MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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

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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

The Multi-Regional Clinical Trials Center (MRCT Center)

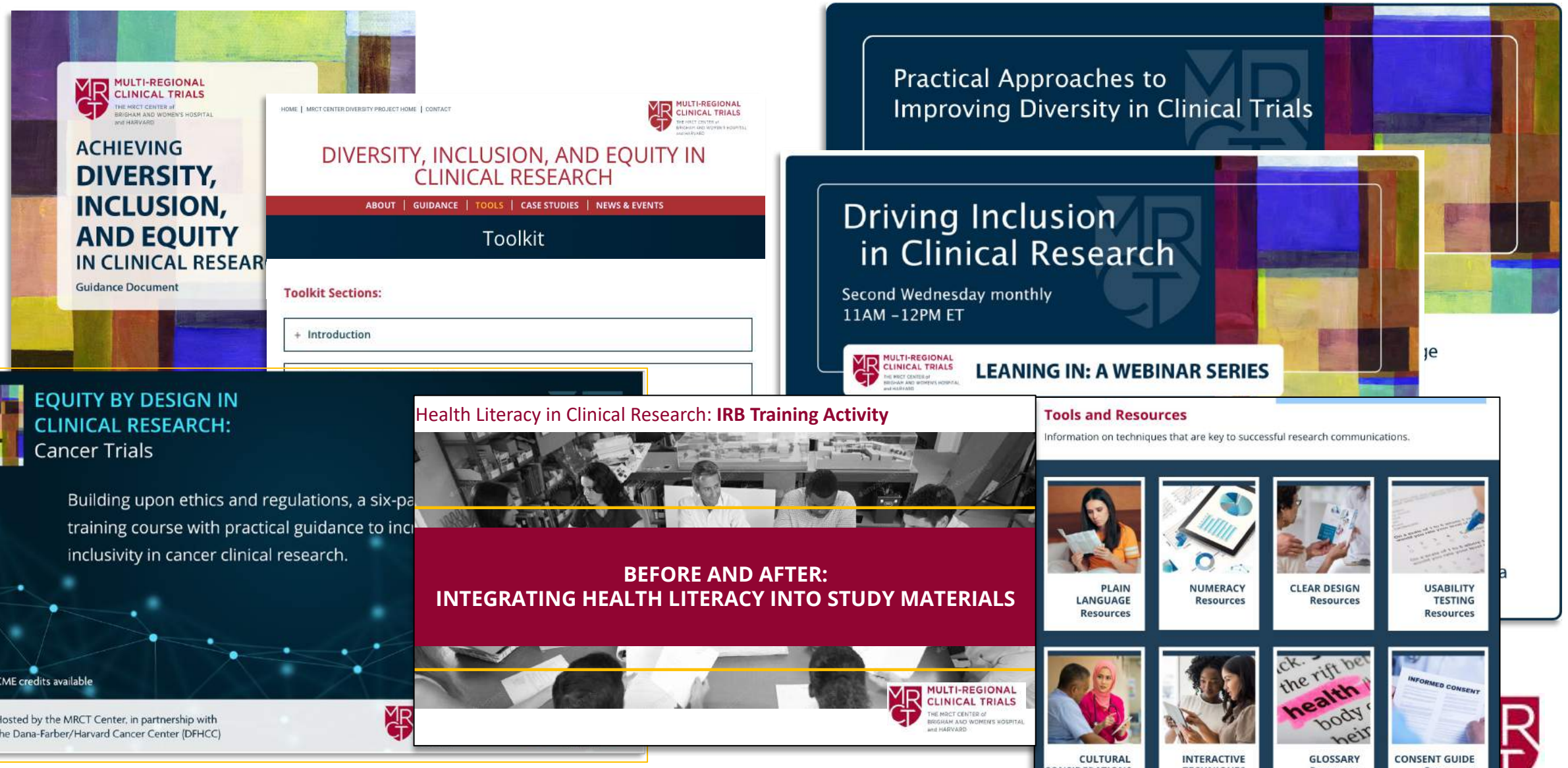
Our Vision

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



DEI: Who is responsible?

Values that improve accountability, regardless of the stakeholder:

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

Diversity and Inclusion in Clinical Research: a role for the IRB?

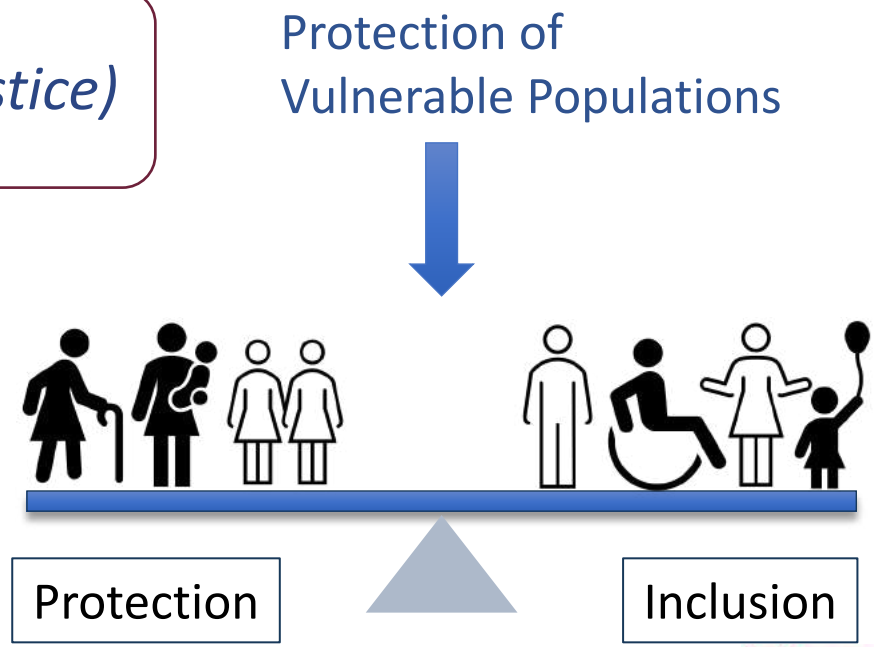
Regulatory Foundations

§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.



Regulatory Foundations

- 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."

Health Literacy and Translation

Regulatory Foundations

- 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.

