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

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

Step 2:
Ask your team members to complete the health literacy training available at 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 to continue integrating health literacy into the clinical research process
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?
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?