Supporting IRB Efforts to Advance Diversity and Inclusion in Clinical Research: Tools and Resources

Multi-Regional Clinical Trials Center (MRCT Center)
of Brigham & Women’s Hospital & Harvard

June 23, 2022
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.

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Today’s Webinar Presentation & Discussion

Barbara Bierer, MD
Faculty Director,
MRCT Center

Ivy R. Tillman, MS, CCRC, CIP
Director of Research Operations
Mayo Clinic

Laura Meloney, MS, MPH
Program Director,
MRCT Center
Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
The Work We’ve Done

Before and After: Integrating Health Literacy into Study Materials

Health Literacy in Clinical Research: IRB Training Activity

Tools and Resources
- Plain Language Resources
- Numeracy Resources
- Clear Design Resources
- Usability Testing Resources
- Cultural Considerations Resources
- Interactive Techniques Resources
- Glossary Resources
- Consent Guide Resources
DEI: Who is responsible?

Values that improve accountability, regardless of the stakeholder:

- Transparency
- Dialogue
- Measurement, tracking, and reporting (metrics)
Regulatory Foundations

§46.111 Criteria for IRB approval of research.
(3) Selection of subjects is equitable.

*Fairness in the distribution of the benefits of research (Justice)*

And beneficence and respect for persons also apply.
• 45 CFR 46.116(a)(3): “The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative,”

• 21 CFR 50.20: “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.”
45 CFR 46.107 & 21 CFR 56.107: The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
RESPECT, BENEFICENCE, JUSTICE

Most regulated clinical research undergoes obligate review and approval by an IRB. IRBs are charged with safeguarding the rights and well-being of human participants in accordance with the foundational tenets of respect for persons, beneficence, and justice, as described in the Belmont Report (8). An IRB’s ethical responsibilities with regard to diversity derive from these and other principles, guidelines, and standards.
Many disagree...

- Not my job!
- SCOPE CREEP!!
- It’s too late. The protocol is written.
- It’s beyond the regulations!
- We’re not trained.
- One more unfunded mandate dumped on the IRB.
Diversity and Inclusion in Clinical Research: a role for the IRB?

Task Force to Promote Justice in IRB Review and Oversight

- Can we agree on the problem?
- Is this within the remit of the IRB?
- What are the limits of IRB consideration?
- What practical steps can be taken?
- What resources or tools could make the work easier?
- How can we learn from experience and from one another?
<table>
<thead>
<tr>
<th>Individual</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Baumann</td>
<td>Indiana University</td>
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<tr>
<td>David Borasky</td>
<td>WCG</td>
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<tr>
<td>Quincy Byrdsong</td>
<td>Lipscomb University</td>
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<td>Linda Coleman</td>
<td>Yale University</td>
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<tr>
<td>Michelle Feige</td>
<td>AAHRPP</td>
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<td>David Forster</td>
<td>WCG</td>
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<td>Lindsay McNair</td>
<td>WCG</td>
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<tr>
<td>Owen Garrick</td>
<td>Bridge Clinical (now CVS)</td>
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<tr>
<td>Nanibaa Garrison</td>
<td>University of California, LA</td>
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<tr>
<td>Luke Gelinas</td>
<td>Advarra</td>
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<td>Christine Grady</td>
<td>NIH*</td>
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<td>Elisa Hurley</td>
<td>PRIMR</td>
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<td>Martha Jones</td>
<td>Mass General Brigham</td>
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<tr>
<td>Sarah Kiskaddon</td>
<td>Dana-Farber / Harvard Cancer Center</td>
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<tr>
<td>Susan Kornetsky</td>
<td>Boston Children's Hospital</td>
</tr>
<tr>
<td>Freda Lewis-Hall</td>
<td>Independent</td>
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<td>Robert Nobles</td>
<td>Emory University</td>
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<tr>
<td>Tina Young Poussaint</td>
<td>Boston Children's Hospital</td>
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<tr>
<td>Suzanne Rivera</td>
<td>Macalester University</td>
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<tr>
<td>Stephen Rosenfeld</td>
<td>NorthStar IRB</td>
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<td>Jessica Rowe</td>
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<td>Michele Russell-Einhorn</td>
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<td>Sana Shakour</td>
<td>University of Michigan</td>
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<td>Benjy C Silverman</td>
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<td>Megan Singleton</td>
<td>Johns Hopkins</td>
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<td>Hayat Ahmed</td>
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<td>Laura Meloney</td>
<td>MRCT Center</td>
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<td>Sarah White</td>
<td>MRCT Center</td>
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*Participation and/or contribution from members does not indicate that materials have been endorsed by the NIH, DHHS, or any branch of the federal government.*
Convergent realms of interactions for success