A qualified and diverse IRB

Science

POLICY FORUM

ETHICS AND DIVERSITY

Justice, diversity, and research ethics review

It is time for institutional review boards and research ethics committees to address the ethics of inclusion

By **David H. Strauss[1,2], Sarah A. White[1,3], Barbara E. Bierer[1,3,4]**

The disproportionate impact of COVID-19 on certain populations, such as Black, Latinx, and Indigenous populations in the United States, has focused attention on inequalities in health and on the need to increase enrollment of racial and ethnic minorities and other underrepresented groups in biomedical research (*1*). Yet too often, in the United States and globally, participant enrollment in research has not reflected the demographic composition of the general population, those affected by the health conditions being studied, or those for whom the investigational product is intended (*2*), with racial and ethnic minorities and the young and the elderly, among others, being consistently underrepresented (*3*). Underlying causes for this underrepresentation have been described (*4*, *5*), but change has been slow. Notwithstanding the roles of other stakeholders in addressing this issue, we maintain that the specific value of institutional review boards (IRBs) and research ethics committees (RECs) in promoting diserve efforts to address mistrust of research and health care (*6*, *7*). Responsibility to the goals of diversity lies with all stakeholders in the clinical research enterprise (*6*), and a commitment to diversity, individually and collaboratively, by research sponsors, funders, academic institutions, contract research organizations, study sites, investigators, and IRBs is necessary.

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 (*9*, *10*).

The discussion of justice in Belmont cites "moral requirements that there be fair procedures and outcomes in the selection of research subjects." As Belmont and other codes of ethics emerged from a historical backdrop of abuse and injustice in

require special efforts to include members of those populations in research" (*9*), and by the World Medical Association Declaration of Helsinki, which states, "Groups that are underre
should be
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acceptable harm or burden.

Belmont describes two ethical convictions in relation to respect for persons, self-determination, and decision-making: the obligations to treat individuals as autonomous agents and to protect those with diminished autonomy. IRBs provide additional safeguards for research involving participants with compromised voluntariness (e.g., prisoners) or impaired comprehension. With regard to the inclusion of diverse populations, respect for persons demands efforts to foster informed and

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Many disagree…

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?

Task Force to Promote Justice in Review and Oversight in Clinical Research

Individual	Organization
John Baumann	Indiana University
David Borasky	WCG
Quincy Byrdsong	Lipscomb University
Linda Coleman	Yale University
Michelle Feige	AAHRPP
David Forster	WCG
Lindsay McNair	WCG
Owen Garrick	Bridge Clinical (now CVS)
Nanibaa Garrison	University of California, LA
Luke Gelinas	Advarra
Christine Grady	NIH*
Elisa Hurley	PRIMR
Martha Jones	Mass General Brigham
Sarah Kiskaddon	Dana-Farber / Harvard Cancer Center
Susan Kornetsky	Boston Children's Hospital
Freda Lewis-Hall	Independent

Individual	Organization
Robert Nobles	Emory University
Tina Young Poussaint	Boston Children's Hospital
Suzanne Rivera	Macalester University
Stephen Rosenfeld	NorthStar IRB
Jessica Rowe	Yale University
Michele Russell-Einhorn	Advarra
Sana Shakour	University of Michigan
Benjy C Silverman	Mass General Brigham
Megan Singleton	Johns Hopkins
David Strauss	Columbia University
Elyse Summers	AAHRPP
Holly Taylor	NIH*
Barbara Bierer	MRCT Center
Hayat Ahmed	MRCT Center
Laura Meloney	MRCT Center
Sarah White	MRCT Center

