Health Literacy in Clinical Research:

IRB Checklist

A HEALTH LITERACY CHECKLIST FOR THE REVIEW OF PARTICIPANT-FACING CLINICAL RESEARCH MATERIALS

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

INTRODUCTION

This Health Literacy Checklist is designed for Human Research Protection Program (HRPP) and Institutional Review Board (IRB) reviewers to consider how well study information is being communicated to study participants.

These questions can also be included in the protocol template or in your institution's informed consent template to promote health literacy best practices in advance of submission.

Additional information on how to integrate health literacy into the clinical research life cycle can be found at: www.mrctcenter.org/health-literacy

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PARTICIPANT-FACING MATERIALS

Have health literacy best practices been applied to develop participant-facing materials?

	Participant-facing Document*:	Recommendations/Comments
Research terms and concepts are explained in plain language	☐	
Participant population is described with sensitivity and care	☐	
Text is at a 6th grade reading level or lower	☐	
Key messages are clear and succinct	☐	
Font size is at least 12 point	☐	
White space is used generously throughout the document	☐	
Content is chunked into sections that are easy to discern	☐	
Section headings are clear and simple	☐	
Images, icons and/or graphics are used to engage and help explain concepts	☐	
Numeric info is explained using additional images or simple graphs	☐	
Study steps are clearly explained and easy for participants to follow	☐	

*Participant-facing documents include recruitment materials, consent/assent forms, study instructions, letters/postcards, etc.

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ASSENT/CONSENT CONSIDERATIONS

What assent/consent-specific health literacy best practices did the study team apply?

Please review and note whether there are any updates that should be made to the assent/consent forms to sufficiently integrate health literacy best practices.

Have each of the following been described clearly using plain language?	Response			Comments/Notes
Research question(s) and study aims	Y ☐	N ☐	NA ☐	
Study design (including information about the study arms, randomization etc., as applicable)	Y ☐	N ☐	NA ☐	
Study visits and procedures	Y ☐	N ☐	NA ☐	
Reasons why a person may or may not want to join the study	Y ☐	N ☐	NA ☐	
Alternatives to being in the study	Y ☐	N ☐	NA ☐	
Study intervention(s)	Y ☐	N ☐	NA ☐	
Process of storing data/specimens and future use of said data/specimens as applicable	Y ☐	N ☐	NA ☐	
Is a study flowchart or similar aid available that could be helpful to participants in the informed consent process or during the study?	Y ☐	N ☐	NA ☐	
If the study is collecting sensitive, potentially stigmatizing information, is this clearly explained, as well as what protections will be put in place to safeguard the information, using culturally familiar language?	Y ☐	N ☐	NA ☐	

ADDITIONAL ASSENT/CONSENT PROCESS CONSIDERATIONS

What targeted assent/consent-specific health literacy best practices did the study team use?

Please note whether recommendations to the study team should be made to include one or both of the health literacy best practices below.

	Response			Comments/Notes
Does the consent process include a set of teach-back questions for the research team to use when consenting participants?	Y ☐	N ☐	NA ☐	
Is there a script for walking through the consent process with potential participants?	Y ☐	N ☐	NA ☐	

Please note any additional observations or recommendations that could help make the study documents more understandable to potential participants: