Advancing DEI in human participant research

Or: We can’t go it alone.

https://www.simplemindfulness.com/the-art-of-helping-others/
Disclaimer

- The opinions contained herein are those of the presenters and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities and well as by grants (see www.MRCTCenter.org).
- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables. This work is licensed under a CC BY-NC-SA 4.0 license.

In the next two days, you will receive a short survey. Please fill it out. We will post a recording of the seminar and the slides.
Presenters

Barbara Bierer, MD
Faculty Director,
MRCT Center

Ivy R. Tillman, MS, CCRC,
CIP
Executive Director
PRIM&R

Michelle Feige, MSW,
LCSW-C
Executive Vice President
AAHRPP

Martha F. Jones, MA, CIP
Vice President of Human
Research Affairs at Mass General Brigham
IRB role in DEI

SCOPE CREEP!!
IRB role in DEI

SCOPE CREEP!!

IRB review:
Regulations as the floor
Justice as the goal
IRB role in DEI

SCOPE CREEP!!

IRB review:
Regulations as the floor
Justice as the goal

Balance protection with inclusion
IRB role in DEI

SCOPE CREEP!!

IRB review:
Regulations as the floor
Justice as the goal

Balance protection with inclusion

Clinical trials, and clinical research, should reflect the population affected by the condition or disease or for whom the intervention is intended.
IRB role in DEI

IRB review:
Regulations as the floor
Justice as the goal

Balance protection with inclusion

Clinical trials, and clinical research, should reflect the population affected by the condition or disease or for whom the intervention is intended.
Objectives

• Where to start
• Explore resources and tools already available to use
• Identify those resources that would be helpful to build
• Hear strategies for advancing inclusion in research
• Engage the community in a common goal
Objectives

• Where to start
• Explore resources and tools already available to use
• Identify those resources that would be helpful to build
• Hear strategies for advancing inclusion in research
• Engage the community in a common goal

The MRCT Center has developed a suite of DEI resources for IRBs, HRPPs, and investigators to adapt or use.
So where do I start?

Know your IRB, HRPP, Institution, Community, and Friends

Plan and Communicate

Negotiate for resources necessary for change

How can we HELP?

REACH | Research Ethics Action Collaborative for HRPPs
Clinical Research DEI Toolkit & Case Studies

Audience: Sponsors, CROs, PIs and study teams, IRBs
- Tools directed at different time points in the design and conduct of a clinical trial
  - Overview documents
  - Participant & Community Engagement
  - Participant awareness, knowledge, access
  - Workforce training and development
  - Data variables, collection and reporting
  - Study design, conduct, and implementation
  - Stakeholder commitments
  - Case studies (therapeutic and programmatic)
- Downloadable, editable → adaptable

https://mrctcenter.org/diversity-in-clinical-research/tools/toolkit/
IRB and IRB/HRPP Statements of Commitment

IRB Statement of Commitment

The [Organization’s] Institutional Review Board (IRB) is committed to diversity, equity, inclusion, and justice in the review, approval, and oversight of human participant research.

The mission and purpose of an IRB is to safeguard and protect the rights and welfare of all human participants who volunteer to participate in research. Consistent with the principle of justice, human participant research should aim to be broadly inclusive and representative of the population whose conditions are the focus of study, unless justified by scientific, ethical, or safety concerns, without exclusion on the basis of age, race, ethnicity, national origin, sex, gender, sexual orientation, language, disability, religion, socio-economic status, or other characteristics that distinguish people from one another.

As an IRB, we will strive to support investigator and institutional efforts to ensure diversity, promote inclusion, and drive health equity. As the entity that reviews protocols for scientific and ethical integrity and holds researchers accountable, we, as IRB members, are also accountable. We are committed to advancing research that is responsive to and supportive of the well-being of our communities, and endeavor to reduce health disparities and promote social justice.

HRPP and IRB Statement of Commitment

This statement affirms the commitment of the [Organization’s] Human Research Participant Programs (HRPP) and its Institutional Review Board (IRB) to diversity, equity, inclusion, and justice through maintaining the highest ethical standards in the conduct of human participant research. Diversity includes age, race, ethnicity, national origin, sex, gender, sexual orientation, language, disability, religion, socio-economic status, and other characteristics that distinguish people from one another. Consistent with the principle of justice, the inclusion of underrepresented and understudied individuals is within the purview of IRB responsibility, as it is with other clinical research stakeholders.

The mission and purpose of an IRB is to safeguard the rights and welfare of human participants in research, to both include and protect those whose conditions are the focus of study. IRBs are responsible for the evaluation and approval of all human participant research and should ensure that any exclusion from participation is justified and based on scientific, ethical, or safety concerns.

As an IRB, we recognize our responsibility to address ethical and regulatory concerns regarding diversity, equity, and inclusion in research and to support researchers and institutional efforts that are foundational to achieving these goals. We are committed to evaluating all IRB applications, including eligibility criteria, recruitment materials, consent documents, and processes, and other study documents for inclusive and equitable opportunities for potential participants. As the entity that holds investigators and research personnel accountable, we, as IRB professionals and members, are also accountable: IRB representation and membership will strive to sustain a composition that is reflective of the population we serve and protect.

As part of the research community, we recognize that each member of the human research protection program, the IRB, institutional offices that support human subjects research, researchers and their study teams, research participants, and the community we serve all play an integral role in advancing research that is representative of our communities; we endeavor to reduce disparities and promote social justice. We are committed to this work.
IRB Self Evaluation Survey

- Provides sample questions for institutions, HRPPs, and/or IRBs to select or adapt
- Informs the diversity and perspectives of their IRB members.
- Helpful to understand educational, training, skills development needs.
Support for IRB Members

- Digital access
- Technology
- Software
- Communication platform
- Security
- Encryption
- Internet connectivity & cellular data plan

- Virtual work environment with accommodations
- Recognition and reward
- Compensation considerations
- Institutional policy recommendations

Approaches to Support IRB Members

IRBs are often composed of members affiliated with the institution it serves, as well as of non-affiliated individuals. To maintain a committed and engaged IRB, it is important to acknowledge members’ commitment of time and effort. Such acknowledgement may be provided in different ways, including, but not limited to, fulfillment of service responsibility, course or other commitment release, access to affiliated library services, or financial compensation. To assist IRBs efforts to achieve and maintain a diverse membership, this document outlines considerations for acknowledgement and support of institutionally affiliated and non-affiliated members of the IRB, recognizing that practices and norms will vary by institution, its resources, the demands of IRB service, and the roles and responsibilities of the individual member.

Resources to Support Digital Access and Virtual Work Environment
IRB documents are typically shared electronically, and IRB meetings may be conducted in person or virtually. In the interest of achieving inclusive and diverse participation, regardless of the meeting form, the HRPP/IRB institution should be prepared to support the infrastructure (e.g., technology, software, communication platform, security, encryption, internet connectivity) necessary for all IRB members to access and do their work. This is particularly important for non-affiliated members who may not benefit from easy access to institutional resources as compared to affiliated members. To ensure participation, members should be provided reasonable accommodations to support access.

Support for IRB Members: Institutional Affiliates
How an affiliated member is recognized for their effort and time on the IRB will vary by institution and should be defined by the institution’s Human Research Protection Program (HRPP) with consideration of equivalence for similar responsibilities. For employees, or members affiliated with the institution, some form of institutional contribution such as teaching, research, and service is an expectation of employment; IRB membership may fulfill such a requirement. The contribution of time via IRB membership is viewed as dedicated institutional citizenship but can nevertheless be recognized by a periodic letter of appreciation to the department chair or manager. Acknowledgment of members’ commitment may be supported by other means such as a stipend, portion of base salary, and/or some other type of formal recognition (i.e., IRB member of the month). For example, some non-academic institutions may want to compensate their affiliated members financially for their time and effort outside of their normal institutional responsibilities, in which case a stipend or percent of salary for their roles (e.g., IRB chair, IRB member) could be considered. For academic institutions, acknowledgement of membership may take the form of research or scholarship credits, or the fulfillment of a service requirement, for members’ time and effort.

Support for IRB Members: Non-Institutional Affiliates
Community or other unaffiliated individuals who volunteer to be members of IRB committees should be recognized and acknowledged for their time and service. Unaffiliated members are
Protocol Template Overlays

1. Protocol Summary
1.1. Synopsis

Protocol Title:
Ensure wording here matches the title page. Brief Title:
Ensure wording here matches the title page. Regulatory Agency Identifier Number(s):
Registry ID

- NIH/FDA and TransCelerate Templates for Interventional Trials
- NIH Template for SBER Trials
IRB Health Literacy Checklist

Review of health literacy best practices applies to:
- Recruitment flyers
- Consent/assent forms (and processes)
- Study instructions
- Study retention materials

Checklist:
- 2-page introduction
- 3-page checklist

<table>
<thead>
<tr>
<th>PARTICIPANT-FACING MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have health literacy best practices been applied to develop participant-facing materials?</td>
</tr>
</tbody>
</table>

| Research terms and concepts are explained in plain language | ✔ |
| Participant population is described with sensitivity and care | ✔ |
| Text is at a 6th grade reading level or lower | ✔ |
| Key messages are clear and succinct | ✔ |
| Font size is at least 12 point | ✔ |
| White space is used generously throughout the document | ✔ |
| Content is chunked into sections that are easy to discern | ✔ |
| Section headings are clear and simple | ✔ |
| Images, icons and/or graphics are used to engage and help explain concepts | ✔ |
| Numeric info is explained using additional images or simple graphs | ✔ |
| Study steps are clearly explained and easy for participants to follow | ✔ |

*Participant-facing documents include recruitment materials, consent/assent forms, study instructions, letters/postcards, etc.
MRCT Center’s Health Literacy Tools

Plain Language Clinical Research Glossary

Tools and Resources

Information on techniques that are key to successful research communications.

- PLAIN LANGUAGE Resources
- NUMERACY Resources
- CLEAR DESIGN Resources
- USABILITY TESTING Resources
- CULTURAL CONSIDERATIONS Resources
- INTERACTIVE TECHNIQUES Resources
- GLOSSARY Resources
- CONSENT GUIDE Resources

Now a CDISC standard

https://mrctcenter.org/clinical-research-glossary/

https://mrctcenter.org/health-literacy/
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 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.
An IRB Resource for Investigators
Practical Points to Consider: Payment to Research Participants

Intended Use
This document was created as a resource for IRBs and HRRPs to adapt and use when developing guidance for investigators on payments to research participants. This guidance is intended to be reviewed by IRBs and HRRPs in advance of dissemination to investigators so it can be aligned with institutional policies. This document provides an overview of why investigators and sponsors should consider providing payments to research participants, the different types of payment, the tax implications associated with each (with specific reference to current US regulations), and suggests appropriate forms of communication with research participants regarding payment.

Paying Research Participants
While there are historical concerns about paying research participants, consensus is growing among researchers, reflected in the literature, about the importance of offering payment to participants. This information sheet will not repeat the arguments, discussion, or suggestions for offers of payment in clinical research, including a drive to increase inclusion and fairness, but will focus on practical approaches to implement a framework for ethical payment to participants.

Types of Payment
The list below provides a summary of different types of payments that may be made to a research participant. In general, the term payment is inclusive of, but not restricted to, those listed below:

<table>
<thead>
<tr>
<th>Payment Type</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursement</td>
<td>Re-payments to research participants to cover expenses that they incur while participating in clinical research.</td>
<td>Transportation/travel reimbursement, i.e., taxi/transport fare, parking fees, mileage per standard national rates, food, and accommodation. Direct booking and payment for a flight or hotel room for participant's on-site stay. Direct provision of a parking sticker or meal voucher. Incidentally costs, such as childcare, elderly care, additional medical expenses incurred only as part of research participation.</td>
</tr>
<tr>
<td>Compensation</td>
<td>Cash or cash equivalents provided to research participants as fair value compensation for their time and research-related efforts and burdens.</td>
<td>Checks, gift cards, headphones, in-kind items (e.g., books), etc.</td>
</tr>
<tr>
<td>Tangible Gift</td>
<td>Items of nominal value (e.g., $100 or less) given to a research subject as a token of gratitude for participation. The institution generally sets the threshold for consideration of a nominal payment.</td>
<td>Provisional gift such as a study device (e.g., physical fitness tracker) or gift (e.g., a water bottle, calendar) that a participant can keep after use.</td>
</tr>
<tr>
<td>Incentive</td>
<td>Payments offered, in addition to and/or in place of reimbursement or compensation, to encourage recruitment, participation, retention, and study completion.</td>
<td>Sign-on &quot;consent&quot; bonus; study visit payment; &quot;completion&quot; payment</td>
</tr>
</tbody>
</table>
IRB Resources for Participants: Costs and Payments

• 2-page guide for participants
• Who will pay? Know before you decide
• Care and procedures
• Study visits and time
• Questions to ask
• Costs of injury or harm
• Role of insurance/uninsured

To use or adapt as appropriate

An IRB Resource for Participants: Costs and Payments

About this document
This document was created to be a resource for research participants. IRBs or HRPPs can disseminate this document to participants via investigators and their research teams. As available, this document can also be posted on a web-portal that lists available clinical trials and research studies. This document should be adapted and reviewed to align with institutional policies and procedures.

