Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD
MEDICAL SCHOOL

MULTI-REGIONAL
CLINICAL TRIALS
THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Re: **NOT-OD-24-133**

Strategies for Maximizing Public Engagement in NIH Supported Clinical Research Request for Information

To whom it may concern:

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard ("MRCT Center") appreciates the opportunity to respond to the National Institutes of Health's (NIH's) request for information to inform NIH's "*Strategies for Maximizing Public Engagement in NIH Supported Clinical Research*" (the "Engagement Strategy"), published under Notice #NOT-OD-24-133. Developing a systematic approach to maximizing public engagement is a welcome and critical step in the continued evolution of NIH-supported clinical research.

The MRCT Center applauds NIH's efforts to promote public engagement in its clinical research endeavors as we feel this will foster greater public trust and yield greater perceived value on public investment across NIH's portfolio. We offer the recommendations below in full support of NIH's efforts.

Responses to be submitted to each of the following questions in the online form:

1. **Strategies for researchers to best partner and work with people and communities. For example, developing resources respectful of different cultures, facilitating open dialogues for decision-making, sharing results in a way that is valuable, etc.**

Thank you for the opportunity to respond.

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise.

It should be noted that we invited members of our community with lived experience (e.g., research participants, patient advocates, and research professionals) to take part in the creation of these responses. Where applicable, we also point to free, publicly available resources that the MRCT Center has created specifically **with** the engagement of patient advocates **to support** the engagement of participants.

One strategy to best partner with people and communities is for researchers to demonstrate their value by establishing a known presence in communities where they conduct their research and sharing information and resources that both support the priorities of the community and explicate how the proposed research furthers those priorities. Ideally, such a research presence would be established prior to the commencement of recruitment activities for any research activities. To accomplish this presence in earnest will require direct engagement with community leaders and community members to learn about lived experiences within the community, to understand the community's health needs, and to show how participation in clinical research can help the community meet its health needs.

Further, the engagement approaches we recommend should recognize a community's history of prior experiences with government agencies, clinical researchers, and the institutions they represent. To that extent, the geographic location where the research is planned, the intended participant population, whether potential participants stand to benefit from the intended research, and the potential risks of participation are all crucial factors to consider.

Moreover, as clinical research increasingly becomes a global endeavor, situating individual engagement efforts and research efforts within the context of the global landscape of clinical research can help illustrate how community stakeholders who participate in clinical research can generate tangible returns with and for the people they care about.

Recommended strategies for researchers to establish and sustain effective and meaningful partnerships with people and the communities they represent include:

- The use of clear, understandable plain language throughout the engagement, including languages other than English. One such resource that is not only developed for patients and the public but also engages a team of patient advocates to develop plain-language clinical research definitions is the MRCT Center's Clinical Research Glossary www.mrctcenter.org/glossary.

- Early invitations to clarify need(s), identify key influencers, and integrate multiple perspectives of patients, caregivers, families, patient advocates, and extended community members/organizations into the development of projects/initiatives to generate and build on shared objectives or jointly held priorities.

- Time for relationship-building before and during engagement activities, including onboarding, regular meetings, and personal check-ins, all to ensure patients *feel* that they have value.

- Time for relationship-building prior to study recruitment, for example, having researchers and study staff be introduced, inquisitive, and caring before ever approaching a potential participant to recruit them to a study.

- Plans/budgets to compensate for time and effort.

- Defined process(es) for partnership with community sites, community groups, and their trusted members, processes that must be developed in collaboration with community partners.

- Ample opportunities to provide feedback across multiple modalities, including:
  - Terminology/imagery and communication that respect the preferences of intended audiences
  - Communication platforms and materials that are physically accessible and usable for intended populations, including imagery, audio, and videos that support written text.
  - Communication platforms and materials that are culturally and linguistically accessible and comprehensible to intended populations

- Active efforts to gain input from people with lived experience on aspects such as the science, portfolio, research question, trial design, endpoints, data collection, approach, risk/benefit ratio, and engagement plan to identify which aspects are important to or of interest to them, any limitations or considerations from a cultural or religious perspective, and any other components that are problematic or concerning.

- Regular updates on project status, interim outcomes, and reporting of results, both individual, when relevant, and aggregate. As a reference, recently updated guidance developed with patient advocates is available for returning individual results at https://mrctcenter.org/return-of-individual-results/

- Periodic assessments of roles (institution and community) and whether partners and communities feel that they have had an active voice and been able to fulfill their roles.

- Ongoing expressions of gratitude for contributions and partnership.

Overall, successful partnerships require nurturing relationships with individual partners that support community relationships and, reciprocally, nurturing relationships with communities to support individual relationships.

2. **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities. Examples may include encouraging people/community members to establish shared decision-making on project milestones, prioritizing local community review of research questions and research proposals, specific research design factors, leveraging existing patient-clinician relationships, etc.**

We recommend the following approaches for institutions to support bi-directional partnerships between researchers and people/communities:

- Invest in identifying and nurturing a collaborative network of people/community stakeholders that are available and interested in providing feedback on various health research-related issues directly to institutional representatives e.g. creating an advisory board on a determined basis.