- Institution and institutional support (and harmonized approach)
- IRB considerations in its approach to protocol review
- IRB membership considerations
- Educational tools

Evolution not Revolution

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• Distillation of recommendations from Task Force
• Categories of recommendations
  o HRPP & IRB Responsibilities
  o IRB Review Process
    ▪ Initial Review
    ▪ Continuing Review
  o Communications, translations, and health literacy
  o IRB Membership, support, and training
• Four Delphi voting rounds, 16 participants
What resulted?

- 28 core recommendations for IRBs
  - Range from addressing fair and equitable distribution of research benefits through inclusion of underrepresented groups to specifying support structures for IRB members to facilitate the work
  - Reached positive consensus

Enthusiastic endorsement

- The role of the IRB for DEI in clinical research is not mission creep
- Consistent, steady discussion and training(s) will help direct the work
- Support for wide dissemination of recommendations
IRBs Supporting Diversity and Inclusion in Clinical Research

Ivy Tillman, MS, CCRC, CIP
Director of Research Operations
Mayo Clinic
Where to Start?
HRPP/IRB DEI Philosophy

Strategic Planning
Leadership support and commitment
Defining Diversity
Examining the Approach

Epistemological frame
Guiding principles
Diversity & Inclusion

Defining Diversity

Prioritizing Diversity and Inclusion

Participant Population

IRB Representation
Guiding Principles
Paradigm Shift

- Organization
- HRPP
- Community
- Researchers
Context and History
Do The Work

- Willingness to Start the Journey
- Self-reflection
- Read, Observe, Prepare
- Uncomfortable conversations
- Dialog with stakeholder groups
IRB Policies
Consent Templates
Recruitment Templates
IRB Application

Critical Analysis
How to Begin

Develop a strategic plan

Clearly articulate objectives

Identify Priorities

Establish measurable goals
Resource byway: Support to advance the work

Laura Meloney, MS, MPH
Program Director,
MRCT Center
Resource byway: Support to advance the work

- Call to action: Expectation, endorsement, alignment
- Tools and templates
- Suggested protocol template changes
- Points to consider in review, with relevant questions to ask
- Educational materials
- Necessary institutional support

Go to: [https://mrctcenter.org/diversity-in-clinical-research/](https://mrctcenter.org/diversity-in-clinical-research/)
IRBs are charged with safeguarding the rights and well-being of human participants in accordance with the foundational principles outlined in the Belmont Report: respect for persons, beneficence, and justice. But IRBs have the difficult responsibility of balancing protecting vulnerable populations from harm while helping to ensure the inclusion of underrepresented participants in research. While IRBs are not primarily responsible for diversity, equity, and inclusion (DEI) in clinical research, IRBs do serve as an important checkpoint with the authority to require attention to the principles of DEI.

The notion that IRBs have, as a matter of justice, a role in and a responsibility to diversity and inclusion has been historically underappreciated. There is a need, therefore, for guidance and the development of tools, resources, and methods to approach this responsibility. As a first step, IRBs must set reasonable expectations for diversity and inclusion as a condition of study approval, at continuing review, and at study close out.
IRB and HRPP Toolkit

+ IRB Resources

+ Resources for IRBs/HRPPs to provide to Investigators/Research Teams
IRB and HRPP Toolkit

+ IRB Resources

+ Resources for IRBs/HRPPs to provide to Investigators/Research Teams
<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Membership Self-Assessment Template</td>
<td>An IRB membership self-assessment survey that provides sample questions for institutions to use or adapt to understand the demographic diversity of their members and their members’ perspectives and opinions.</td>
</tr>
<tr>
<td>IRB Statement of Commitment to Inclusion</td>
<td>A concise template example for an IRB statement of commitment to diversity, inclusion, and equity. This example can be adopted and/or adapted by IRBs.</td>
</tr>
<tr>
<td>HRPP and IRB Statement of Commitment to Inclusion</td>
<td>A template example for HRPPs’ and IRBs’ statement of commitment to diversity, inclusion, and equity. This example can be adopted and/or adapted by HRPPs and IRBs.</td>
</tr>
<tr>
<td>Approaches to Support IRB members</td>
<td>This document provides different approaches for how support IRB members, particularly non-affiliated IRB members.</td>
</tr>
<tr>
<td>IRB Health Literacy Training</td>
<td>Health literacy resources specifically for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs).</td>
</tr>
</tbody>
</table>
IRB Self Evaluation Survey

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

- Recognition
- Provision of resources to support digital access
  - Technology
  - Software
  - Communication platform
  - Security
  - Encryption
  - Internet connectivity
- Virtual work environment with accommodations
- Compensation considerations
- Institutional policy recommendations

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 credit, or the fulfillment of a service requirement, for members’ time and effort.

