The Roles and Responsibilities of the IRB in Addressing Diversity in Clinical Research

Sarah A. White, MPH
David H. Strauss, MD
Barbara E. Bierer, MD

MRCT Center of BWH & Harvard

November 10, 2020
PRIM&R presentation
The views and findings expressed in this presentation and the documents are those of the authors and do not imply endorsement or reflect the views or policies of the U.S. Food and Drug Administration or the affiliated organization or entity of any member who contributed to this work. Individuals have served in their individual capacity.

The seminar focuses on the role of the IRB in considering diversity, inclusion, and equity in clinical trial participation. It is not intended as a general diversity training.

The MRCT Center is supported by voluntary contributions and by grants. www.MRCTCenter.org
Agenda

• Sarah A. White, MPH
  Welcome
  MRCT Center introduction
  Introduction to Achieving Diversity, Inclusion, Equity In Clinical Research Project

• David H. Strauss, MD
  Role of the IRB as presented in the Guidance and Toolkit
  Ethical responsibilities

• Barbara E. Bierer, MD
  Practical Approaches to Considerations of Inclusiveness
  Tools and Resources
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.
Addressing emerging issues of MRCTs

The MRCT Center’s work

Recognizing the need to focus on and with the participant

- Post trial access to medicines
- Return of Results, Aggregate and Individual
- Health Literacy
- Diversity, Inclusion, Equity

https://mrctcenter.org
# Health disparities by race and ethnicity in the COVID-19 pandemic

## Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Fold Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>3.4</td>
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<tr>
<td>Latino</td>
<td>3.3</td>
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<tr>
<td>Indigenous</td>
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<tr>
<td>Pacific Islander</td>
<td>2.9</td>
</tr>
<tr>
<td>Asian</td>
<td>1.3</td>
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</tbody>
</table>

[https://www.apmresearchlab.org/covid/deaths-by-race](https://www.apmresearchlab.org/covid/deaths-by-race)
Health disparities by race and ethnicity in the COVID-19 pandemic

Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites

<table>
<thead>
<tr>
<th>Race/Medical Group</th>
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<td>2.9</td>
</tr>
<tr>
<td>Asian</td>
<td>1.3</td>
</tr>
</tbody>
</table>

But are underrepresented in research

Racial Disproportionality in Covid Clinical Trials
Daniel B. Chastain, Pharm.D., Sharmon P. Osae, Pharm.D., Andrés F. Henao-Martinez, M.D., Carlos Franco-Paredes, M.D., M.P.H., Joanne S. Chastain, Pharm.D., and Henry N. Young, Ph.D.

News & Analysis

Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials
Mary Chris Jaklevic, MSJ

https://jamanetwork.com/journals/jama/fullarticle/2769611
Participation of Black or African American individuals in clinical trials for oncology, cardiology, and psychiatry

Cardiovascular Disease
N = 92,329
2.50%
1,415
97.50%
55,118

Oncology
N = 7,691
2.74%
211
97.26%
7,480

Psychiatry
N = 5,810
24.18%
1,405
75.82%
4,405

https://www.fda.gov/media/106725/download

2015-2016
Black/African
Other race

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Leadership

• RADM Richardae Araojo, PharmD, MS, U.S. FDA
• Barbara E. Bierer, MD, MRCT Center
• Luther T. Clark, MD, Merck & Co., Inc.
• Milena Lolic, MD, U.S. FDA
• David H. Strauss, MD, Columbia University
• Sarah White, MPH, MRCT Center

MRCT Center staff:
• Carmen Aldinger, PhD, MPH
• Hayat Ahmed, MS
• Laura Meloney, MS, MPH
• Joshua Smith-Sreen, MPH

And the invaluable contributions of >50 workgroup members, representing:

• Patients, Patient Advocates
• Academia
• Pharmaceutical companies
• CROs
• Non-profit organizations
• Trade associations
• Government agencies
• Research institutes