*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

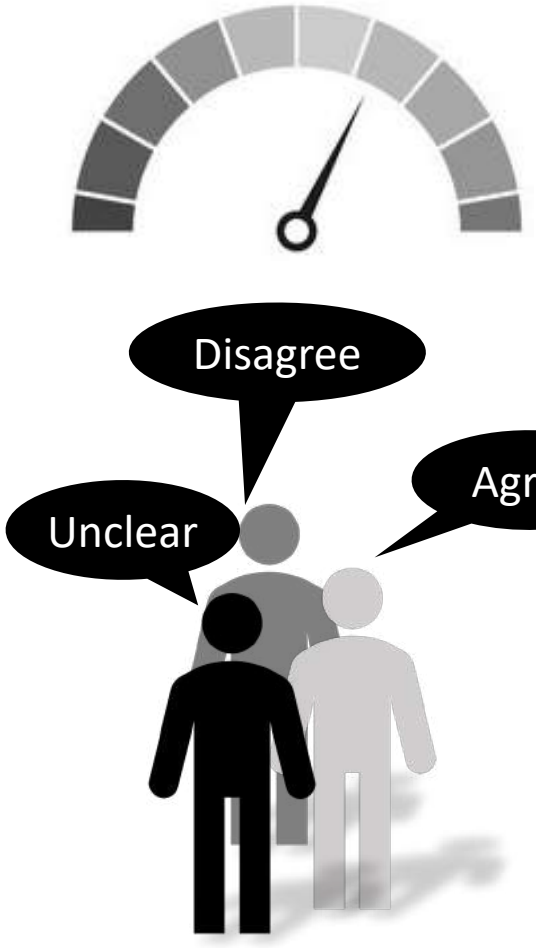
Less

Evolution not Revolution

More

Modified Delphi Study – IRB Recommendations for DEI in Clinical Research

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



Modified Delphi Study – IRB Recommendations for DEI in Clinical Research

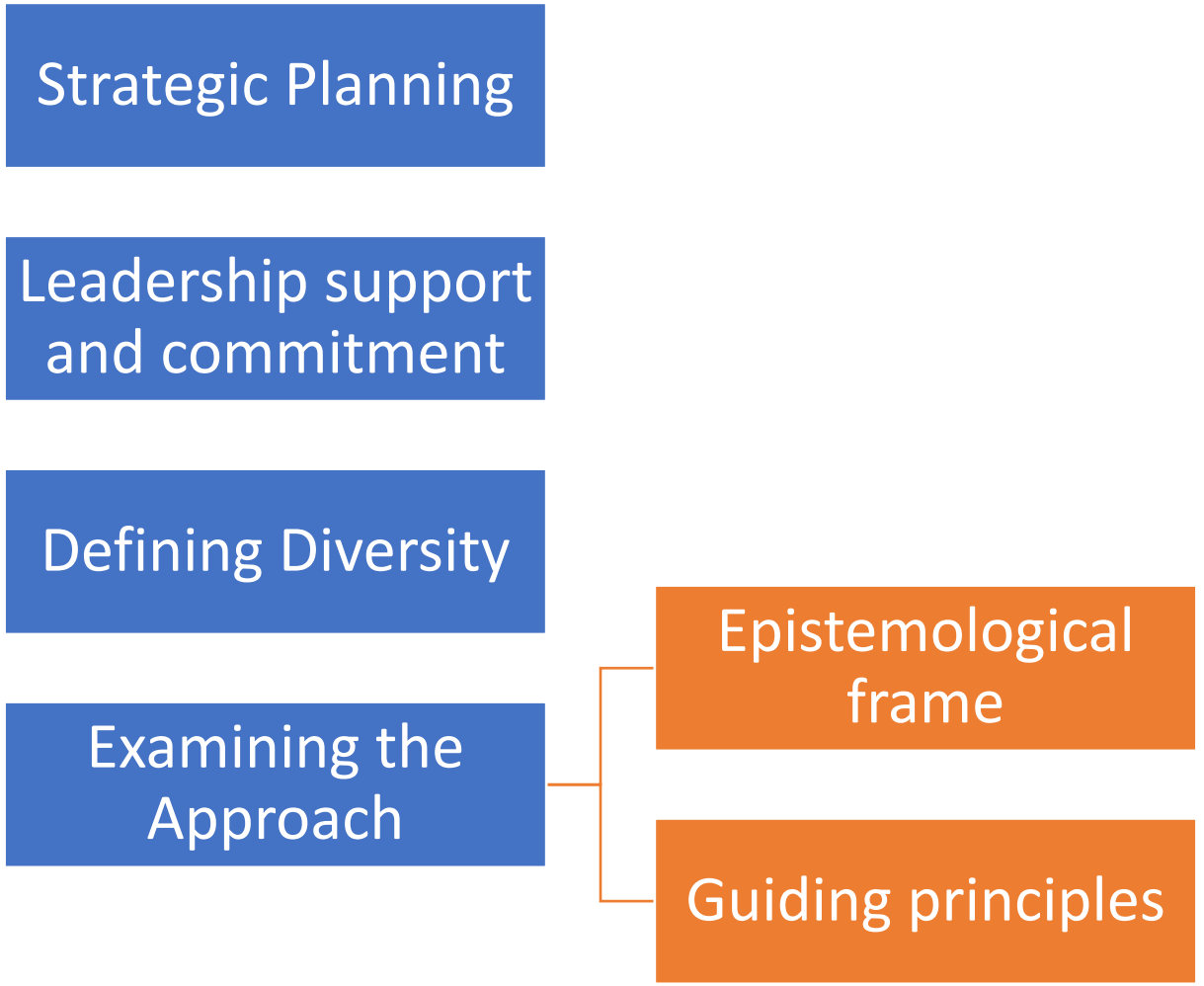
- What resulted?
  - 28 core recommendations for IRBs
    - Range from addressing fair and equitable distribution of research benefits through inclusion of underrepresented groups to specifying support structures for IRB members to facilitate the work
  - Reached positive consensus
- Enthusiastic endorsement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



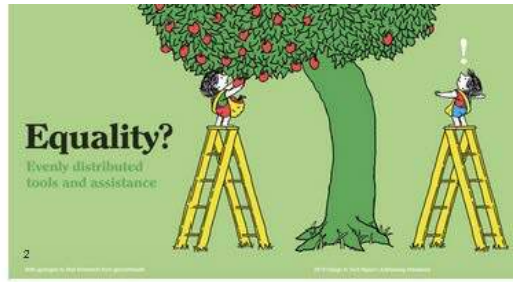
Diversity & Inclusion

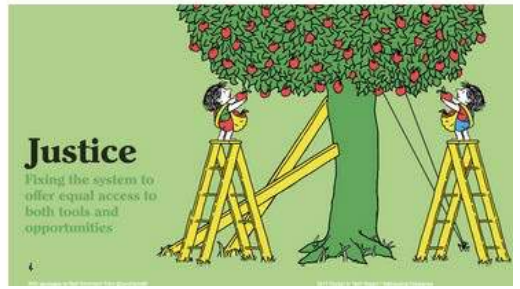
Defining Diversity

Prioritizing Diversity and Inclusion

Participant Population

IRB Representation

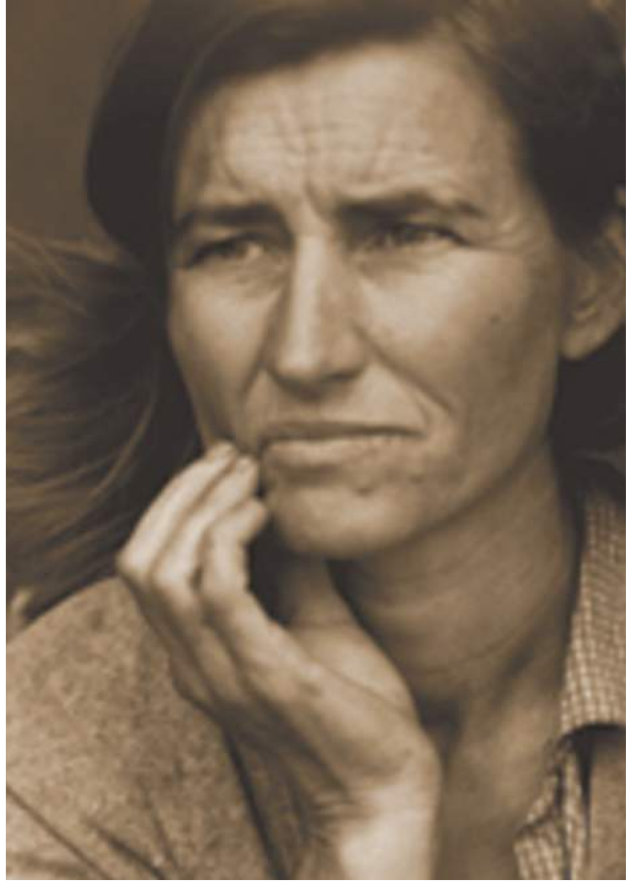




Guiding Principles

Paradigm Shift






Context and History

Do The Work

- Willingness to Start the Journey
- Self-reflection
- Read, Observe, Prepare
- Uncomfortable conversations
- Dialog with stakeholder groups

IRB Policies

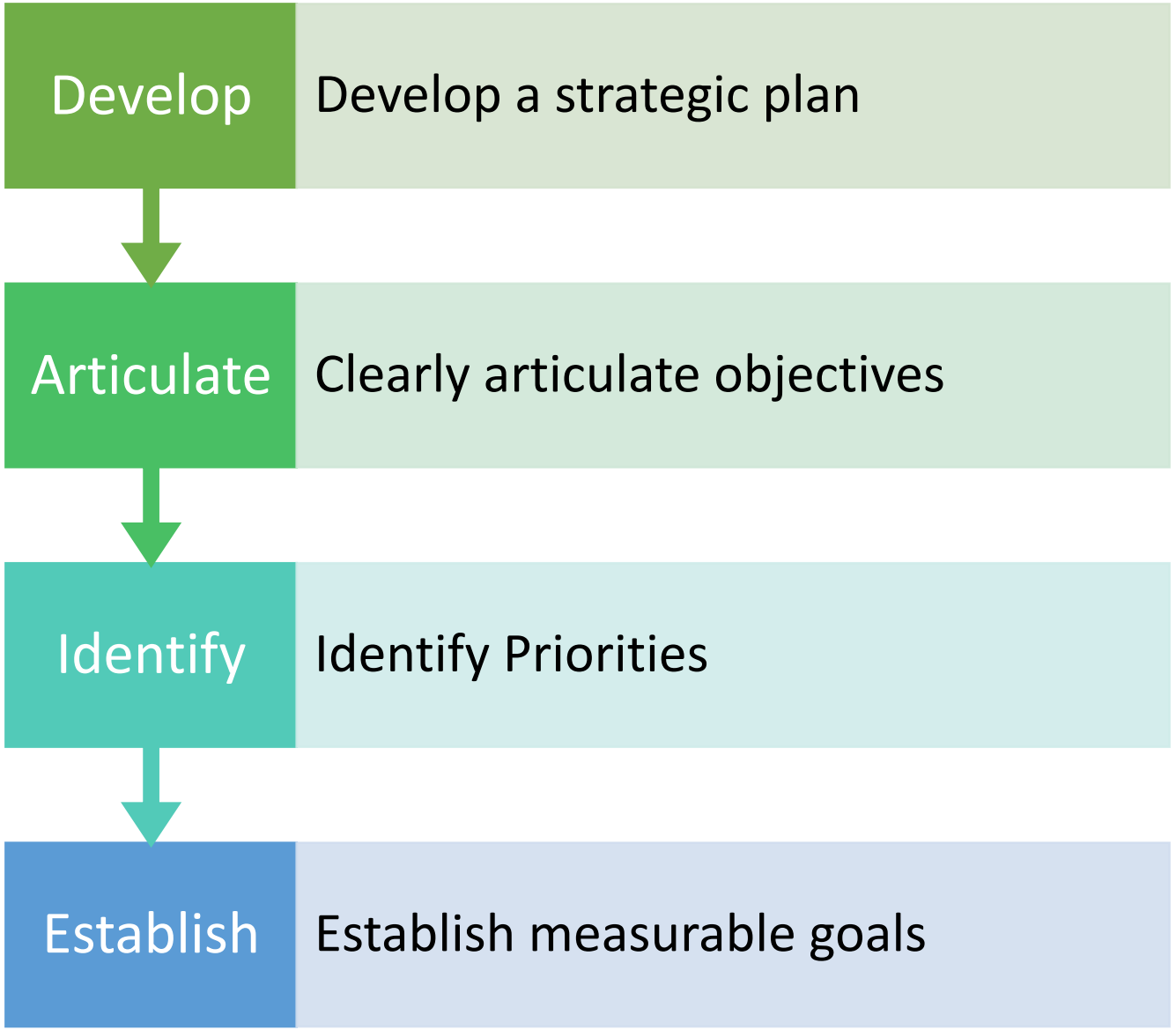
Consent Templates

Recruitment Templates

IRB Application

Critical Analysis

How to Begin


Develop
Develop a strategic plan
Articulate
Clearly articulate objectives
Identify
Identify Priorities
Establish
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/

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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

IRB and HRPP Toolkit

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.

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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

IRB and HRPP Toolkit

+ IRB Resources

+ Resources for IRBs/HRPPs to provide to Investigators/Research Teams

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IRB Resources

IRB Membership Self-Assessment Template (Self-Evaluation Survey)	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.
IRB Statement of Commitment to Inclusion	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.
HRPP and IRB Statement of Commitment to Inclusion	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.
Approaches to Support IRB members	This document provides different approaches for how support IRB members, particularly non-affiliated IRB members.
IRB Health Literacy Training	Health literacy resources specifically for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs).

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.

Example
IRB Self Evaluation Survey

The goal of the IRB Member Self Evaluation survey to provide sample questions for institutions, HRPPs, and/or IRBs to select or adapt to help guide and inform the diversity and perspectives of their IRB members. It can also be helpful to understand educational, training, skills development needs.

The choice of what to include and how each question is phrased will be determined by the institutions, HRPPs, and IRBs, and may change over time. The HRPP/IRB may choose to implement this survey as anonymous or identified. Questions listed below that are already part of a routine HRPP or IRB's Membership Survey can be disregarded. Alternatively, this survey could be integrated into the periodic Membership Survey. The questions below are simply suggestions for HRPPs and IRBs to consider, to align with their institutional goals for representation on their IRBs and for the greater considerations of diversity and inclusion in clinical research.

The purpose of this survey is:

- To reflect on member participation and roles
- To provide feedback to IRB and HRPP leadership
- To serve as a basis for potential areas of improvement and education
- To consider inclusion in IRB membership and representation of the research participants in the research that it reviews

