Driving Inclusion in Clinical Research

Second Wednesday monthly
11AM –12PM ET

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

LEANING IN: A WEBINAR SERIES

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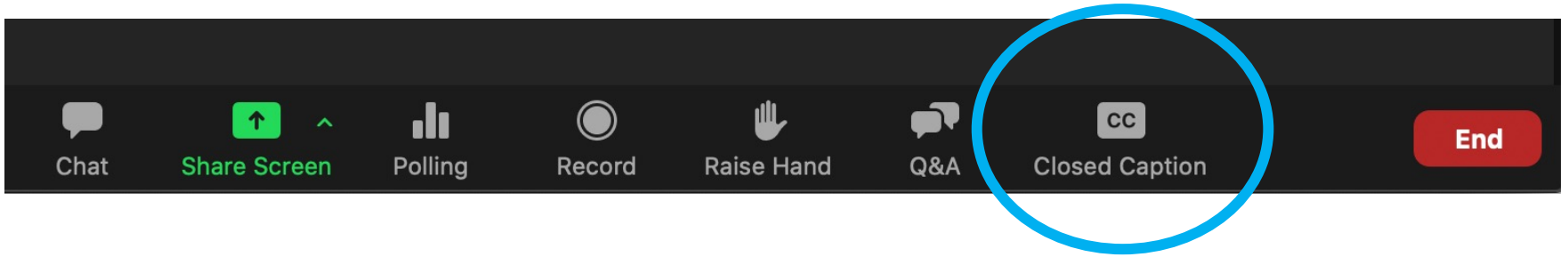

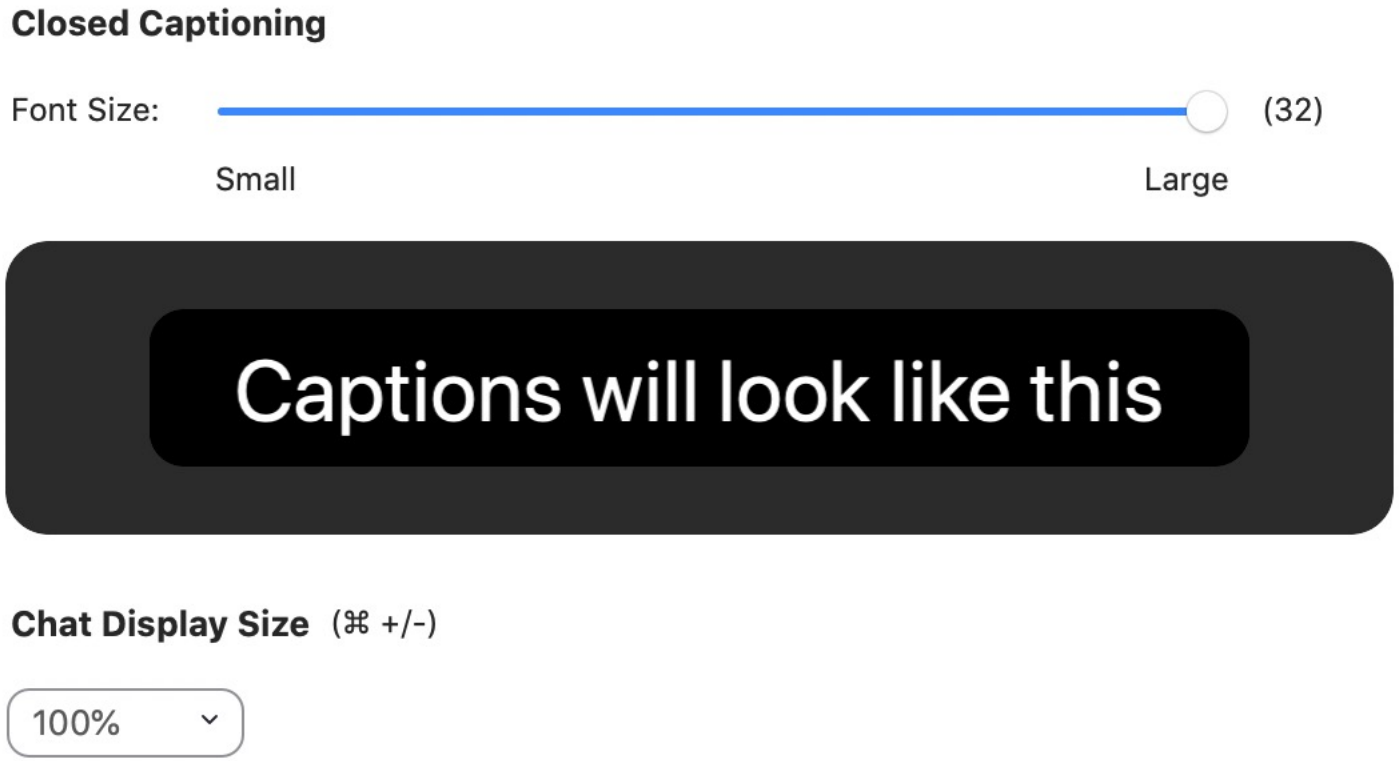

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Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM –12noon ET

