

# 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 **onboarding 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

## The Introductory Health Literacy Training for HRPPs and IRBs includes:



A self-guided online training for individuals to take



A facilitation guide for IRB/HRPP leaders\* to start a discussion with their teams about health literacy best practices

*\*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).*

# FACILITATION INSTRUCTIONS

## How to use these Training Materials

If you are interested in facilitating a health literacy training for your HRPP/IRB team:

### Step 1:



Complete the online health literacy training available at [cpd.partners.org/content/irb-health-literacy-clinical-research](https://cpd.partners.org/content/irb-health-literacy-clinical-research)

### Step 2:



Ask your team members to complete the health literacy training available at [cpd.partners.org/content/irb-health-literacy-clinical-research](https://cpd.partners.org/content/irb-health-literacy-clinical-research)

### Step 3:



Lead a facilitated discussion with your team using the Group Discussion Guide (available on page 4)

### Step 4:

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](https://www.mrctcenter.org/health-literacy) to continue integrating health literacy into the clinical research process

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# GROUP DISCUSSION QUESTIONS

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# GROUP DISCUSSION QUESTIONS



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?**



# 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?