Each serving in their individual capacity.
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Stacey Bledsoe*, Eli Lilly and Company
Shari Bodnoff*, Novartis
Racquel Bruten, Biogen
Elizabeth Cahn, Cancer Connection
Li Chen, Amgen
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Anthony Edmonds, Takeda
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Jonathan Jackson*, Massachusetts General Hospital
Marcia Levenstein, Vivi
Roberto Lewis, Columbia University
Eldrin Lewis, Brigham and Women’s Hospital, currently Stanford University
*involvement limited in time

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Erin Muhlbradt, National Cancer Institute (NCI)
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Paul Underwood, Boston Scientific
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Robert Winn*, University of Illinois
Gerren Wilson*, Genentech/ A Member of the Roche Group
Crispin Woolston, Sanofi
Honghui Zhou*, Johnson&Johnson

10 November 2020 PRIM&R ©MRCT Center
• Multi-stakeholder contributions and consensus
• Practical and actionable recommendations
• Accountability section considers how each stakeholder can change the paradigm
• Toolkit provides adaptable resources not easily found elsewhere

mrctcenter.org/diversity-in-clinical-trials
David H. Strauss, MD
Senior Advisor, MRCT Center
Special Lecturer, Columbia University
• Beyond COVID-19, is there a problem to solve?
• Is a role for the IRB justified?
• What practical steps can be taken?
In 2015, of 45 novel drugs approved, and with over 105,000 enrolled participants, only 40% of patients were women, and strikingly only 5% were African American.

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>WOMEN</th>
<th>WHITE</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>HISPANIC</th>
<th>AGE 65 and OLDER</th>
<th>UNITED STATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of prostate cancer</td>
<td>0</td>
<td>79</td>
<td>3</td>
<td>13</td>
<td>3</td>
<td>87</td>
<td>9</td>
</tr>
</tbody>
</table>

https://www.fda.gov/media/135337/download
Prostate Cancer (CDC, 2017)

- Prostate cancer rates are highest among African-Americans
- African-Americans are twice as likely to die from prostate cancer
- Increase risk is associated with low SES, unequal access to diagnosis and treatment, and (?) other factors

https://gis.cdc.gov/Cancer/USCS/DataViz.html
### Drug Trial Snapshots (2019): US Food and Drug Administration

<table>
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<td>3</td>
<td>13</td>
<td>3</td>
<td>87</td>
<td>9</td>
</tr>
<tr>
<td>Treatment of advanced breast cancer</td>
<td>100</td>
<td>66</td>
<td>1</td>
<td>22</td>
<td>14</td>
<td>44</td>
<td>9</td>
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<tr>
<td>Treatment of schizophrenia</td>
<td>24</td>
<td>21</td>
<td>75</td>
<td>1</td>
<td>9</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>

https://www.fda.gov/media/135337/download
• Analyses of group differences in safety and efficacy among diverse populations can promote identification of both underlying biological factors and socially relevant factors that affect health, the “social determinants of health” (Beneficence)

• Seeks fairness in the distribution of the benefits of research (Justice)

• Builds public trust
Justice:

• “Who ought to receive the benefits of research and bear its burdens?”

• “…moral requirements that there be fair procedures and outcomes in the selection of research subjects.”

• “An injustice occurs when some benefit to which a person is entitled is denied without good reason…”

§46.111 Criteria for IRB approval of research.

(3) Selection of subjects is equitable.
Beneficence

• In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits…

• In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result…
• Respect for Persons

  • Obligations to treat individuals as autonomous agents

  • Obligations to protect those with diminished autonomy
Application of the Belmont principles

- Ethics and protection from research risk
- Ethics and access to the direct benefits of novel/investigational therapies
- Ethics, Inclusion, and access to the benefits of scientific knowledge
Attention to diversity and inclusion may be an under-recognized and under-appreciated role for many IRBs, but it is embedded in the language of Belmont and the Common Rule. It is essential to the ethical conduct of clinical research.
Barbara E. Bierer, MD
Faculty Director, MRCT Center
Professor of Medicine (Pediatrics), Harvard Medical School
bbierer@bwh.harvard.edu
The role of the IRB

- Ensuring ethical research
- Creating expectations, promoting dialogue
- Establishing accountability
- Fostering competence, education, and the development of infrastructure
- Institutional support for the role and responsibility of the IRB
- Responsibilities of HRPP in addition to IRB

Ask the question.
• Optimal recruitment target: Epidemiology of the disease and/or those for whom the product is intended

• Reasonable reasons for deviation, e.g.,
  o Phase 1 healthy volunteers
  o Exploratory study
  o A given population is the object of specific study
  o Geophysical mapping

• Exceptions should be justified and documented

• If one starts from the assumption of the recruitment target, the study protocol should contain:
  o Information about the demographics of the disease and/or those for whom the product is intended
  o Prior research relevant to the current study
IRB: Overall plan

AGGREGATE POPULATION RECRUITMENT TARGET

SITE 1
N=330

SITE 2
N=265

SITE 3
N=95

SITE 4
N=205

SITE 5
N=105

N=1000

GROUP A

GROUP C

GROUP B

GROUP D
Initial Review:

- Study Aims and Subject Selection
  - Do the demographics of the proposed sample reflect that of the population affected by the condition or for whom the intervention is intended?
    - When it does not, is the deviation adequately justified?
    - Is planned under- or over-representation by age, race, ethnicity, or gender in the sample scientifically justified?
    - Is there a statistical plan for examining heterogeneity in outcome or across subgroups?
• Criteria for Inclusion and Exclusion
  o Will inclusion and exclusion criteria inadvertently or unnecessarily result in under- or over-representation of understudied subgroups?
  o Have alternative approaches to minimizing risk that do not rely on exclusion been considered?

• Recruitment
  o Have recruitment procedures considered specific approaches to engage underserved populations?
  o Are materials available in languages understandable/primary to the participants?
  o Are participant materials translated? If not, why not?
  o Do all participant-facing materials conform to health literacy principles?
• Study Conduct
  o Are study procedures flexibly organized to accommodate the needs of under-represented groups?
  o Are all in-person visits essential? Can any be done locally or virtually if appropriate?
  o Is reimbursement for expenses of participation provided?

• Payment
  o Is payment sufficient to cover costs of participation?

• Return of results
  o Are study results intended to be returned in a manner that meets the needs of the populations studied?
• Continuing review:
  o Has the study fulfilled its recruitment/accrual goals?
  o Is demographic distribution on track to approximate the study goals?
  o If not, are adequate corrective actions described, sufficient, and likely to be successful?
What tools can an IRB leverage to support investigators in advancing diversity for multi-center trials?

- Trial design and site selection
- Trial implementation planning
- Monitoring Progress

Initial review

Continuing review
Site Selection – ensuring study sites have capacity to enroll a diverse population

Feasibility Assessment tool

Potential capacity

Historical capacity

Projected capacity

Does the site have the **potential capacity** to enroll the desired subgroup(s)?

Site relationships, community relationships, geo-mapping, etc.

Does the site have the **historical capacity** to enroll the desired subgroup?

Data available, modified feasibility questionnaire, site visit, etc.

Does the site have the **projected capacity** to enroll the desired subgroup(s) for this particular trial?

Internal forecasting tools if available

Trial design and site selection
Site Selection – ensuring study sites have capacity to enroll a diverse population

Site selection decision tree tool

### Checkpoint 1: Potential Capacity
- **Purpose**: Assessment of methods used to determine a site’s lack of “potential capacity” for enrollment of desired subgroup(s). If bias/inaccuracy is detected in these methods, the site remains eligible for consideration in site selection for enrollment of that subgroup(s).

### Checkpoint 2: Historical Capacity
- **Purpose**: Identification and assessment of factors that contribute to a site’s lack of “historical capacity” for diverse enrollment, the changes needed in order to build that capacity in the future, and whether supportive measures might be feasible for the sponsor/CHO to provide. If changes are deemed feasible to make, the site remains eligible for consideration in site selection for diverse enrollment.

