Health Literacy in Clinical Research Principles

Clear communication with potential, enrolled, and past research participants supports understanding and decision-making that aligns to their values. Health literacy focuses on a person's ability to access, process, and understand health information to make informed health decisions. Clear communication , however, requires the communicator to share information in ways that the participant and their family, friends, and/or caregivers can understand and act upon. As such, clear communication is both respectful and ethically responsible, and important throughout the clinical research study life cycle - from access, recruitment, and informed consent to the end of a trial and the sharing of results. The MRCT Center Health Literacy in Clinical Research workgroup has developed foundational principles to help guide the adoption and integration of health literacy practices into clinical research. These are intended to support sponsors and funders, investigators and study teams, and institutional review boards and ethics committees in their communications with potential, enrolled, and past participants.

1. All clinical research communications should be clear and easy to understand.
2. Clear communication is necessary throughout the clinical research life cycle.
3. All clinical research stakeholders share an ongoing responsibility for ensuring research communication is clear and easy to understand.
4. Clinical research communications should be developed by partnering with the intended audience(s).
5. Cultural respect is an integral part of communicating appropriately about clinical research.
6. Clinical research materials for participants should integrate health literacy practices, including plain language, numeracy, clear design techniques, and cultural considerations.
7. Clinical research materials for participants should be evaluated to ensure the intended audience(s) can understand the information.
8. In-person communication with the intended audience(s) should encourage dialogue and confirm understanding.
9. All clinical research stakeholders should support the development and implementation of organizational policies that integrate health literacy into clinical research.
10. Integration of health literacy into clinical research requires proactive planning to develop, test, modify, and confirm understanding of clinical research communications.

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

For more information about the MRCT Center's work on health literacy in clinical research, visit: https://mrctcenter.org/health-literacy/

Principle 1: All clinical research communications should be clear and easy to understand.

Voluntary and informed clinical research participation is an ethical requirement. Clear communication respects autonomy and empowers decisions that are in line with personal values. All communication with potential, enrolled and past participants should be clearly designed to support understanding and informed decision-making.

Principle 2: Clear communication is necessary throughout the clinical research life cycle.

Health literacy applies to the entire clinical research experience – from the point of learning about research and gaining access to study information, through the recruitment and consent process, during the on-study period, to trial results reporting. Clear communication can benefit participants any time clinical research information is presented and discussed.

Principle 3: All clinical research stakeholders share an ongoing responsibility for ensuring communication is clear and easy to understand.

Sponsors and funders, investigators and study teams, institutional review boards and ethics committees, as well as participants, caregivers, and their community, all play important roles in developing clear clinical research communications. The clarity of clinical research communication will improve when stakeholders work together to foster understanding, support transparent dialog, and respond to the information needs of the participant population.

Principle 4: Clinical research communications should be developed by partnering with the intended audience(s).

Clinical research stakeholders should be sensitive to the vulnerability of potential, enrolled, and past participants, and open to learning from the participant community as research partners. Participants, their caregivers, and their community should all be included in the process of developing and reviewing clinical research information. Stakeholders should engage with the intended audience(s) to learn from them, co-develop communications with them, and solicit feedback before, during and after the clinical research study, from study design to the reporting of research results. This engagement increases the likelihood that the way information is communicated meets the population's needs and is understandable and actionable.

Principle 5: Cultural respect is an integral part of communicating appropriately about clinical research.

All clinical research communication should be sensitive to cultural differences in order to better support autonomy and informed decision making. In the context of developing research communications, culture should be considered broadly, and go beyond country of origin to include race, ethnicity, sex, gender identity, sexual orientation, physical ability, disability, geography, and so on. Considering what culture means to different groups, and engaging in training on cultural humility and methods like teach-back, can lead to communication that is more likely to meet the information needs of the intended audience, especially given the power imbalance that is inherent within the context of medicine, research, and illness.

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

For more information about the MRCT Center's work on health literacy in clinical research, visit:
https://mrctcenter.org/health-literacy/

Principle 6: Clinical research materials for participants should integrate health literacy practices, including plain language, numeracy, clear design techniques, and cultural considerations.

