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

A Resource for HRPPs: Planning a Strategy to Address Diversity, Equity, and Inclusion

Developing a strategy for Diversity, Equity, and Inclusion (DEI) in Human Research Protection Programs (HRPP) requires careful consideration and advanced planning. As the governing and oversight body to protect the rights and welfare of research volunteers by providing support, guidance, and education to facilitate ethical and scientific research, the HRPP is tasked with outlining a strategy and designating roles for the work to be done fairly, intentionally, and well. All members of the research community are part of the HRPP – institutional leaders, the institutional review board (IRB), researchers, faculty, staff, and students – and all should be supported by and included in the DEI strategic plan. Developing a plan to initiate or address DEI issues in research is difficult. Here we outline an approach to engage an institutional HRPP in DEI efforts.

The ultimate goal of diverse inclusion and representation in clinical research is an improved and personalized evidence-base that addresses differences of biological and medical relevance. When studies are appropriately inclusive and equitable, the knowledge that results is generalizable and representative; public opinion, and particularly the trust of underrepresented and underserved groups, will benefit. Thus, the HRPP should address DEI issues in clinical research; the fundamentals of DEI uphold ethical principles that are foundational to human research protections including respect for persons, beneficence, and justice, and help to support scientific integrity in clinical research.

Institutional leadership should put forth an overall commitment to DEI that can help align priorities throughout the organization. Programs and departments are impacted by the path set forth and affirmed by institutional leadership, and resource commitments can be aligned with strategy. This includes, but is not limited to, developing an infrastructure that facilitates access to and participation in research as well as the treatment, care, and inclusion of diverse, underrepresented, underserved, and hard-to-reach populations.

For HRPPs, having a detailed DEI plan at for research can be challenging. When developed, the plan should be disseminated, roles and responsibilities clarified, and cooperation and collaboration expected. Strategies for DEI require leadership engagement and endorsement; a commitment to transparency, education and resourcing change; continuous evaluation; adjusting the course of action; and continuing to improve and change. The four steps below (Figure 1) provide a broad overview of the elements necessary for a plan of action.

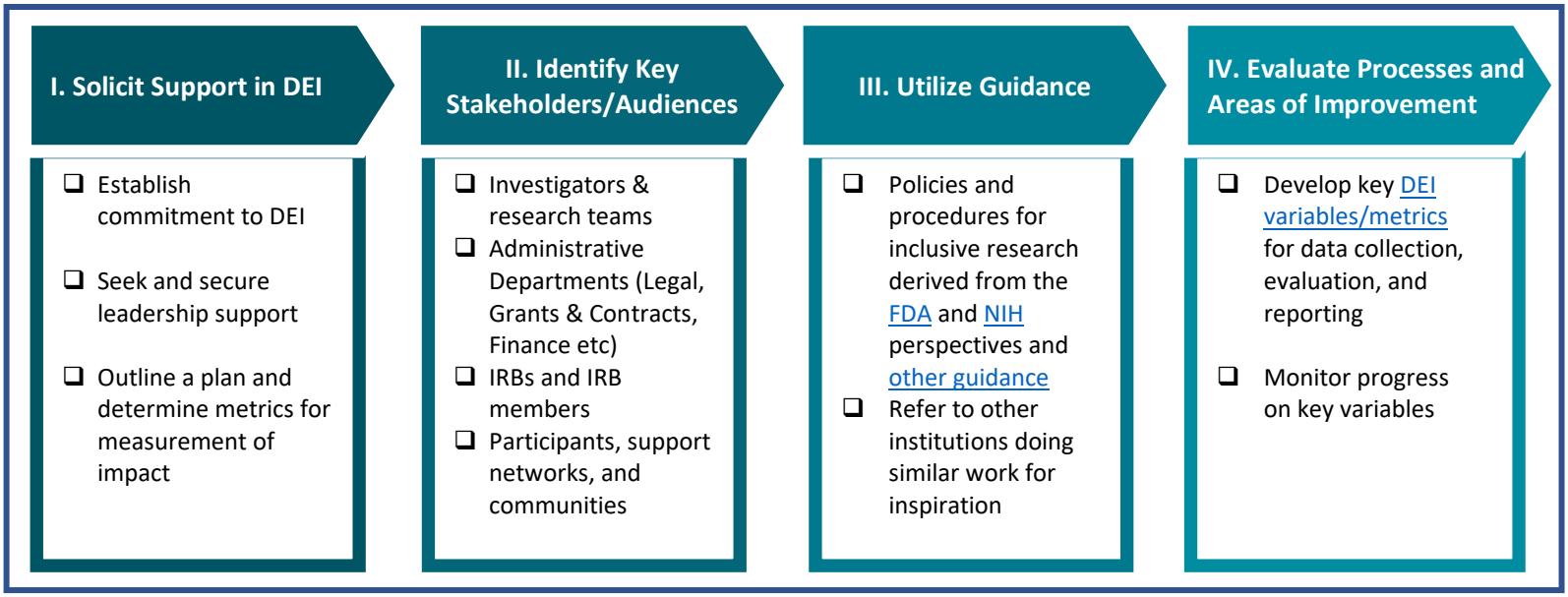

Figure 1: Broad overview of suggested elements to include in a plan of action.