### Checkpoint 3: Projected Capacity
- **Purpose**: Similar to that of “historical capacity,” identification and assessment of those factors limiting a site’s “projected capacity” for diverse enrollment in the trial at hand, according to whatever diversity goal and target population established by the sponsor. If identified changes are feasible to make, the site should be included in the study at hand.
Site Selection – ensuring study sites have capacity to enroll a diverse population

Modified Feasibility Questionnaire

**ACTION:**
Modify feasibility questionnaires to include questions in designated areas focused on enrollment of representative populations

**OUTCOME:**
Data generated on site capacity to enroll specified populations

**IMPLICATION:**
Informed decision-making for site selection to achieve enrollment of a representative population in aggregate throughout the trial

---

**Population Questions for Demographic Data:**

- **Guidance Questions for Demographic Data:**
  - How likely are potential study participants to be non-English speakers? (Very Unlikely, Unlikely, Neutral, Likely, Very Likely)
  - Are there other languages (Spanish, Mandarin, etc.)?
  - How likely is the demographic composition (by sex, age, race/ethnicity and income) of the study population based on demographic and epidemiological data describing the site's catchment area? Provide a justification for this predicted composition.

---

**Population Accessibility**

- **Guidance Questions for Demographic Data:**
  - Provide evidence of the historical accessibility of specified subpopulations to the site, based on prior search results, responses, longitudinal studies, past participation, etc.
  - Provide evidence of community engagement for this site for specified demographic subpopulations, through letters of commitment from community leaders, sites, primary care physicians, etc.
  - Provide evidence of prior recruitment success in recruiting and/or retaining specified demographic subpopulations.

---

**Targeted Recruitment Strategy**

- **Guidance Questions for Demographic Data:**
  - Describe the recruitment team's experience recruiting and retaining particular demographic subgroups and underrepresented populations in general. If no experience, describe how your team will acquire the cultural competencies.
  - Describe specific recruitment activities to ensure the enrollment of specified subpopulations and who will be responsible for execution of these activities.
  - Describe the use of compensation, reimbursement of costs and other financial incentives for participants of the specified subpopulation if applicable.

---

**Barriers & Supports**

- **Guidance Questions for Demographic Data:**
  - What barriers does the site anticipate for recruiting the specified subpopulation (either inherent to the protocol, the site, or the subpopulations) in the given timeline?
  - What supports does the site have to aid the study team in targeted recruitment of the specified subpopulation?
  - What supports/resources/trainings would the site need to overcome unaddressed barriers? Other than the sponsor/CRO, what are some additional avenues that the site could use to acquire anticipated supports?
Recruitment Strategies – planning for recruitment of a diverse population

<table>
<thead>
<tr>
<th>Recruitment Strategy Documents – Potential Key Performance Indicators (KPIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Output indicators</strong></td>
</tr>
<tr>
<td>Trial-level recruitment plan for diversity available at site, including all the proposed elements to consider (See Achieving Diversity, Inclusion and Equity in Clinical Trials Guidance Document, Table 12, Part E, Section 13.5)</td>
</tr>
<tr>
<td>Site-specific recruitment plan for diversity available at site</td>
</tr>
<tr>
<td>Monitoring mechanisms for recruitment targets by demographic established</td>
</tr>
<tr>
<td>Suggested recruitment strategies tailored to target population(s) available at site</td>
</tr>
<tr>
<td><strong>Outcome indicators</strong></td>
</tr>
<tr>
<td>Site investigator-reported understanding of diversity enrollment objectives</td>
</tr>
<tr>
<td>Data on demographic profile of enrolled participants available to sponsor in a suitable amount of time</td>
</tr>
<tr>
<td>In the case that demographic profile data indicate site will not meet target enrollment of target subpopulation, contingency plan implemented</td>
</tr>
</tbody>
</table>
## Elements to consider within a trial-level recruitment strategy document