Costs and payments involved in joining a clinical research study
People join a clinical research study for many reasons. Before you decide if you want to join, you should know whether there will be costs associated with participation or payments made to you if you take part.

Who will pay? Know before you decide!

Care and procedures: When funders or sponsors (e.g., drug companies, foundations, or federal agencies, etc.) run clinical trials, they often pay for the medicines being studied. Whether they also pay for other costs (such as a hospital stay or if you are injured in the study) is more varied. The informed consent form should tell you if there will be costs to you to participate, and you can always ask somebody on the study team.

If you have health insurance, your insurance company will often pay for charges related to routine care. These are items that would normally happen at your visit even if you are not in a study. Your health insurance may have co-pays and other deductibles. You can refer to the ‘Questions to Ask the Study Team About Payment’ list at the bottom of this page for guidance on questions to ask related to this topic.

For all studies, check with the study doctor and/or study team who recruited you into the study about costs that you may be responsible for.

Study visits and time: There may be costs related to study visits and your participation in the research study. For example, you may have to travel to the research center, pay for child or elder care, stay overnight in a hotel near the study site, or have someone come with you if you cannot travel alone. Some research studies—but not all—will pay you back for those expenses. Ask ahead of time what the study will pay for so you know what to expect. If the study plans to pay you back (reimburse) for your expenses, keep all receipts! This will make your reimbursement process easier. Note that you

An IRB Resource for Participants: Costs and Payments
Version 1 – June 2022
Inclusion of People with Disabilities

Accessibility by Design Key Points Summary
A. Planning for AbD in Clinical Research: General Considerations
B. Implementing AbD in Clinical Research: Communication Accessibility
C. Implementing AbD in Clinical Research: Physical Accessibility
D. Innovating AbD in Clinical Research: Newer Strategies for Inclusion
E. Upholding AbD: Accountability and Advocacy

https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/
What you can measure you can change

- Continuous assessment:
  - Is demographic distribution on track to approximate the study goals?
  - If not, are adequate corrective actions described, sufficient, and likely to be successful?

- Has the study fulfilled its recruitment/accrual goals?
  - If not, request/require a plan for correction.

https://www.nationalww2museum.org/students-teachers/student-resources/research-starters/women-wwii
So where do I start?

Know your IRB, HRPP, Institution, Community, and Friends
- Statement of Commitment
- Survey(s)
- Review/Modify Policies
- Review/Modify Templates

Keep your friends, allies, and bosses close

Plan and Communicate
Provide resources, tools and training
- Review data
  - Initial review
  - Continuing review
  - Closeout
  - Report out
- Revise best practices

Develop business plan for change

Negotiate for resources necessary for change
- Translation, Interpreters
- Plain language
- Return of results
- Accommodations
- Other resource needs
So where do I start?

Know your IRB, HRPP, Institution, Community, and Friends
- Statement of Commitment
- Survey(s)
- Review/Modify Policies
- Review/Modify Templates

Keep your friends, allies, and bosses close

Plan and Communicate
Provide resources, tools and training
- Review data
  - Initial review
  - Continuing review
  - Closeout
  - Report out
- Revise best practices

Develop business plan for change

Negotiate for resources necessary for change
- Translation, Interpreters
- Plain language
- Return of results
- Accommodations
- Other resource needs
Resources: Preparation

Know your IRB, HRPP, Institution, Community, and Friends

• A Resource for HRPPs: Planning a Strategy to address DEI
• HRPP & IRB Sample Statement of Commitment to Inclusion
• IRB Membership Self Assessment Template
• Approaches to Support IRB Members
• IRB Health Literacy Training
Resources: Protocol Development & Review

Plan and Communicate

For PIs and Research teams:

- IRB Resource for PIs and Research teams: PTC payment to participants
- IRB Resource for PIs and Research teams: Including the Community Voice in Clinical Research
- Procedural and Logistical Checklist
- Incorporating DEI into Clinical Research Protocol Templates
- DEI Overlay TransCelerate Common Protocol Template
- DEI Overlay of NIH-FDA Clinical Trial Protocol Template
- Integration Consideration of DEI into Recruitment Strategy Document
- Accessibility by Design toolkit (AbD)

For IRBs:

- IRB Oversight PTC for reviewers to assess DEI factors in Initial and Continuing Review

For Participants:

- IRB Resource for Participants: Costs and Payments
- Clinical Research Glossary: Helping you understand clinical research
We believe that everyone must have fair and equitable access to the benefits of science.

Working to eliminate systemic injustices in the research endeavor is at the core of our mission to advance ethical research.

Our program offerings are designed to facilitate an expansive and dynamic understanding and implementation of diversity, equity, inclusion, and justice within the broader research community.
Complimentary DEIJ Resources

Resource Collection: Diversity, Equity, Inclusion, and Justice Resources

https://primr.org/resources/deij-resources
PRIM&R has scholarship programs to assist individuals with the costs associated with attending our annual Conferences.

PRIM&R Annual Conference Institutional Capacity Building Scholarship Program

General PRIM&R Annual Conference Scholarship Program
People & Perspectives (P&P) is a digital story-telling library featuring stories of those working in the human subjects and animal care and use enterprise.
DEIJ Resources Available to Members

Webinar: (2021-09) LGBTQIA+ Equity in Human Subjects Research: Strategies for Justice-Focused IRBs

Webinar: (2021-02) The Colors of COVID-19: Embracing the Novel Ethical Challenges and Opportunities in COVID-19 Vaccine Trials

Webinar: (2019-02) Race-Based Medicine and Race-Based Research: Ethical Considerations for Institutions

Webinar: (2018-05) Exploring and Enhancing Diversity for IACUCs and IRBs

Podcast: Trust in the Participant-Researcher Relationship
DEIJ Resources Available to Members

American Indian/Alaskan Natives

Webinar: (02-2023) Responsible Management and Sharing of American Indian/Alaska Native Participant Data under NIH Policy

Webinar: (2018-10) Governance, Trust, and Culture: Strengthening Tribal-Academic Research Partnerships

Webinar: (2017-10) Data Sharing in Research with American Indians and Alaska Natives: Informed Practices, Considerations, and Case Studies

Webinar: (2016-09) Preserving a Role for Tribal Review of Research in the Context of Single IRB Policies
Upcoming Programs

- PRIMR24 - Annual Conference, November 2024
- December 2024 Virtual Panel: Diversity Equity Inclusion Justice Access & Belonging (DEIJA&B)
- Pending partnerships & collaborations
Collaborative AAHRPP Network (CAN):
DEIA WORKING GROUP

Mission Statement and Objectives
Collaborative AAHRPP Network (CAN):

DEIA WORKING GROUP

Mission Statement and Objectives
Working Groups are a Critical Initiative of the Collaborative AAHRPP Network (CAN)

The goals of the CAN include:

• Leveraging the experience and commitment of accredited organizations to identify issues adversely affecting human research protections, which AAHRPP can facilitate addressing

• Creating a pathway for AAHRPP to obtain timely feedback from organizations to drive updates to AAHRPP documents (e.g., guidance, evaluation instrument, Tip Sheets) and the identification of other educational materials or initiatives (e.g., tools, whitepapers, webinars, conference topics)

• Providing ongoing opportunities to promote networking and sharing best practices outside of the annual AAHRPP conference that meet the needs of the range of accredited organizations and the broader HRPP community
CAN Initiatives

• 2021 survey of accredited organizations to identify impact and value of accreditation and needs as accredited organizations

• Annual workshops, a forum for:
  • AAHRPP to disseminate and obtain input on working group recommendations
  • AAHRPP-accredited Organizations to identify challenges they face that AAHRPP can assist in mitigating and work together on resources that support and promote best practices for the protection of research participants and regulatory compliance

• Working groups
  • Reaccreditation
  • Metrics
  • DEIA

• Accredited organization discussion forum (forthcoming)
• Platform for accredited organizations to share innovative resources (forthcoming)
AAHRPP’s CAN:
DEIA Working Group Mission Statement

AAHRPP is committed to promoting high-quality research by helping organizations strengthen their Human Research Protection Programs (HRPPs).