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LEANING IN: A WEBINAR SERIES

PREVIOUS WEBINAR RECORDINGS AND SLIDES AVAILABLE TO DOWNLOAD **HERE**

- Community Awareness, Access, Knowledge
- Workforce Development
- Study Design, Eligibility, Site Selection & Feasibility
- Study Conduct (Recruitment, Retention)
- Data Standards and Analysis
- Stakeholder Roles and Responsibilities
- Role of Data in Diversity: Genetics & Real World Data

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Webinars in this series

+ April 14, 2021: How to Begin
+ May 12, 2021: Inducement or Fair Compensation? Impact on Diverse Participation
+ June 9, 2021: Improving Inclusion of Persons with Disabilities in Clinical Research
+ July 14, 2021: Simplifying the Complexity of Translation in Clinical Research

Webinar recordings and slides available

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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.

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Guidance Document and Online Resources

Outstanding Leadership and the invaluable contributions of >50 Workgroup members, representing:

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

Each serving in their individual capacity.

https://mrctcenter.org/diversity-in-clinical-research

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Today's topic and guest speakers

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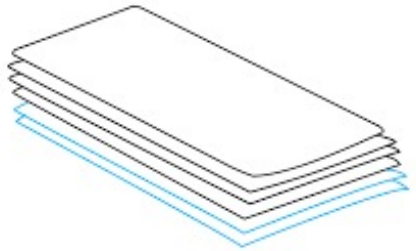
Mr. G

- Admitted with ultra rare condition to my service in February 2021

37-page informed consent document
In English



One paragraph
Spanish short form

- Is this sufficient?
- When should documents be translated?
- Should people ever be excluded for language reasons alone, and if so, when?
- What steps should we take to increase inclusion while protecting the rights and welfare of participants?

Ethical Considerations

- The routine exclusion of individuals with limited English proficiency (LEP) (i.e., limited ability to read, speak, write, and/or understand English) from clinical research is a **significant issue--and discriminatory.**
- The routine exclusion of individuals with LEP from clinical research is an **ethical issue**

Justice

- Individuals with LEP are unfairly prevented from accessing the benefits of clinical research participation
- The generalizability of research is limited, potentially contributing to health inequities

Autonomy

- While informed consent is a process, provision of the "short form" consent is insufficient to provide for **the informed and voluntary participation of individuals with LEP**

Beneficence/ non-maleficence

- In the absence of interpreter services and other accommodations, **the safety and well-being of individuals with LEP may be jeopardized during their participation in a clinical trial**

1. Betancourt JR, Renfrew MR, Green AR, Lopez L, Wasserman M. Improving patient safety systems for patients with limited English proficiency: a guide for hospitals. Agency for Healthcare R esearch and Quality [Internet]. 2012. Available from: https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf

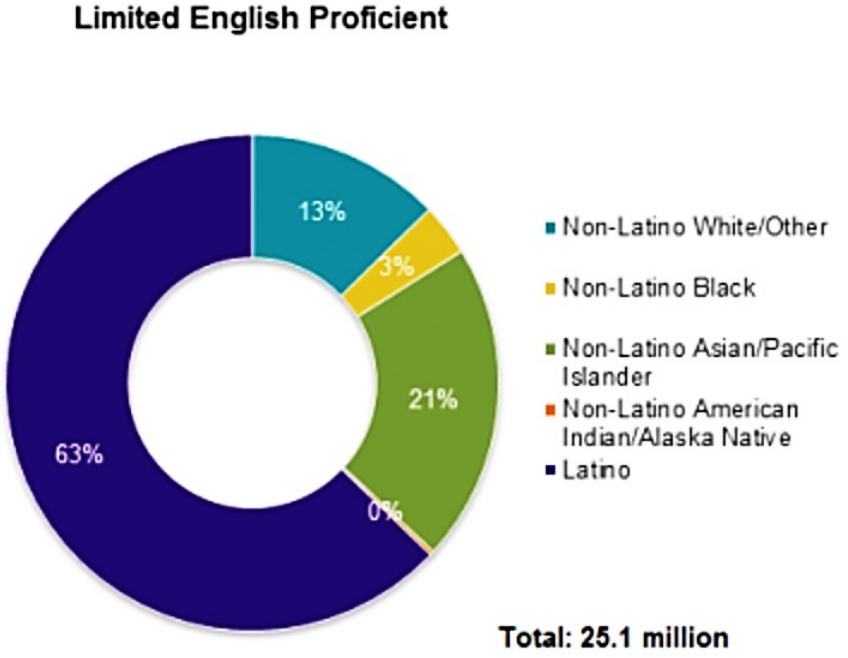
US regulation: "…in language understandable…"

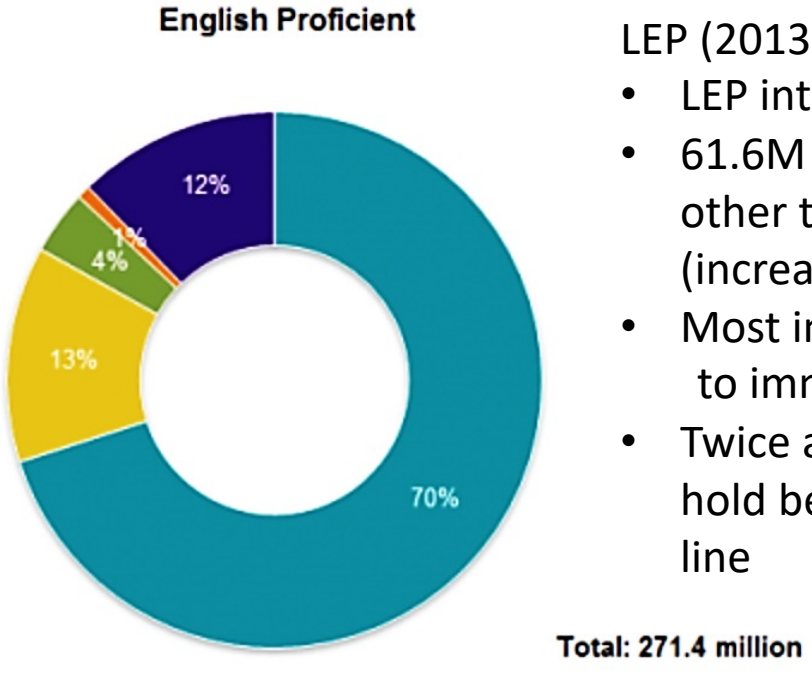
- Common Rule and FDA both require "information that is given to the subject or the representative shall be in language understandable to the subject or the representative."
- FDA advises, "When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate."[1]

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent#content

Limited English Proficiency

- Limited English Proficiency (LEP) is a spectrum





LEP (2013 data)*

- LEP intersects with race/ethnicity
- 61.6M in US spoke a language other than English at home (increasing over time)
- Most immigrants (~80%) or born to immigrant parents (~20%)
- Twice as likely to live in a household below the federal poverty line

- Today, focus on people whose preferred language is other than English

*https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013

Background

- Not a small problem:
  - Of all interventional trials for adults with one site in US registered between 1/1/2019 and 12/1/2020, **approximately 19% required the ability to read, write, and/or speak English or be a native English speaker**
  - Studies in 4 therapeutic areas, with a posted protocol, revealed additional studies with English language requirements, suggesting that the finding on English language requirements is an **underestimation**
  - Results varied by funding source and by therapeutic area
- Note that there is no official language at the federal level in the US.
- What is appropriate institutional (and company) policy for translation/interpreter services, given the need to balance time and expense with practical utility?

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Practical Considerations

- Aim: To communicate and provide documents in a language understandable to the participant

Anticipated

Population

- Dependency on geography and catchment area
- In advance of or after study initiation
- Timing impacts recruitment of LEP populations
- How many languages are suggested/required?
- Is back-translation necessary or is “good” “good enough”?

IRB
Sponsor

Sporadic or Incidental

Participant

- Use of interpreter services and short form documentation: when is this insufficient?
  - Does risk of the research impact decision?
- Should there be a minimum threshold after which translation is required? If so, what is that threshold of risk?

Investigator
Institution

Disincentives

- Time
  - Interpreter time-intensive
  - Document translation, back-translation or validation
  - IRB review and approval
- Cost:
  - At sites, cost of translation and of interpreters generally not provided, charged to study funds
  - Incremental cost not anticipated
  - If industry-sponsored, cost (time, resources, legal) of negotiating contract, and uncertain outcome
- Utility
  - Will translation be used sufficiently?
- Participant safety
  - If cannot communicate and an adverse reaction/event occurs, how can the participant reach the appropriate person?

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Discussion

- When is it necessary to translate? Alternatively, when is it not necessary?
- Do the same standards apply for minimal risk and greater than minimal risk research?
- Can we agree upon threshold numbers of non-English speakers to recommend or require translation?

- If translation indicated, what to translate?
- How soon should translations be available? Can we agree upon a preferred timeline?

- Are there special considerations for interpreters or interpreter services?

- What are expectations of:
  - Investigator
  - Clinical trial site/institution
  - IRB
  - Sponsor

What is 'good enough?'

What standards would inform best efforts?

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Discussion and Questions

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