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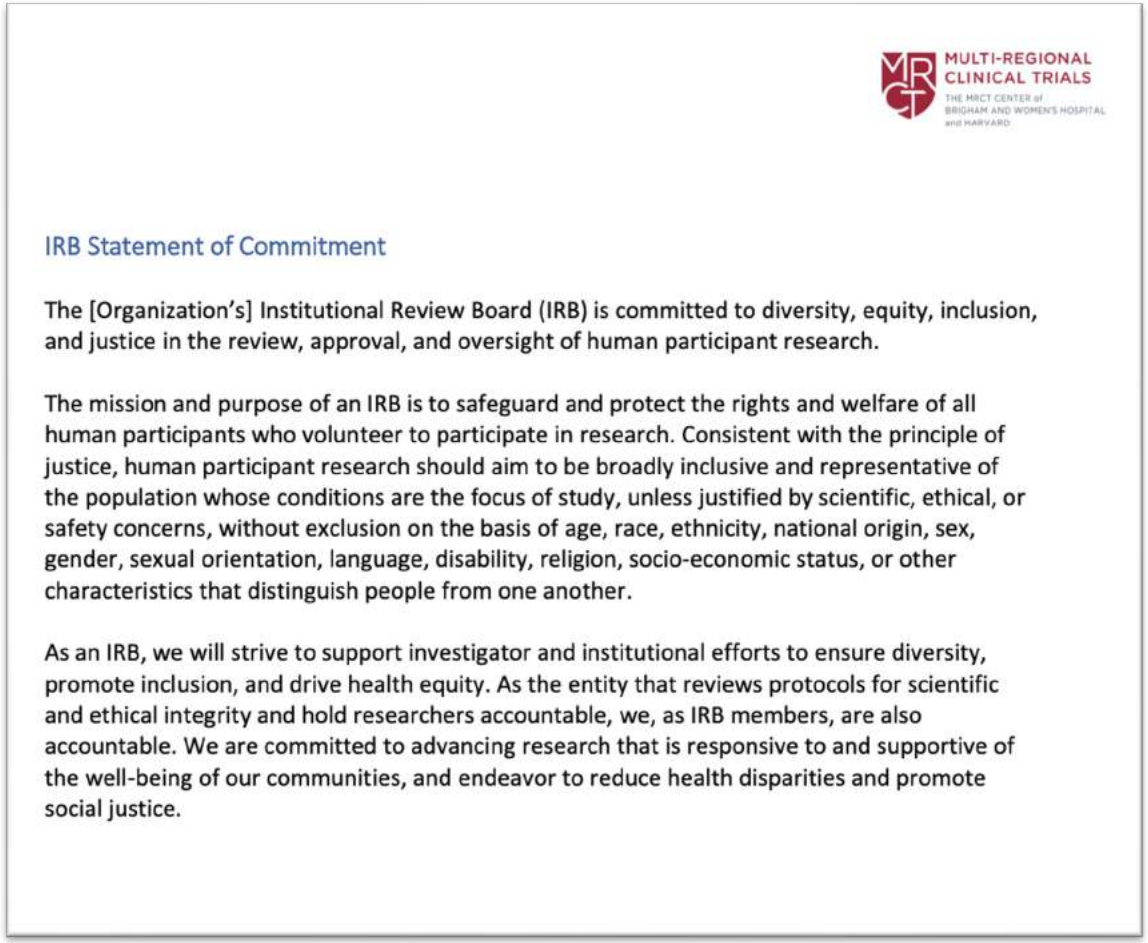
Survey Instructions: Please answer all questions as truthfully and honestly as possible. Please submit tis completed evaluation by _____to _____. If you have questions, please contact _____.

A. Demographic Information	
1. Ethnicity: Please select one or more ethnicity with which you most closely identify	☐Hispanic or Latinx ☐Not Hispanic / Not Latinx ☐Other ☐Prefer not to answer
2. Race: Please select one or more ethnicity with which you most closely identify	☐American Indian or Alaska Native ☐Asian or Asian American ☐Black or African American ☐Native Hawaiian or Other Pacific Islander ☐White ☐Other (please specify below) ☐Prefer not to answer
Other specification	_____

IRB Membership Self-Assessment Template Version 1 – June 2022

IRB and IRB/HRPP Statements of Commitment



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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 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.

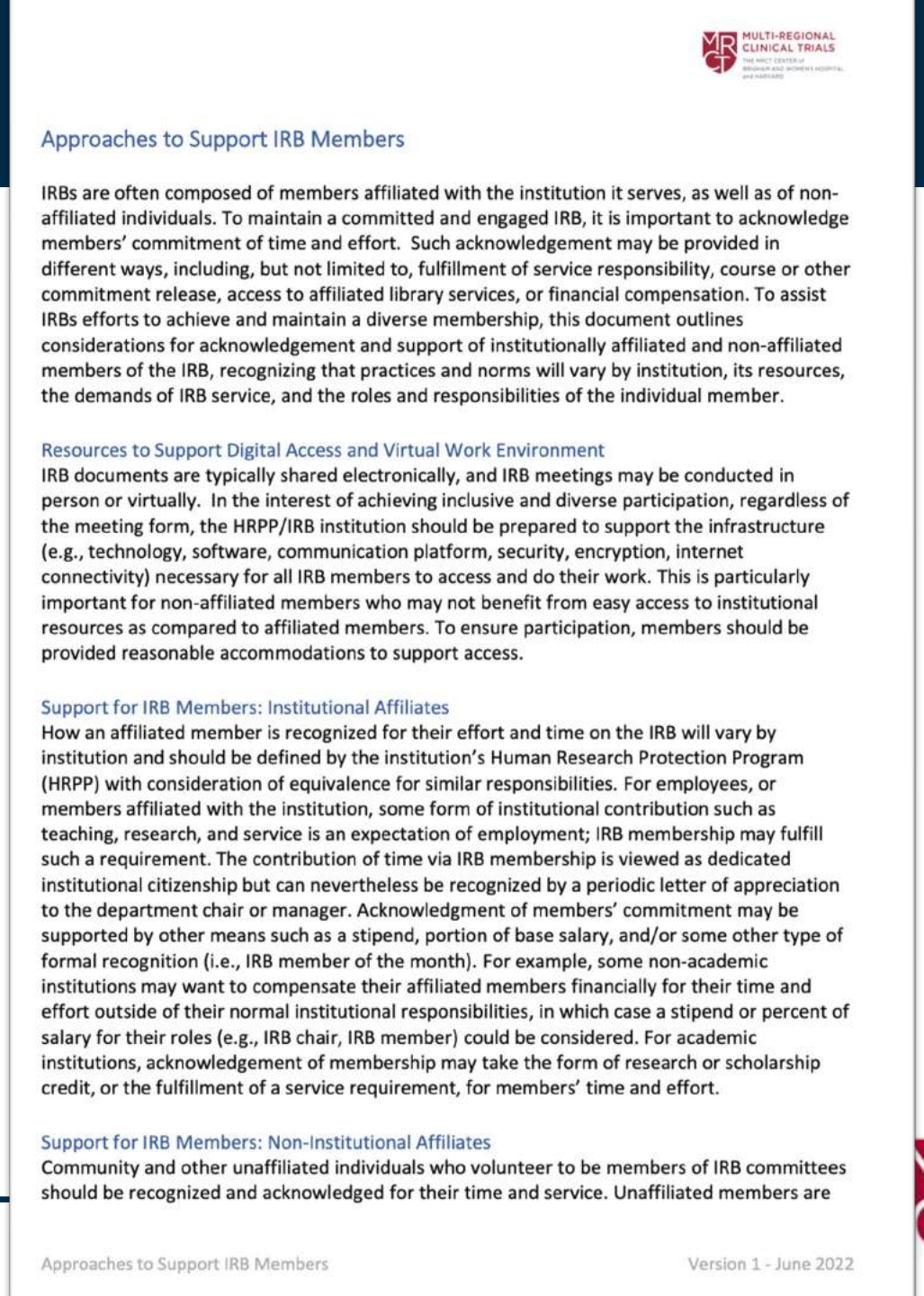
The mission and purpose of an IRB is to safeguard the rights and welfare of human participants in research, to both include and protect those whose conditions are the focus of study. IRBs are responsible for the evaluation and approval of all human participant research and should ensure that any exclusion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

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



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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 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

Online Health Literacy Training

Mass General Brigham Office of Continuing Professional Development

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Home » IRB Health Literacy in Clinical Research

IRB HEALTH LITERACY IN CLINICAL RESEARC

OVERVIEW | ACCREDITATION | REGISTER/TAKE COURSE

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

IRB HEALTH LITERACY IN CLINICAL RESEARCH

HEALTH LITERACY IN CLINICAL RESEARCH INTRODUCTORY VIDEO

← RETURN TO COURSE HOME

COURSE PROGRESS

- HEALTH LITERACY IN CLINICAL RESEARCH INTRODUCTORY VIDEO — REQUIRED — RESUME
- TEACH BACK QUESTIONS
- BEFORE & AFTER: POWERPOINT
- BEFORE & AFTER: ACTIVITY
- FINAL QUIZ
- EVALUATION
- CERTIFICATE

HEALTH LITERACY IN CLINICAL RESEARCH INTRODUCTORY VIDEO

Please review the Health Literacy in Clinical Research video, then proceed to complete the Teach Back Questions.

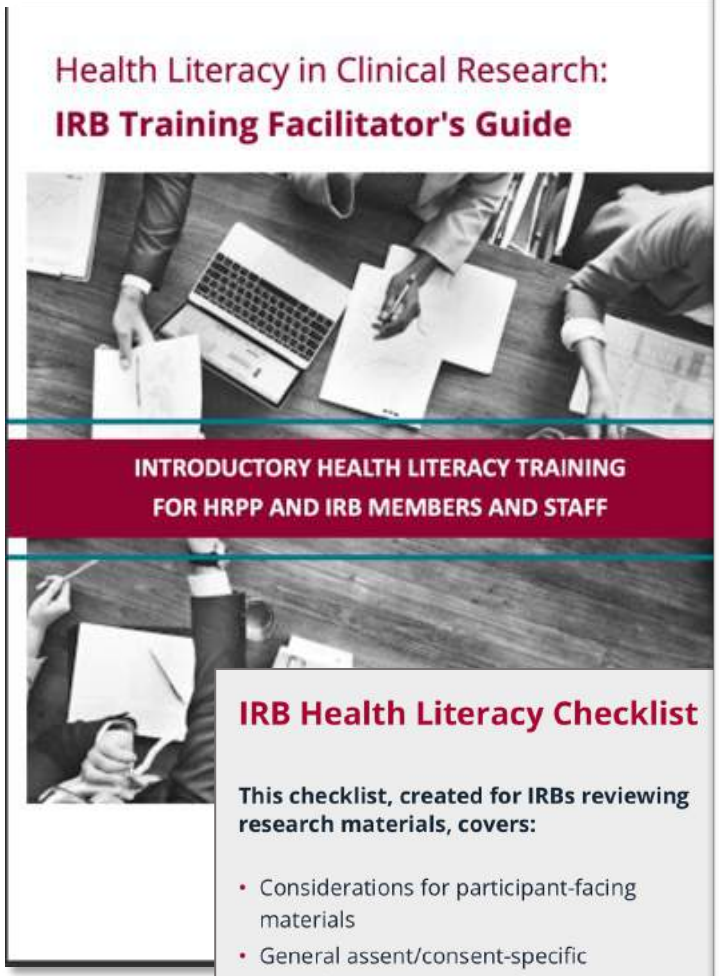
If you are having trouble accessing the embedded video, please use this link to watch the introductory video: HERE

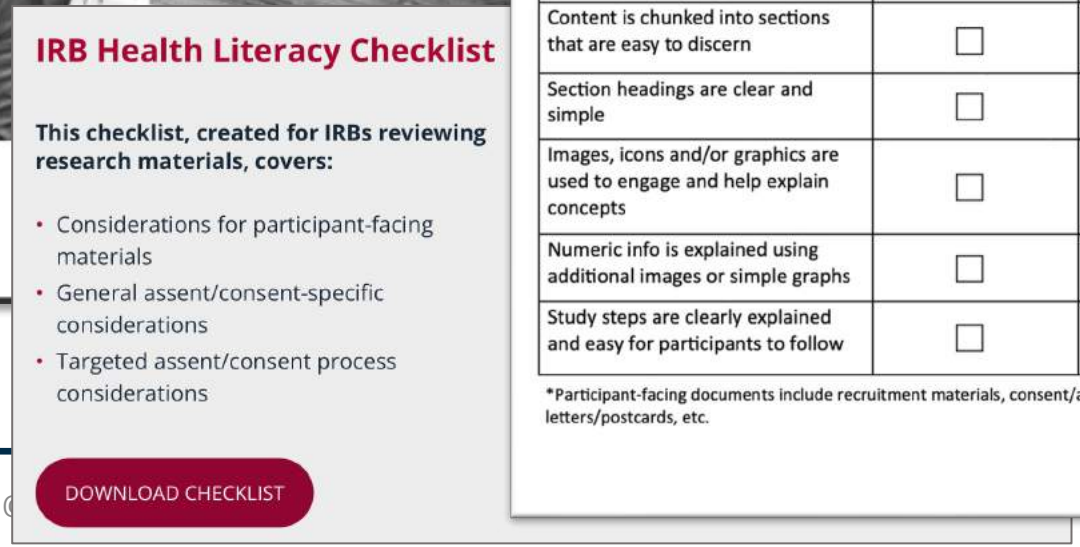
A transcript of this video is available: [pending]

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:
  - Recruitment flyers
  - Consent/assent forms (and processes)
  - Study instructions
  - Study retention materials
- Checklist:
  - 2-page introduction
  - 3-page checklist





PARTICIPANT-FACING MATERIALS

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

	Participant-facing Document*:	Recommendations/Comments
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.

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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

IRB and HRPP Toolkit

+ IRB Resources

+ Resources for IRBs/HRPPs to provide to Investigators/Research Teams

Resources for IRBs/HRPPs to provide to Investigators/Research Teams

Procedural & Logistical Checklist	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.
An IRB Resource for Participants: Costs and Payments	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.
An IRB Resource for Investigators and Research Teams– Practical Points to Consider: Payment to Research Participants	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.
An IRB Resource for Investigators and Research Teams: Including the Community Voice in Clinical Research	This document lists available resources for IRBs to provide to investigators and their research teams on how to begin and implement community engagement and partnership in clinical research.
Incorporating DEI into Clinical Research Protocol Templates	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.