This includes acknowledging that addressing systemic injustices concerning inequities involves all parts of the HRPP.

AAHRPP has created a working group of members from AAHRPP-accredited organizations that represent different perspectives and organization types to expand the lens of how Human Research Protection Programs (HRPPs) can impact the culture and consciousness of inclusion and equity.

We expect to create innovative and actionable ways to incorporate and broaden best practices so that inclusion and equity becomes the norm in our research culture rather than the exception.
Working Group’s Objectives and Key Steps:

1. Form a Diverse Working Group
2. Conduct an Initial Assessment
3. Research and Best Practice Review
4. Collaborative Strategy Development
5. Implementation and Monitoring
6. Knowledge Sharing and Dissemination
7. Continuous Improvement and Adaptation
AAHRPP CURRENT REQUIREMENTS

Standard 1-4

The organization responds to the concerns of research participants.
Element I.4.A. Responding to Concerns of Research Participants

- Organizations should provide information to current, former, and prospective research participants about whom to contact for concerns, questions, or complaints about the research; obtain information; or offer input
  - DEIA:
    - Are there barriers that might cause some communities to be less likely to contact research organizations?
    - Might there be benefits from different ways of contacting organizations? (e.g., txt messages/apps, phone calls, in-person via office hours, in-person groups such as community advisory boards, patient advocates)
    - Might who responds to questions make a difference? (e.g., person responding shares similar background with prospective participants?)
    - What is the budget for responding to concerns? How much does it cost to respond to questions in ways that address the needs of prospective participants and communities?
    - How to measure success: Does improving how an organization responds to questions improve research participation, enrollment, or retention?
Element I.4.B.: Outreach to communities

• To enhance understanding of research by participants, prospective participants, or their communities, organizations should perform outreach activities
  • DEIA:
    • Are there barriers to participating in research and to barriers to trusting information from research organizations?
    • What are the needs of the communities in which organizations conduct research? (e.g., languages used in community vs languages used in outreach)
    • Who are trusted sources of information in the community? What resources (e.g., education about research) might be needed to help trusted sources in the community explain research?
    • Is there organizational support and budgets for long-term community outreach to build partnerships and community advocates (not necessarily tied to specific research studies)?
Element I.4.C. Engaging communities in the design, conduct, and analysis of research, and dissemination of results

- In some instances, the design and implementation of research can be enhanced when individuals from the community in which the research will be conducted are involved in the design, conduct, and analysis of data from the research, and dissemination of results.
  - DEIA:
    - How to support researchers who wish to conduct community-based participatory research? Can take a long time, barriers for junior faculty – benefits of organizational support for this?
    - What mechanisms might be most successful (e.g., patient or community advisory boards)?
    - How to provide education to communities about design of research, conduct (including recruitment and retention), and dissemination of results?
    - What resources do IRBs/ECs need to develop the expertise to review community-based participatory research?
Standard I-4: FDA Draft Guidance

- FDA Draft Guidance (April 2022): Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry
  - Provides recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States
  - [https://www.fda.gov/media/157635/download](https://www.fda.gov/media/157635/download)
Coming Soon:

Collection of Innovative Practices and Tools to Share:
AAHRPP Website

1st step: Collect materials/resources
Real World Implementation: Getting Started on Equity and Inclusion

Examples from Mass General Brigham
Is your HRPP/IRB positioned to influence/require change?

Consideration for promoting change:

Do you have an identified Human Research Protection Program?

Is your HRPP/IRB “at the table” — *change cannot happen in isolation*

Identify the key leadership and stakeholders that are needed to promote, support and effect equity and inclusion.
Leadership You Might Engage

• Chief Academic Officer/VP ResearchProvost
• Equity/Inclusion Office
• Digital Health (EPIC/Patient Gateway)
• Finance/Tax Office
• Human Resources
• Research contracting/agreements offices
• Legal/General Counsel

• Chief Research Information Officer
• Data Science Office
• Innovation
• Marketing/Communications
• Patient Experience
• Research Compliance Officer
• Research Education
Mass General Brigham – Pillars Impacting Equity & Inclusion