Support for IRB Members: Non-Institutional Affiliates
Community and other unaffiliated individuals who volunteer to be members of IRB committees should be recognized and acknowledged for their time and service. Unaffiliated members are
Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs) can play an important role in supporting research study participants by applying health literacy best practices to their reviews of participant-facing materials.

The purpose of the training is to introduce the concept of health literacy and how it applies to the review and approval of clinical research. Trainees will also have the opportunity to put what they learn into action through the completion of application exercises.

This training is designed to be self-guided. Individuals can take this training and earn a Certificate of Completion. After completing the training, there is also an option for someone at your organization to facilitate a team discussion about this content using the Facilitator’s Guide.

Additional information about Health Literacy in Clinical Research can be found here: https://mrctcenter.org/health-literacy/

A health literacy checklist for IRB reviewers can be found here: https://mrctcenter.org/health-literacy/instructional-resources/overview/irb-checklist

To access the modules, please follow these instructions: Health Literacy Enrollment Instructions.pdf

For any questions, please contact: Sylvia Baedorf Kassis

https://cpd.partners.org/content/irb-health-literacy-clinical-research#group-tabs-node-course-default1
Health Literacy Training and Checklist for IRBs: Overview

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

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

INTRODUCTORY HEALTH LITERACY TRAINING FOR HRPP AND IRB MEMBERS AND STAFF

IRB Health Literacy Checklist

This checklist, created for IRBs reviewing participant-facing materials, covers:

- Considerations for participant-facing materials
- General assent/consent-specific considerations
- Targeted assent/consent process considerations

Have health literacy best practices been applied to develop participant-facing materials?

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

*Participant-facing documents include recruitment materials, consent/assent forms, study instructions, letters/postcards, etc.
IRB and HRPP Toolkit

Home > Tools > IRBs and HRPPs Toolkit

+ IRB Resources

+ Resources for IRBs/HRPPs to provide to Investigators/Research Teams
<table>
<thead>
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<tr>
<td>Procedural &amp; Logistical Checklist</td>
<td>This resource is a checklist of logistical and procedural considerations to enhance representation of diverse populations in research. It is intended for HRPPs/IRBs to provide to investigators and their research teams.</td>
</tr>
<tr>
<td>An IRB Resource for Participants: Costs and Payments</td>
<td>This document is a resource for participants to consult and familiarize themselves with questions to ask about payment(s) in clinical research. This document can be disseminated by HRPPs or IRBs to participants via online portals, resource libraries, and/or through investigators and study teams. This document should be adapted and revised to align with institutional policies and procedures.</td>
</tr>
<tr>
<td>An IRB Resource for Investigators and Research Teams: Practical Points to Consider: Payment to Research Participants</td>
<td>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 suggestions for appropriate communication with research participants regarding payment. This document was created as a resource for HRPPs and their IRBs to adapt when developing guidance for investigators on payments to research participants. Developed guidance should align with institutional policies and should be reviewed by HRPPs/IRBs in advance of dissemination to investigators.</td>
</tr>
<tr>
<td>Incorporating DEI into Clinical Research Protocol Templates</td>
<td>This document provides considerations for diversity and inclusion when drafting a clinical research protocol. This overview may be used concurrently with any detailed protocol template or as a stand-alone guidance for incorporating DEI elements into a clinical research protocol.</td>
</tr>
</tbody>
</table>
Procedural and Logistical Checklist

Audience: Investigators and their research teams, Sponsors, CROs, Research Sites, IRBs, QA/QI Teams

Purpose: This checklist is for investigators, their research teams, sponsors, and others to use when considering Diversity, Equity and Inclusion (DEI) in a clinical trial. At each stage of a research study, there are logistical and procedural considerations to help lower the barriers for inclusion of underrepresented populations. This is a non-exhaustive list, intended to prompt attention to affirmative steps to address DEI.