Questions to Consider when Planning the Strategy

Before creating an HRPP strategic plan for DEI, a few foundational components should be understood. To help guide the process, the following questions and considerations serve to ground the strategy for DEI. The list below provides non-exhaustive and basic questions from which to start:

- ❑ Within the institution, is **leadership** supportive of DEI, and are there any efforts specific to clinical research?
    - Does the institution have a statement of commitment to DEI? Does the institution have goals and priority areas for DEI?
        - Does the institutional DEI strategy include clinical research?
        - Does the HRPP have a commitment to DEI?
        - Does the IRB have a commitment to DEI?
        - Are these commitments explicit and communicated?
- ❑ **Who is included** in the development process for the HRPP DEI strategy? Are there representative groups or individuals missing from leadership or the discussion?
    - Within the institution, with whom does the HRPP work, collaborate, interact with? (e.g., consider IRBs, investigational research teams, administrators, finance, grants and contracts, privacy office, IT services, etc.)
- ❑ Is there a designated **budget to execute** the strategic plan?
- ❑ Who will be **accountable** for **reporting** on progress and reviewing the strategy?

Stakeholders and Audiences

The HRPP DEI strategy should address all stakeholders involved in research at the institution to ensure engagement and commitment. Each stakeholder—and each individual—may have different needs, different areas for improvement, and different dependencies on other members within the institution. Having a detailed strategy can streamline both internal and external working processes by creating supportive DEI resources for the IRB, investigators, and institutional staff.

The HRPP strategy should consider the following stakeholders and the impact of the DEI approach. Below are some factors for consideration for each stakeholder.

- ❑ **Institutional Leadership**
  - o Institutional leadership holds the primary responsibility in committing to DEI objectives that can set forth priorities throughout the organization.
  - o Organizational departments, divisions, and programs are impacted by the course initiated and communicated by leadership. Strategies can be put in place to redistribute resources including establishing systems that advance the inclusion of diverse, underrepresented, underserved, and hard-to-reach populations.
- ❑ **IRBs**
  - o HRPPs can establish policies and procedures to suggest or require IRBs to address DEI for their review processes.
    - For example, include DEI elements[1] during their review process of Protocols[2] and ICFs, to help ensure that study question and design encompasses community or participant feedback[3] and that materials are clear, respectful, and inclusive.
  - o HRPPs can review the composition of IRB membership[4] and provide mechanisms to enhance diverse representation by providing training, education, compensation, and technological support to facilitate diverse IRB membership and participation. In addition, enhancing community representation will help address the diversity of IRB membership.
  - o HRPPs can encourage self-assessments (for the HRPPs themselves as well as the IRB) to assess whether diverse voices are represented and whether those voices are heard.
  - o HRPPs can provide directive guidance for review processes that are inclusive and supportive of DEI elements (e.g., consider the demographic variables by which the study population is defined and described, how enrollment values at continuing review compared to the intended study population, whether inclusion is optimized in the recruitment plan, whether participant-facing materials such as the informed consent forms are translated into different languages, etc.).

[1] Mrctcenter.org. 2022. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2022/06/MRCT-Center-Overview-of-Approach-to-Research-Protocol-Template.pdf
[2] Mrctcenter.org. 2022. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2022/06/MRCT-Center-UPDATED-CPT_BWE-v009.pdf
[3] Mrctcenter.org. 2022. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2022/06/MRCT-Center-Including-Community-Voice-1.pdf
[4] Mrctcenter.org. 2022.Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2022/06/MRCT-Center-IRB-Membership-Self-Assessment-Template-.pdf

- Infuse DEI elements within an IRB review process to enhance diverse representation of clinical research and clinical trials and to help ensure that submitted protocols are designed for inclusion.

❑ **Participants/Communities**

- HRPPs should have an obligation to ensure that there are systems and processes in place that ensure inclusive accommodations for participants, as well as safeguarding protections necessary for their participation.
- HRPPs should work with community partners to establish a community engagement committee or a community advisory board to enhance community involvement.[5]
- All studies should have a point of contact for participants who have questions about their participation in the study; the point of contact should be able to communicate with the research participants clearly and effectively (i.e., use of respectful language, interpretation in the preferred language of the participant).
- Community partnerships for research should be genuine and sustained. They should not overburden and/or exploit individuals or communities.
- Participants and their families or caregivers should be reimbursed for their participation and compensated for their time and burden.
- Results of the research should be returned to the participants and the community.

❑ **Investigators/Research teams**

- HRPPs can provide resources to the investigators and their research teams to help make research more inclusive and accessible.
  - Training and educational resources should be provided to investigators to facilitate community engagement and to reduce the burden of participation.
  - Guides to developing objective **Eligibility Criteria** that are broad as possible and narrow as necessary to ensure greater participation
  - The preparation of **Recruitment plans** that are dynamic, consider epidemiological data as applicable, and resourceful to advance wider reach and representation.
  - **Reimbursement** and **payment** for participants to alleviate financial burden of participating in clinical research.
  - **Translation** and **interpretation** of participant facing documents.
  - The facilitatation of **accessibility** of sites and research resources for persons with disabilities.
  - Measures to **lower barriers** to diverse representation, for example:
    - Transportation assistance
    - Childcare, eldercare support as applicable/necessary
    - Flexibility with research visit schedules
    - Decentralized or hybrid trial design
    - Funding needs for improvement

[5] Mrctcenter.org. 2022. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2022/06/MRCT-Center-Including-Community-Voice-1.pdf

Focus Areas for Improvement

The following is a summary of three target areas where HRPPS can take action steps to improve and enhance DEI efforts in clinical research.

POLICIES AND PROCEDURES

- Review and update policies, procedures, and best practices to reflect the commitment towards DEI in research.

OVERSIGHT AND PROGRESS REVIEW

- Establish a process for review of the DEI strategy, its strengths, and areas for improvement. Surveying stakeholders for qualitative feedback on the HRPP strategy is one way to obtain input from the HRPP community.

COLLECTING AND REPORTING OF DATA

- Establish data collection and a reporting plan that include commitment to transparency, sharing results, and change
- Survey IRB members and administrative staff, as well as investigators and research teams, to illuminate attitudes and questions, review representativeness, and develop approaches to uphold the HRPP DEI strategy.