**Research Infrastructure**
- Research Review Committees (IRB, SRC, etc)
- Institutional Policies
- Partnerships/Funding
  - For-profit
  - Non-profit
  - Philanthropy
- Research workforce

**Education**
- Conferences
- Symposia
- Workshops
- Publications
- Toolkits

**Policy, Regulation and Legislation**
- Federal
- State
- Local

**Research Methods & Implementation**
- Study Design
- Protocol development
- Instruments and measurement
- Data and analytics

**Participant Experience**
- Recruitment
- Retention
- Relationships
- Partnerships

**Data & Analytics**
### IRB Initiatives

**IRB Membership**
- Recruited diverse leadership in our Chairs/Vice Chairs
  - Dedicated %FTE for equity & inclusion work
- Community Outreach to recruit nonscientists
  - Don’t allow scientist from community
  - Recruit through study teams/research centers
  - Don’t rely on IRB staff as your nonscientist

**Training & Education**
- IRB members IRB Staff
  - General
  - Protocol review/screening
- Part of required training for researchers
- Additional optional researcher education offerings

**Protocol**
- Update protocol template
  - Recruitment/retention plan
  - I/E criteria
  - Visit schedule/location
- Budget to support equity & inclusion efforts

---

**Pillars: Research Infrastructure, Education, Participant Experience, Research Methods & Implementation**
Subject Payment Policy Changes

- Working with Finance, Research, Digital Leadership
- Researcher advisory groups
- Revised threshold under which SSN is required from $50 to $250
  - Creating alternative UUID system for tracking
- Increase options for payments, particularly around use of gift cards
- Reduce/eliminate cost for researcher to provide debit/gift cards

Pillars: Research Infrastructure, Participant Experience, Research Methods & Implementation
Translation & Interpretation

- Working with system Patient Experience leadership, translation offices, financial leadership
- Researcher feedback
- Ensure that interpretation services are available for research encounters – developing clear processes and education
- Budget for translation of consents (we have 6 “required” languages)
- Ongoing discussions regarding use of assessments/tools that are not validated for other languages

Pillars: Research Infrastructure, Education, Participant Experience, Research Methods & Implementation
## Additional Initiatives

<table>
<thead>
<tr>
<th>MCA Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• IRB identified inequities in device trials that were excluding those without insurance</td>
</tr>
<tr>
<td>• Worked with Clinical Trials Office, Research Leadership</td>
</tr>
<tr>
<td>• Met with impacted researchers</td>
</tr>
<tr>
<td>• New requirement for company to go through the MCA process prior to IRB approval</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Return of Aggregate Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pilot to provide results via the “Rally for All” website/program</td>
</tr>
<tr>
<td>• Collaboration with hospital and system Public Relations to develop lay summaries</td>
</tr>
<tr>
<td>• Exploring use of AI to support activities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Developing a registry for all participants to collect basic demographic information</td>
</tr>
<tr>
<td>• Baseline metrics for equity and inclusion</td>
</tr>
<tr>
<td>• Track progress</td>
</tr>
<tr>
<td>• Integrate with payment and return of results initiatives</td>
</tr>
</tbody>
</table>

**Pillars:** Research Infrastructure, Education, Participant Experience, Research Methods & Implementation
Membership on system-wide Disability Council
  • Subcommittee for research
  • Subcommittee for education

Partnersed with Research Compliance office to add education to mandatory Responsible Conduct of Research (RCR) training

Supported reversal of the original NIH working group decision NOT to designate those with a disability as a health disparity population.
  • No one with a disability on the committee
  • Decision was reversed

NIH designates people with disabilities as a population with health disparities | National Institutes of Health (NIH)

Submitted comment to the NIH RFI on the new NIH mission statement
Words Matter, Actions Have Impact: Updating the NIH Mission Statement – NIH Director's Blog

Pillars: Policy, Regulation & Legislation, Research Infrastructure, Education, Participant Experience, Research Methods & Implementation
Takeaways

• Small steps are ok – start doing the little things while you work on bigger initiatives
• Collaborate with others that are doing this work
• Engage leadership wherever and whenever you can
Thank you

• We need your ideas, energy, collaboration, and commitment

• REACH out:
  • To your institution and investigators
  • To your patients and participants
  • To your own IRB and others
  • To your community
  • To the public
  • To us