- Develop budgets with earmarked departmental/institutional funding to support engagement activities that prioritize patient/community input on research objectives, study plan, including aspects of its design, conduct, endpoints, and outcome assessments,

- Train researchers to develop skills that support engagement including:
  - empathy and emotional intelligence
  - accessibility (and see https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/)
  - cultural congruence
  - cultural humility
  - linguistic abilities
  - experience working with different populations

- Strongly encourage researchers to develop engagement plans that enumerate the ways in which people and communities have been, and will be, engaged. (and see https://mrctcenter.org/diversity-in-clinical-research/)

- Create participant-facing research-related templates that are easy to understand and not overly technical or legalistic.
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- Establish a team of research navigators to help guide the research participant and support individualized research education– drawn from people who have participated in research before.

- Offer training programs, such as workshops and seminars, for people/community members to build their research literacy and capacity to meaningfully engage in research processes effectively.

- Acknowledge and celebrate the contributions of people/community members to research projects.

- Establish a post-study forum where researchers can communicate study outcomes to participants and community stakeholders, and where community members can debrief their experiences with researchers.

3. Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.

Approaches for research funders to incorporate partnerships between people, communities, and researchers into their programs and priorities:

- Identify research funding priorities based on the funders' own work and experiences with specific communities or issues of interest.

- Explicitly expect, proactively promote, and disburse funds earmarked to create/sustain engagement-by-design.
    - Strongly encourage Patient/Community Engagement Plans that specifically highlight how researchers integrated patient/community feedback into their proposals and the planned research.

- Prioritize research that involves people and communities in contributing to and reviewing the research study plan, including input on meaningful patient-centric endpoints, outcomes, and procedures, as well as plans to continue to involve key subject matter experts in ensuring the study is conducted in ways that work best for participants and support achieving the study's goals.

4. **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions. Examples may include specific technologies to reduce the burden of research participation, opportunities, fair compensation, cultural competence training, and/or culturally competent research models, etc.**

Examples of actions and behaviors that may make people and communities more likely to engage with researchers and research institutions include:

- Evidence of past successful engagement with people and communities that are not transactional – long-term presence and investment beyond the research itself.

- Evidence of patient-centered practices – doing, endorsing, and promoting patient-centric activities

- Remuneration to participants, accompanied by resources to help participants explore whether such payment(s) would affect whether participants (or their families) qualify for other means-tested social assistance or public benefits they may be receiving.

- Open communication, transparency, and ownership that acknowledges where research has harmed people and communities in the past and how the research enterprise has evolved to mitigate harms and protect participants.

- Clear demonstration that the research workforce includes representatives from the people/communities to be engaged.

- Participant-led dissemination of plain language research findings by encouraging participants to take an active role in sharing research findings through community presentations, storytelling, or co-authored publications.

- A return of tangible value to communities through capacity building – e.g., establishing community communication pathways and resource centers where participants can access information about the research and other available resources that could be of benefit to them.

- Remembering that participants are people first, not "subjects" and connecting on a personal level beyond the study – e.g., ask about work/school, family members, a favorite hobby, etc

5. **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions. Examples may include no/unfair compensation, participation opportunities only happening during typical work hours, lack of awareness of opportunities, etc.**

Examples of actions and behaviors that may make people and communities less likely to engage (or cause disengagement) with researchers and research institutions include:

- Perceptions that the researcher/institution has been transactional and only taken from, but not given back to, the people and communities being engaged.

- Affiliation with health centers that have caused harm in the past, for example, healthcare-related bankruptcy in specific groups of patients.

- Not offering any kind of appreciation to participants for their contributions.

- Failing to provide participants with updates on research progress and results. The MRCT Center has specifically developed resources to support the return of individual and aggregate results with practical steps (aggregate results: https://mrctcenter.org/resource/return-of-aggregate-results-to-participants-toolkit-version-3-1/ individual results: https://mrctcenter.org/return-of-individual-results/)

- Using jargon-heavy or highly technical language instead of plain language, images, or videos at the correct age/educational levels

- Complicated and time-consuming consent procedures

- Failure to speak directly with the participant, including children

- Scheduling appointments during work, school, or after-school activities

- Including activities or study items like wearables that make the person stand out as different at school, during after-school activities, or at a friend's house.

- Insensitivity to cultural differences and community norms.

- Failure to demonstrate a return on public investment following study completion. How has this study made a difference? What happens next?

As mentioned above, the MRCT Center supports NIH's efforts to promote bidirectional community engagement. The MRCT Center appreciates the opportunity to contribute to this Engagement Strategy. We would welcome an opportunity to discuss. Please feel free to contact the MRCT Center or me (bbierer@bwh.harvard.edu) if we can be helpful.

Respectfully submitted,

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