Diversity, Equity, and Inclusion (DEI) in Clinical Research: Tools & Resources for Incorporating DEI in IRB/HRPP Processes

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Background

In 2021, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) convened a task force of 28 IRB and HRPP professionals to develop practical tools that IRBs/HRPPs could use or adapt to promote DEI of underrepresented populations in clinical research. The first available15 tools are the product of an iterative 18-month process of meetings, creation and revision of draft resources by the MRCT Center, and commentary and review by the taskforce. We feature three examples of tools from the IRB/HRPP DEI Toolkit.

- The HRPP Strategy to Address DEI provides a broad overview of the four elements necessary for a Plan of Action.
- The Incorporating DEI into Clinical Research Protocol Templates Overview, which highlights sections where DEI prompts can be added.
- The Checklist of Logistical and Procedural Considerations provides [non-exhaustive] thinking prompts for IRBs/ HRPPs to lower barriers to inclusion.

Scan the QR Code to get to the full list of tools developed.

HRPP Strategy to Address DEI

I. Solicit Support in DEI

- ❑ Establish a commitment to DEI.
- ❑ Seek and secure leadership support
- ❑ Outline a plan and determine metrics for measurement of impact.

II. Identify Key Stakeholders/Audiences

- ❑ Investigators & research teams
- ❑ Administrative Departments (Legal, Grants & Contracts, Finance etc.)
- ❑ IRBs and IRB members, participants, support networks, and communities

III. Utilize Guidance

- ❑ Policies and procedures for inclusive research derived from the FDA and NIH perspectives and other guidance
- ❑ Refer to other institutions doing similar work for inspiration

IV. Evaluate Processes and Areas of Improvement

- ❑ Develop key DEI variables/metrics for data collection, evaluation, and reporting.
- ❑ Monitor progress on key variables.

Incorporating DEI into Clinical Research Protocol Templates

INTRODUCTION

Clinical research protocols summarize the background of scientific rationale for and objectives of a research study. They describe and justify the design, methodology, and statistical analysis plan when conducting research with human participants. In the tool we highlight specific areas within the protocol that are important for advancing DEI efforts within clinical research.

APPROACH

We utilized protocol templates from the NIH as well as TransCelerate and added annotated prompts that illuminate DEI considerations.

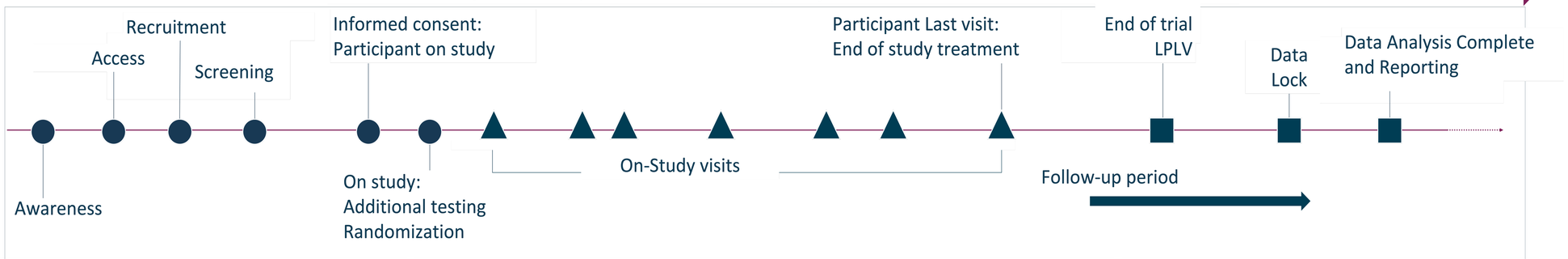
PROTOCOL SECTIONS

To assist in the consideration of DEI, suggestions were made in every section of the protocol, including but not limited to:

- The Protocol Summary
- Study Rationale
- Study Design
- Study Population
- Inclusion/Exclusion Criteria
- Statistical consideration, etc.

A Checklist of Logistical and Procedural Considerations

DIVERSITY, EQUITY, & INCLUSION (DEI) STUDY LEVEL CONSIDERATIONS



Pre-Study Considerations

- ❑ Form and nurture partnerships with underserved communities. Engage with community physicians, patients, and others (e.g., cultural ambassadors) to inform the study question, design, and conduct.
- ❑ Develop health-literate communications and support educational activities to enhance diverse participant awareness, access, recruitment and retention (e.g., translation of study materials, participation in local health fairs, engage with community health centers).
- ❑ Establish processes to minimize burden (e.g., protocols for payment, flexible appointments, accommodations, translation services). Consider if decentralized/hybrid trials would be an appropriate option to reduce burden.
- ❑ Create/adapt a standard mechanism to collect, record, and track demographic and non-demographic variables of participants screened, offered, and consented into study.
- ❑ Develop objective screening approaches and systematically collect and record reasons for screen failure.
- ❑ Periodically analyze/evaluate screen failure data.

On-Study Considerations

- ❑ Document the basis of the decision for excluding participants from a trial.
- ❑ Devise a simple, honest, and clear informed consent process for participants that is conducted in a health-literate, culturally- and linguistically-appropriate manner.
- ❑ Provide translation services of the informed consent form and/or interpreter services for individuals with limited or no English proficiency, as applicable.
- ❑ Apply accessibility principles to study documents and provide accommodations for people with disabilities as required.
- ❑ Allow flexible strategies that enable participants and their caregivers to adhere to the expectations of the study (e.g., amenable clinic hours, locations, virtual visits; provision of childcare, eldercare, and food during study visits; transportation assistance; appropriate reimbursement and compensation).
- ❑ Offer regular, open, and respectful communication through the platform of participant preference (i.e., phone, text, email, virtual meeting, etc.) to foster participant understanding.
- ❑ Establish a monitoring and evaluation system to ensure timely interventions if actual enrollment does not meet expected enrollment or if the actual enrollment does not reflect the expected demographic(s) intended for the study.
- ❑ Monitor retention to study by demographic and non-demographic factors.
- ❑ Put practices in place that provide continuous education, support, and outreach to participants and their communities.
- ❑ Train all staff interacting with participants and their caregivers in principles of respectful communications, bias, and cultural humility.

Post Study Considerations

- ❑ Plan for data analyses that includes sub-group analysis and examination for heterogeneity of treatment effects as applicable to the study.
- ❑ Provide clear communication around end-of-study expectations, including transitions of care, potential later outreach, timing of further communications.
- ❑ If the study involved an investigational product, anticipate continued access to the investigational product for participants who are benefitting from the treatment and have no other equivalent options for treatment
- ❑ Return aggregate and, to the extent possible, individual study results in health literate and understandable language to study participants.
- ❑ Return aggregate results, if applicable, to the community in a culturally- and linguistically-appropriate manner to the community.
- ❑ Conduct post-study survey of participants to learn what worked well and areas for improvement.
- ❑ Review study performance for lessons learned and to help plan future studies.