Written, printed, and electronic media clinical research communications, including any standard templates and boilerplates, should incorporate the concepts of plain language, numeracy, readability reader-friendly document design, and visual aids like infographics to augment the recipient's ability to understand.

Principle 7: Clinical research materials for participants should be evaluated to ensure the intended audience(s) can understand the information.

Health literacy evaluation methods increase the likelihood that the audience will be able to understand and act on the clinical research information presented to them. These methods include some combination of testing for readability, piloting study materials and research processes, and performing usability testing with members of the potential participant community.

Principle 8: In-person communication with the intended audience(s) should encourage dialogue and confirm understanding.

All stakeholders should develop a plan that allows for multiple conversations with participants and gives them the time needed to process the information provided and ask questions. To this end, using scripts that clearly explain common terminology and key takeaways can help to ensure that the communicators share consistent information with each participant. Researchers and their study teams should also use interactive methods like teach-back to confirm understanding at all points of the clinical trial life cycle that involve sharing and collecting information, not just when obtaining informed consent.

Principle 9: All clinical research stakeholders should support the development and implementation of organizational policies that integrate health literacy into clinical research.

Organizational policies and funding mechanisms, announcements and conditions should support health literacy processes being integrated into all aspects of clinical research, including study design and development. Corporate, non-profit, and academic sponsors and funders should specify that health literacy concepts be incorporated into all participant-facing communications, including recruitment materials, consents, research summaries, and templates. Institutional review boards and ethics boards should promote the inclusion of health literacy best practice in all participant-facing materials they review.

Principle 10: Integration of health literacy into clinical research requires proactive planning to develop, test, modify, and confirm understanding of clinical research communications.

A true commitment to developing clear research information and engaging in meaningful study-related conversations is reflected in the adoption of health literacy practices throughout an organization's clinical research infrastructure. In many cases, integrating health literacy is a matter of enhancing processes that are already in place. All clinical research stakeholders and their organizations should optimize their workflows to include developing, testing, modifying, and confirming understanding of research communications and be open to continuously improving their processes.

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

For more information about the MRCT Center's work on health literacy in clinical research, visit:
https://mrctcenter.org/health-literacy/

Authored by members of the MRCT Center's Health Literacy in Clinical Research Workgroup

Jessica Ancker, MPH, PhD
May-Lynn Andresen, DNP, RN
Maria Apostolaros, JD, PharmD, MS, FASCP, CCEP
Sylvia Baedorf Kassis, MPH
Behtash Bahador, MS
Amy Ben-Arieh, JD, MPH
Teal Benevides, PhD, MS, OTR/L
Barbara, Bierer, MD
Poorvi Chablani
Reetu Dandora, JD
Theresa R. Devins, DrPH
James Duhig, PhD
Diana Lynette Fisher
Claire Foster
Valery Gordon, MPH, PhD
Lori Hall, RN, BSN
Zachary Hakkinan
Renee Jenkins
Rebecca Johnson, MPH
David Leventhal, MBA
Becca Lory, CAS, BCCS
Michael Paasche-Orlow, MD, MA, MPH
Lisa Palladino Kim, MS
Laura Pigozzi, PhD
Newell McEllwee, PharmD, MSPH
JoAnn Muir
Laurie Myers, MBA (co-chair)
Marilyn Neault, PhD
Catina O'Leary, PhD, LMSW
Margaret Rancovik, Med, CIP
Mary Roary, PhD
Dominic Roberts
Erin Rothwell, PhD
Jennifer Scanlon
Vanessa Simonds, ScD
Louise Scott, LSW
Rhonda Smith, MBA
Kathy Spiegel, PhD
Christopher Trudeau, JD (co-chair)
Jessica Valencia, PhD
Michael Villaire, MSLM
Desiree Walker
Michele Weitz, MA
Sarah White, MPH
Earnestine Willis, MD, MPH

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

For more information about the MRCT Center's work on health literacy in clinical research, visit:
https://mrctcenter.org/health-literacy/