eliminate.
- Interview past participants about their experiences with consent and enrollment to determine areas that could be streamlined and forms that could be combined.

² Luma Institute. "Experience Diagramming." <https://www.luma-institute.com/experience-diagramming/>

Ideally, program and evaluation consent and enrollment processes should take place simultaneously for all potential participants (Feeny 2021). Integrating program and evaluation consent processes will allow potential participants to hear about the HMRE program; learn about the evaluation; provide consent (if they choose); and complete program intake forms and evaluation data collection (for example, a baseline survey) at the same time. Combining program and evaluation enrollment into a single step also lessens the need to follow up with participants to obtain consent and complete baseline data collection after program enrollment.



Tip 3: Identify who will consent and enroll participants

Although the consent form is an essential aspect of the process, obtaining informed consent is more than just completing a written form. Informed consent is a process that involves conversing with potential participants and answering their questions about the evaluation (Markman et al. 2023). Staff in charge of obtaining informed consent and enrolling participants in the study should feel comfortable explaining all aspects of the evaluation using plain language and should be able to answer any questions (Kadam 2017). Staff who will consent and enroll participants should also be able to connect with participants on a personal level. For example, they should demonstrate sensitivity and familiarity working with the identified community (Feeny 2021). Developing rapport with participants who have had adverse experiences with evaluations is especially important (Box 1.4).

Box 1.4. Understand participants' experiences with research

Understanding the research experiences of potential participants, especially those from traditionally excluded groups such as undocumented immigrants, people of color, and families with low incomes, is critical to tailoring the consent and enrollment procedures to their needs (Doucet 2021). Introducing the study is an excellent opportunity to build rapport with participants and to discuss their past experiences with research. For example, while describing details of the evaluation, ask whether participants have had previous experiences with research and whether they were positive or negative. If they were negative, ask open-ended questions to understand what contributed to the negative experiences and describe how this evaluation would differ. If they were positive, describe how the current evaluation would replicate those positive experiences, as appropriate.

When selecting who will serve in this role, it is best practice to have the same person both consent and enroll a participant in an evaluation.³ Involving multiple staff in different parts of this process can introduce systematic differences between participants and could affect who consents to the evaluation, which could potentially affect the external validity of the study (Zief et al. 2011). HMRE evaluators should monitor the consent rates for each staff person to identify those who are particularly successful or unsuccessful at consenting and enrolling participants and adjust accordingly.



Tip 4: Equip staff with proper training and tools

Staff members who will consent and enroll participants will need the right training and tools. Training could focus on how to communicate important information about the evaluation accurately and empathetically. By the end of training, these staff should feel confident describing the purpose, procedures, risks, and benefits of the evaluation to potential participants (Feeny 2021). Training should also prepare staff to answer potential participants' questions and address their concerns, for example, by role-playing an informed consent process where a participant is concerned about the study maintaining their privacy.

³ For larger evaluations, multiple staff may serve this role, or one staff person may consent and enroll multiple participants in a group setting.

HMRE local evaluators may consider including community members, particularly from underrepresented populations, in trainings to provide context about the community and insight into local preferences and standards. For example, if the HMRE program is working with fathers of color, staff could invite fathers from the community, community leaders, or staff from other community organizations that serve fathers to discuss how potential participants might perceive participating in research and the group's historical experience with research, which might influence their perceptions of the evaluation. Similarly, if an HMRE program is working in a school, evaluators may want to seek input from members of the parent-teacher association or from the principal on how to best communicate the evaluation to students, parents, and teachers in their school district.



Tip 5: Keep track of consent rates to adjust strategies as needed.

HMRE local evaluators should track who is and is not consenting to participate in the evaluation and use that information to improve their strategies for consenting and enrolling participants (Zief et al. 2011). Evaluators can track which staff have particularly high consent rates and observe what they are doing to help other staff improve. If the HMRE program has previously conducted evaluations of the program it should use, use existing data to help inform the current approach and set realistic benchmarks for enrollment (Avellar et al. 2017). Furthermore, HMRE local evaluators can analyze demographic information early in the evaluation to understand which populations they are unable to reach, and refine their consenting approach accordingly. If youth participants aren't returning parental consent forms, for instance, staff can consider providing incentives or reminders through multiple formats (text, email, and so on).

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