Procedural and Logistical Checklist

Procedural and Logistical Checklist

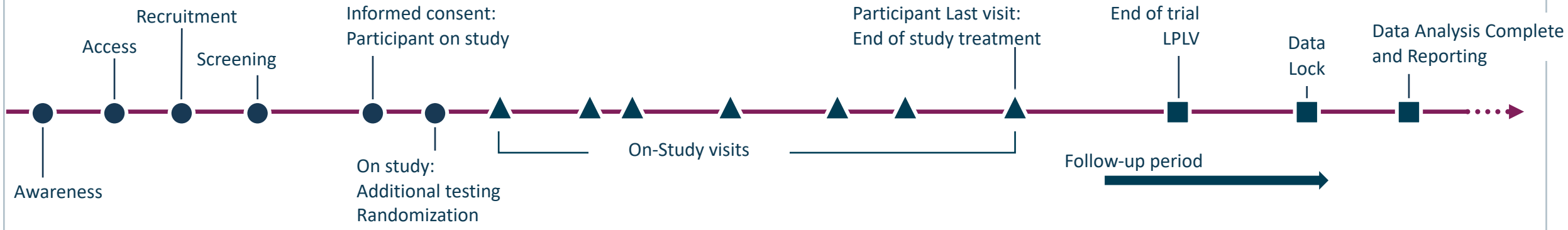
Audience: Investigators and their research teams, Sponsors, CROs, Research Sites, IRBs, QA/QI Teams

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

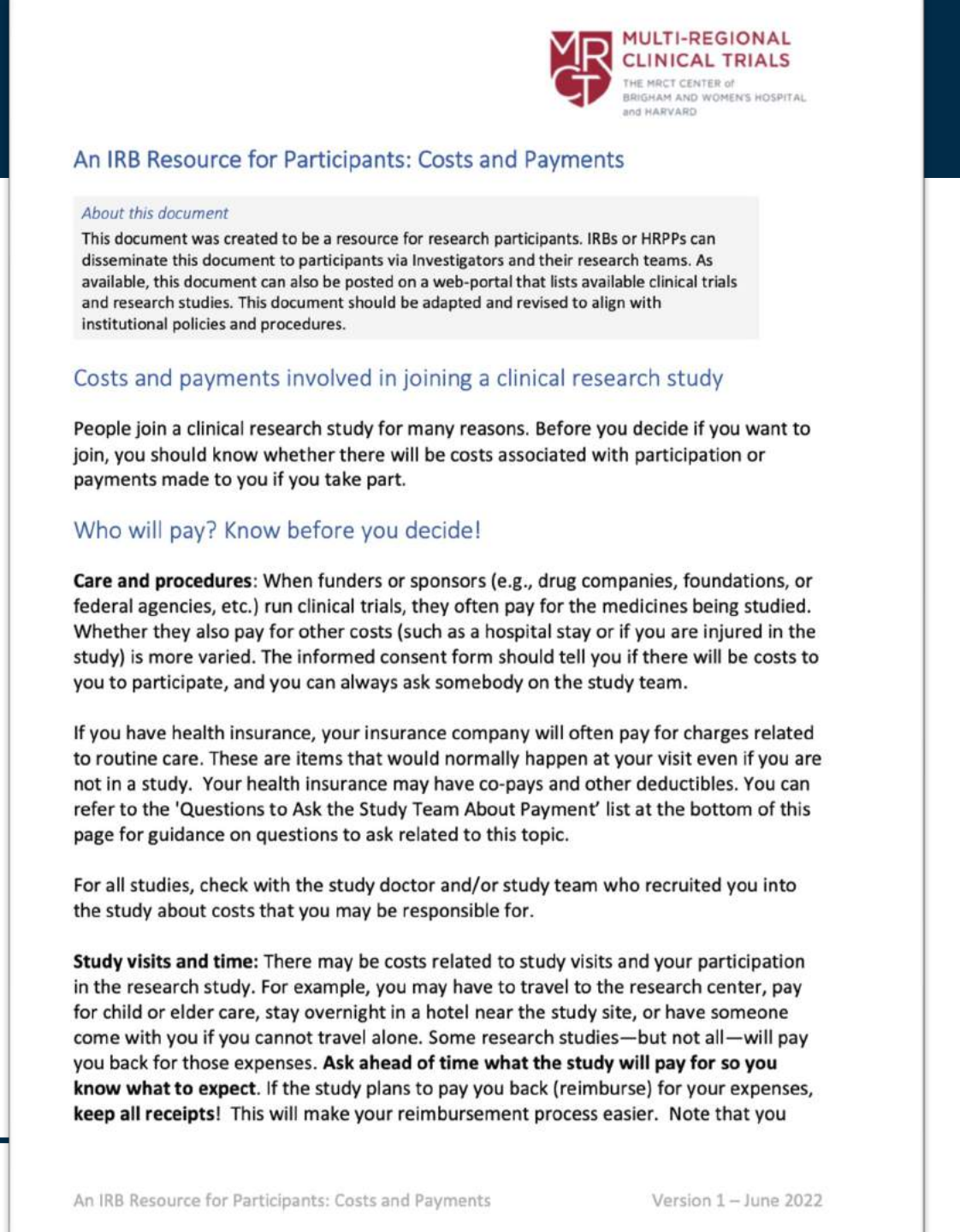
- ❑ Document the basis of the decision for excluding participants from a trial.
- ❑ Devise a simple, honest, and clear informed consent process for participants that is conducted in a health-literate, culturally- and linguistically-appropriate manner.
- ❑ Provide translation services of the informed 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 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.

IRB Resource for Participants: Costs and Payments

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



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

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 revised 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.

