Health Literacy in Clinical Research:

IRB Training Facilitator's Guide

INTRODUCTORY HEALTH LITERACY TRAINING FOR HRPP AND IRB MEMBERS AND STAFF

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

INTRODUCTION

Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs) can help participants and individuals considering participation **understand research,** by reviewing study materials for best practices in health literacy.

HRPPs and IRBs can learn about health literacy issues and **embrace best practices** through education and training sessions that can be included in **on-boarding and continuing education activities** for IRB members and staff.

This training resource can be used to integrate health literacy principles into IRB/ HRPP activities.

IRBs can integrate health literacy best practices into:

- educational activities for research community
- templates and boilerplate language
- consent forms and other participant-facing materials
- recommendations to investigators and study staff

This Introductory Health Literacy Training for HRPPs and IRBs includes:

- A Health Literacy in Clinical Research introductory video
- Teach-back Questions to Consider (page 4)
- Group Discussion Questions (page 9)
- Health Literacy in Action Before and After Examples and Practice (see PowerPoint)
- Resources to support health literacy best practices in IRB activities

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FACILITATION INSTRUCTIONS

There are many ways to use these materials.

One suggested approach is for HRPP/IRB leadership to introduce and facilitate this training for their teams. The facilitator should be an individual in a leadership role at your organization (e.g., the HRPP Director, IRB Chair, or senior staff person with facilitation experience).

Step 1: Watch

Invite the team to view the introductory video: Health Literacy in Clinical Research: https://youtu.be/_QMvzciEIN8 or **click here.**

Step 2: Reflect

Ask the team to take time to review and reflect on the Teach Back Questions.

Step 3: Discuss

Lead a facilitated discussion with your team through the Group Discussion Questions

Step 4: Practice

Review the Health Literacy in Action Before and After Examples and Practice PowerPoint to apply health literacy best practices to some sample research language.

Step 5: Act

Start integrating health literacy into research review and approval activities. These may include:

- Adding the **IRB Health Literacy Checklist** for Review of Participant Study Materials into routine IRB activities
- Ongoing Learning: Use the MRCT Center Health Literacy Website **www.mrctcenter.org/health-literacy** to continue integrating health literacy into the clinical research process.

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TEACH BACK QUESTIONS

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I. What are at least 3 concepts that are included under the umbrella of health literacy?

II. What are at least 2 factors that can lower a person's health literacy level?

III. What are at least 5 reasons why health literacy is important in the context of clinical research?

IV. What are at least 4 ways health literacy can be applied throughout the clinical research life cycle?

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PAUSE!

Please make sure you have answered all of the Teach Back Questions before reviewing possible responses on the following pages.

TEACH BACK ANSWERS

I. What are at least 3 concepts that are included under the umbrella of health literacy?

Possible responses include:

- How well someone can understand and use health information
- How well someone can share and explain health information
- Reading and writing
- Numeracy
- Design principles
- Recognizing that a higher education level does not necessarily mean having a higher health literacy level

II. What are at least 2 factors that can lower a person's health literacy level?

Possible responses include:

- The newness of the information being presented (content)
- Where and when the information is being presented to them (context)
- Not having a friend or family member present to help interpret the information
- Stress

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TEACH BACK ANSWERS

III. What are at least 5 reasons why health literacy is important in the context of clinical research?

Possible responses include:

- Enhances recruitment activities
- Enhances participant autonomy, promotes justice, and contributes to beneficence
- Promotes participant understanding during the informed consent process
- Helps participants follow the study instructions
- Supports retention of participants
- Improves generalizability of results if studies are more successful in recruiting a representative and diverse sample with tailored, understandable materials
- Builds trust between the scientific community and the general public
- Allows clinical research results to be shared in more meaningful ways

IV. What are at least 4 ways health literacy can be applied throughout the clinical research life cycle?

Possible responses include:

- In raising awareness about clinical research to the general public
- In the creation of study materials for patients, participants and caregivers
- In the review of materials for patients, participants and caregivers
- In usability testing of research materials with people who are like the intended audience

GROUP DISCUSSION QUESTIONS

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Please review these discussion questions with your team.

What role can HRPPs/IRBs play to help promote health literacy more generally?

Possible responses include:

- Creating IRB templates, following health literacy principles
- Training and communicating with IRB members and staff in a health literate manner
- Training and communicating with investigators about health literacy, including:
  - Utility of participant discussions in developing materials
  - Sharing of available resources
  - Reviewing, assessing, and approving health literacy of clinical trial documents
  - Fostering a culture of self-assessment that includes usability testing of materials and measuring the reading level of printed documents

What does our HRPP/IRB already do to help make participant facing materials clear and understandable?*

Consider, what do we already do?

- How do we engage community representatives?
- What questions do we ask our investigators about the information, language, and formatting of recruitment flyers, consent forms, study letters, and other study materials (e.g., study flowcharts, schedules, instructions, etc.)?
- Is there a culture of self-assessment and self-improvement at our institution?
- Do researchers have materials reviewed by individuals similar to those whom they would like to recruit/enroll?
- Are grade level reading assessments used to benchmark the understandability of participant materials?
- Is additional training (e.g. implicit bias, teach-back) available to the HRPP/IRB and research community?

*** Note: If you don't do anything yet, that's ok! Are there ways you could start? How?**

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GROUP DISCUSSION QUESTIONS

How could the IRB integrate health literacy best practices? What might that look like in practice?

Consider:

- Would a health literacy information session for investigators be helpful?
- Could health literacy resources (e.g. MRCT Center's Health Literacy in Clinical Research website) be promoted in an institutional newsletter or publication?
- Would a health literacy checklist in the IRB application template be helpful?
- Could you use a health literacy checklist in your IRB review process?
- In addition to including at least one community member as an IRB representative would a Research Participants Advisory Panel be helpful in your review activities?