<table>
<thead>
<tr>
<th>RECRUITMENT DOCUMENT ELEMENT</th>
<th>JUSTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial sample size (N) calculation to achieve treatment effect as provided in protocol</td>
<td>Typical power calculation included in recruitment planning to provide the goal for overall study population across all sites</td>
</tr>
<tr>
<td>Overall epidemiology of disease</td>
<td>Available measures of disease frequency (prevalence, incidence, etc.) to characterize the burden of disease by geographic region</td>
</tr>
<tr>
<td>Epidemiology of disease by demographic</td>
<td>Measures of disease frequency (prevalence, incidence, etc.) by available demographics and by region, to highlight the subpopulations for whom the intervention is intended</td>
</tr>
<tr>
<td>Heterogeneity assessment across subgroups and effect on sample size</td>
<td>Assessment based on literature, ongoing trials, or prior evidence for differences in disease manifestation or treatment response in particular subpopulations, to justify modified methods for recruitment, sample size and analyses of the intended subpopulations.</td>
</tr>
<tr>
<td>Potential limiters and enablers for strategic recruitment</td>
<td>Logistical, economic, capacity-related, and sociocultural elements that might enable or limit recruitment in particular subpopulations or regions</td>
</tr>
<tr>
<td>Diversity guidelines and subpopulations for trial</td>
<td>Development of objectives to achieve a diverse trial population, with overall trial-level enrollments for specified subpopulations, to highlight recruitment expectations</td>
</tr>
</tbody>
</table>
Recruitment Strategies – making the plans to recruit a diverse population

Recruitment Strategy Document

Study Title
Protocol #
NCT #

Sponsor Logo

CRO Logo

Study Logo
Recruitment Strategy Document

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### Eligibility and Enrollment Log – monitoring tools for investigators

#### A. Study Information

<table>
<thead>
<tr>
<th>Protocol Number:</th>
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<tbody>
<tr>
<td>Protocol Title:</td>
<td></td>
</tr>
<tr>
<td>Principal Investigator:</td>
<td></td>
</tr>
</tbody>
</table>

#### B. Participant Information:

<table>
<thead>
<tr>
<th>Age:</th>
<th>&gt;18 - &lt;65 years</th>
<th>&gt;=65 - &lt;74 years</th>
<th>&gt;=75 - &lt;84 years</th>
<th>&gt;=85 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex:</td>
<td>Male</td>
<td>Female</td>
<td>Unknown or undifferentiated</td>
<td></td>
</tr>
<tr>
<td>Gender:</td>
<td>Male</td>
<td>Female</td>
<td>Trans-Male</td>
<td>Trans-Female</td>
</tr>
<tr>
<td>Ethnicity¹:</td>
<td>Hispanic or Latino</td>
<td>Not Hispanic or Latino</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race²:</td>
<td>American Indian or Alaska Native</td>
<td>Asian</td>
<td>Black or African American</td>
<td>Native Hawaiian or other Pacific Islander</td>
</tr>
</tbody>
</table>

#### C. Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria (From IRB approved protocol)</th>
<th>Yes</th>
<th>No</th>
<th>Supporting Documentation²</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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<tr>
<td>5.</td>
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</tr>
</tbody>
</table>

#### D. Enrollment Tracking

<table>
<thead>
<tr>
<th>Enrolled?</th>
<th>If no, why? Provide supporting Documentation³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

#### E. Statement of Eligibility⁴

This individual is [ ] eligible / [ ] ineligible for participation in the study.

Signature: __________________________________________  Date: ____________

Printed Name: ________________________________________

---

¹ There are no specific ethnicities listed, but the participant can indicate if they identify as Hispanic or Latino.
² Supporting documentation could include medical records, patient history, or other relevant information.
³ If the participant is not enrolled, the reason should be documented to understand why.
⁴ Eligibility criteria should be clearly defined by the study's protocol.
Support of the institution

- Institutional endorsement and support of the IRB
- Policies that support the positions of the IRB
- IRB membership:
  - Diverse membership
  - Community voice represented
  - Cultural competence and implicit bias training
- Challenging in a world of single site review of multi-site trials

Argument for collective approach and harmonization
Key Performance Indicators

The importance of:
- Metrics
- Transparency
- Accountability

Progress takes time