Considerations for Use: This checklist maybe a useful educational and ‘best-practices’ guide:
- For HRPPs and their IRBs to review and distribute
- For investigators and their study teams to have and consult
- For institutional quality assurance/quality improvement (QA/QI) programs to use in monitoring
- For sponsors to plan, conduct, and report trials
- For CROs to consider to plan site engagement strategies.
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 benefiting 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.
IRB Resource for Participants: Costs and Payments

• 2-page guide for participants
  o Important questions to ask
  o Who will pay? Know before you decide
  o Payment for care and procedures
  o Payment for study visits and time
  o Role of insurance/uninsured
  o Costs of injury or harm

• To use or adapt as appropriate
An IRB Resource for Investigators – Practical Points to Consider: Payment to Research Participants

• Types of payments
• Decision tree to determine most appropriate form of payment
• Considerations to safeguard participants
  o Research related injury
  o Undue influence
  o Risk of eligibility to entitlements
• Communications with participants about payments
• Tax considerations; NOT tax advice!
An IRB Resource for Sponsors and Investigators – Diversity & Inclusion Overlay on Protocol Templates

- Overview document and two of the most used protocol templates
  - TransCelerate Common Protocol Template
  - NIH-FDA Phase 2 and 3 IND/IDE Clinical Trial Protocol Template
- Highlights specific areas within the protocol that are important to advancing DEI efforts
- Guidance for sponsors and investigators, and a resource for IRBs

1.1 SYNOPSIS

<table>
<thead>
<tr>
<th>Title:</th>
<th>&lt;Full title&gt;</th>
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<tbody>
<tr>
<td>Study Description:</td>
<td>Provide a short description of the protocol, including a brief statement of the study hypothesis. This should be only a few sentences in length. A detailed schematic describing all visits and a schedule of assessments should be included in the Schema and Schedule of Activities, Sections 1.2 and 1.3, respectively.</td>
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<tr>
<td>Objectives:</td>
<td>Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol. These align with Primary Purpose in clinicaltrials.gov.</td>
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<tr>
<td>Primary Objective:</td>
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<td>Secondary Objectives:</td>
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</tr>
<tr>
<td>Endpoints:</td>
<td>Include the primary endpoint and secondary endpoints. These should be the same as the endpoints contained in the body of the protocol.</td>
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<tr>
<td>Primary Endpoint:</td>
<td></td>
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<tr>
<td>Secondary Endpoints:</td>
<td></td>
</tr>
<tr>
<td>Study Population:</td>
<td>Specify the sample size, gender, age, demographic group, general health status, and geographic location.</td>
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<td>Phase:</td>
<td>&lt;2 or 3 or N/A&gt; Phase applies to drugs and biologics.</td>
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<tr>
<td>Description of Sites/Facilities Enrolling Participants:</td>
<td>Provide a brief description of planned facilities/participating sites enrolling participants. Indicate general number (quantity) of sites only and if the study is intended to include sites outside of the United States.</td>
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<tr>
<td>Description of Study Intervention:</td>
<td>Describe the study intervention. If the study intervention is a drug, biologic, include dose and route of administration. For device description of each component, ingredient, principle of operation of the device.</td>
</tr>
<tr>
<td>Study Duration:</td>
<td>Estimated time (in months) from when the study opens to completion of data analyses.</td>
</tr>
<tr>
<td>Participant Duration:</td>
<td>Time (e.g., in months) it will take for each individual patient to complete all participant visits.</td>
</tr>
</tbody>
</table>

Is this a study focused on a specific disease, disease pathway, or intervention? If yes, the burden and epidemiology of the disease should be described. Further, any unmet medical need or needs of the population and/or subgroup should be described here. If possible, a design that offers remote or flexible visit options wherever possible is encouraged.

During the design phase, the study should consider features that enable ease of access to the trial, including (when possible) virtual visits, weekend hours, using local labs, or offering home health care to allow those who may have challenges with transportation, job hours or childcare. Visit frequency should be minimalized to the extent possible consistent with the study goals.
DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

IRB and HRPP Toolkit

+ Additional resources to be added include:
  - Mapping a strategy for change
  - IRB checklist for initial and continuing reviews
  - Guidance on translation
  - Revised Recruitment Strategy Document
  - Social Behavioral Protocol Template revision

+ We encourage you to explore, to use, to adapt, and to suggest additional resources or revisions to our available resources.
• All updates will be announced in MRCT Center Newsletter: sign up!
• Next week:

Equity by Design in Clinical Research: EbD METRICS FRAMEWORK
Webinar and Public Launch
Thursday June 30, 2022
1:00-2:00pm EDT

https://mrctcenter.org

June 30, 2022
1-2 pm EDT
Questions and Discussion
Thank you