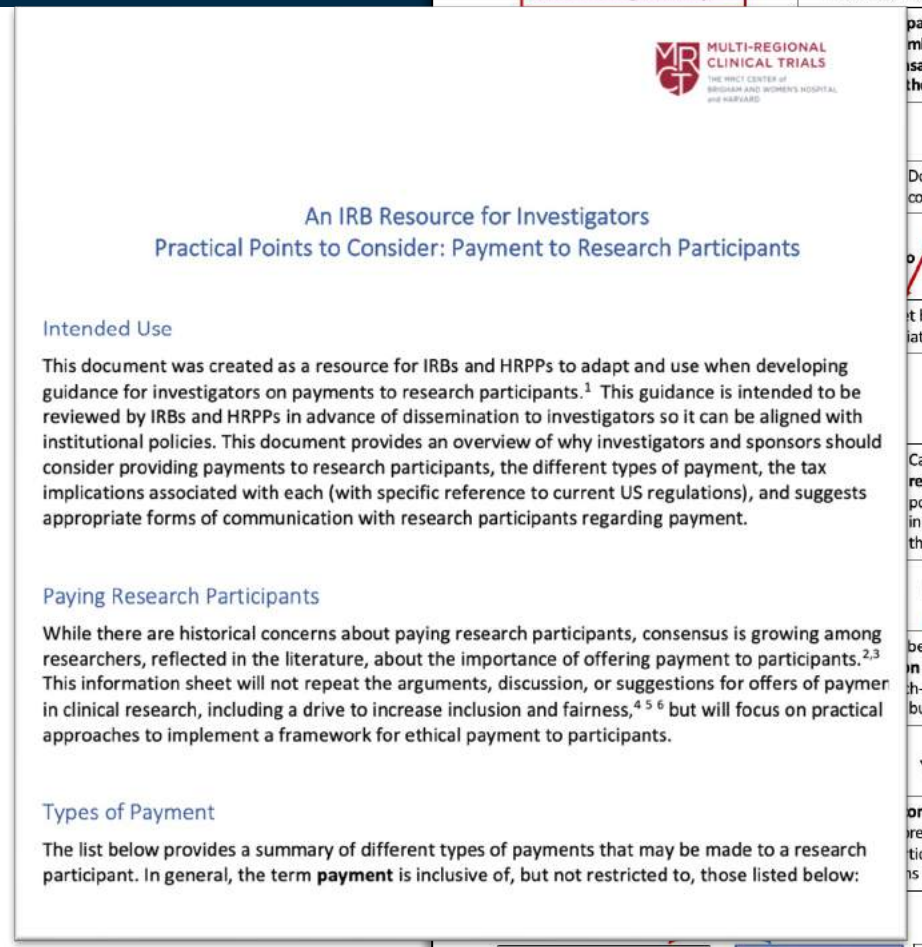
If you have health insurance, your insurance company will often pay for charges related to routine care. These are items that would normally happen at your visit even if you are not in a study. Your health insurance may have co-pays and other deductibles. You can refer to the 'Questions to Ask the Study 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 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
  - Research related injury
  - Undue influence
  - Risk of eligibility to entitlements
- Communications with participants about payments
- Tax considerations; *NOT* tax advice!



MULTI-REGIONAL CLINICAL TRIALS

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 HRPPs to adapt and use when developing guidance for investigators on payments to research participants.[1] This guidance is intended to be reviewed by IRBs and HRPPs 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

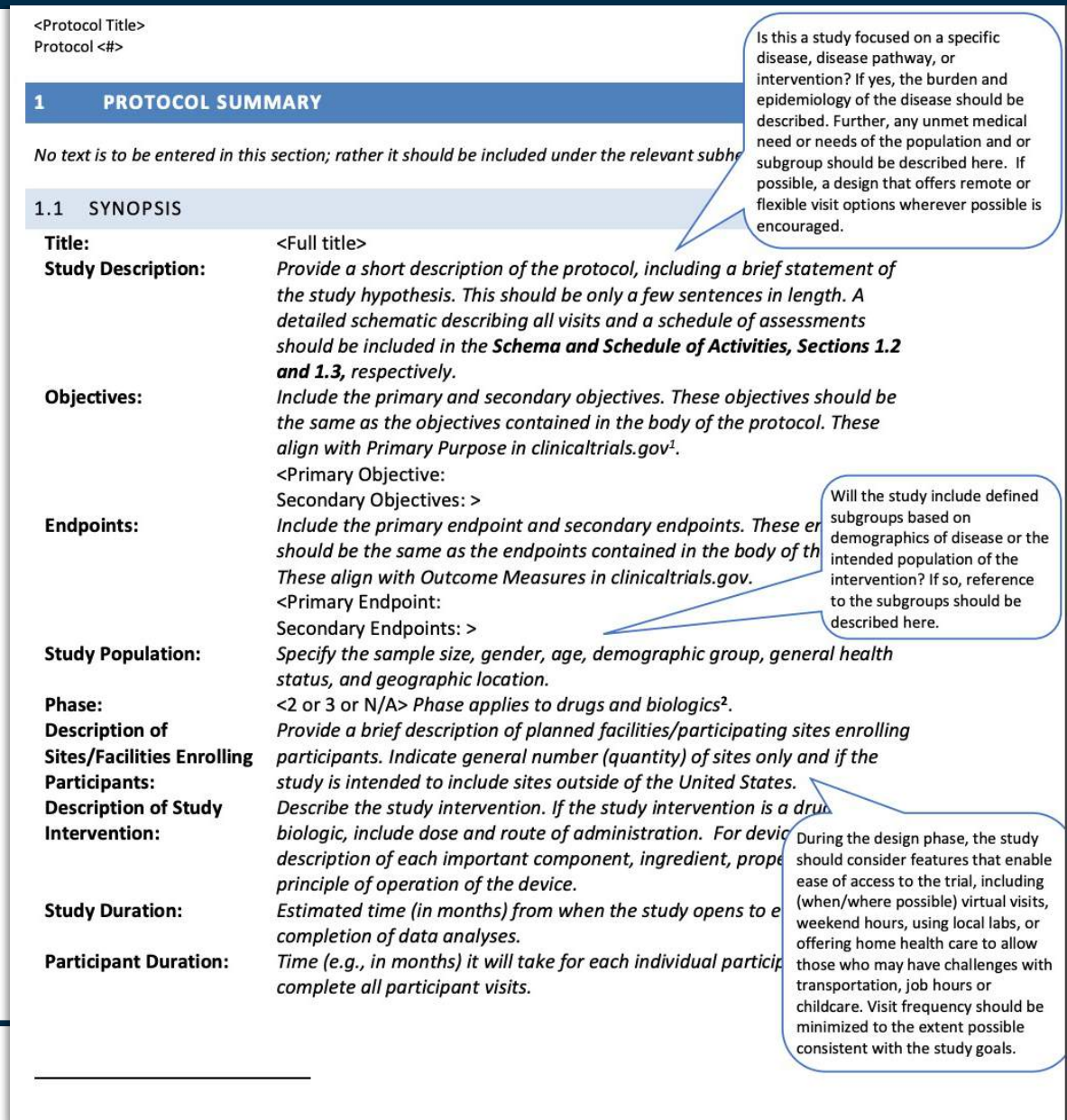
While there are historical concerns about paying research participants, consensus is growing among researchers, reflected in the literature, about the importance of offering payment to participants.[2,3] This information sheet will not repeat the arguments, discussion, or suggestions for offers of payment in clinical research, including a drive to increase inclusion and fairness,[4,5,6] 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:

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



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DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

IRB and HRPP Toolkit

IRBs and HRPPs 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:

June 30, 2022
1-2 pm EDT

https://mrctcenter.org

Questions and Discussion
Thank you