

# RESHAPING RESEARCH

A Guide to Enhancing Cultural Considerations into Research

## Module 3: Cultural Considerations in the Informed Consent Process



Case Center for Reducing Health Disparities

# ABOUT THE CENTER

## About the Center

In January 2004, the Center for Reducing Health Disparities was created by Case Western Reserve University and the MetroHealth System. In 2007, the Center received a P60 grant from the National Institutes of Health, which allowed the Center to pursue new projects related to hypertension, kidney disease, and organ donation. The Center also links students to mentors who have interests in health disparities to foster awareness of and interest in the issues of health equity in Cleveland.

The Center helps to direct the Community Research Partnership Core of the Clinical and Translational Science Collaborative involving Case Western Reserve University, MetroHealth Medical Center, University Hospitals of Cleveland, the Cleveland Clinic, and the Louis Stokes Cleveland VA Medical Center. The aim of this Core is to facilitate community based research among faculty, students, community organizations, and community residents. The Center is under the direction of Ashwini Sehgal, MD and J. Daryl Thornton, MD, MPH.

## MISSION STATEMENT

To reduce health disparities through (a) research on root causes, mechanisms, and interventions, (b) education of students, providers, and policy makers, and (c) partnership with community organizations and government agencies.

## LONG-TERM GOALS

- To create a durable academic-community partnership to develop innovative interventions that achieve measurable reductions in health disparities in the greater Cleveland area.
- To promote successful intervention strategies that can be replicated in other regions.
- To train a new generation of health activists committed to eliminating health disparities

# ACKNOWLEDGEMENTS

## Acknowledgements

The Center for Reducing Health Disparities would like to thank the following members of our Community Partnership Committee for serving on our Community Review Board:

Michele Abraham, MSSA, LISW

Don Allensworth-Davies, PhD, MSc

Cyleste Collins, PhD.

Elise Ellick

Marisa Herran, MD

Kyle Hodges, MBA

Meia F. Jones, BS

Beverley Keyes

Jacqueline Matloub, MB, BS

Stanley Miller

Susan Neth, MS, LSW

Mahboob Rahman, MD, MS

Jasmin Santana

Kurt C. Stange, MD, PhD.

Patricia Terstenyak, MPH

Joan Thoman, RN, PhD, CNS, CDE

Renee Whiteside

## PREFACE

There have been significant demographic shifts in the United States in recent years. The U.S. Census projects that by 2060, minorities, now 37 percent of the U.S. population, will comprise 57 percent of the population.<sup>1</sup> The widening racially, ethnically, and culturally diverse population in the United States present unique challenges to human service practitioners and organizations.<sup>2</sup> Cultural competence has been defined in the context of health care delivery and providers, specifically focusing on the provider-patient interaction. It has also captured the attention of health care policymakers, providers, insurers, and educators as a possible strategy to improve quality and eliminate racial and ethnic disparities in health care.<sup>3</sup> The executive summary of the national standards for culturally and linguistically appropriate services in health care states that cultural competency training should be integrated into health professions education and training at all levels, including academic and functional.<sup>4</sup>

While cultural competency education for clinicians is becoming widespread, little is being done to provide cultural competency education for clinical researchers. A lack of cultural competence on the part of researchers may hinder their ability to engage certain communities, such as minority or non-English speaking individuals, and may lead researchers to unknowingly impose their beliefs, values, and patterns of behavior upon those from other cultural backgrounds.<sup>5</sup> A recent survey of clinical researchers found that they wanted to learn more about the needs and perspectives of different groups.<sup>6</sup> In response to these needs, the Case Center for Reducing Health Disparities has developed this guide to fill gaps in cultural competency education training for researchers.

Research in the health sciences (i.e. biomedical, clinical, health services, and community-based participatory research) has only recently begun to explore the importance and linkages between culture and research design, analysis and interpretation.<sup>7</sup> There is a growing need to develop and implement research studies that are culturally relevant to the needs of various groups. It appears that there are substantial participant barriers to research among minority populations, which have negatively impacted enrollment and retention rates of minorities in research studies.<sup>8</sup> In addition, there are researcher, structural and organizational barriers that contribute to low recruitment and retention of minority groups.<sup>9</sup>

In order to address these barriers and to engage, recruit, and retain certain demographic populations, cultural considerations need to be integrated into the research process. Starting with the planning stages of the research study, researchers must ask whether they are using the

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appropriate constructs, measures, and methodology in relation to their target population. This enables researchers to move beyond between-group comparisons and examine within-group competence. This requires a dual commitment, which includes respecting and honoring cultural values, beliefs, and needs, without sacrificing scientific rigor.<sup>10</sup> This guide is designed to assist researchers in their efforts to conduct quality research in a culturally appropriate manner.

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# LEARNING ICONS

## Learning Icons

Cultural competence begins with awareness, grows with knowledge, enhances with specific skills, and is polished through cross-cultural encounters. There will be a review at the end of the guide, which will be based on the following concepts:

<p><b>Awareness</b></p> 	<p>This section will encourage you to assess your personal awareness of the information and how it relates to your role as a researcher.</p>
<p><b>Knowledge</b></p> 	<p>Knowledge is obtained through continuing education and cross cultural encounters as it relates to conducting research. This section will include a brief summary of important key concepts.</p>
<p><b>Skill</b></p> 	<p>Skill building includes the ability to apply knowledge learned in a way that is culturally appropriate. This section will focus on how you can integrate the information within this guide into your current research efforts using a culturally sensitive approach.</p>

Pesquera, M., Yoder, L. & Lynk, M. (2008) Improving cross-cultural awareness and skills to reduce health disparities in cancer. *MEDSURG Nursing*, 17 (2), 114-120.

## Overview

This is not an all-inclusive resource for researchers. This is designed to help researchers begin the process of learning more about the cultural background and considerations of the individuals, groups and populations they encounter, and how these factors impact how research is conducted.

### **The primary purposes of this guide are to:**

- ✓ Assist researchers with increasing knowledge, skill, and confidence in working with diverse populations.
- ✓ Guide researchers in the process of integrating cultural considerations into the research process.
- ✓ Increase awareness and sensitivity during the process of developing research studies and engaging with diverse populations.



# MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

## Module 3: Cultural Considerations in the Informed Consent Process

UPON COMPLETION OF THIS MODULE, YOU SHOULD BE ABLE TO:

- Identify strategies to incorporate cultural considerations into the informed consent process.
- Understand the role of family in the decision making process.

### INTRODUCTION

According to the Declaration of Helsinki, medical research involving human participants requires that each potential participant be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential participant must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.<sup>1</sup> The Department of Health and Human Services (DHHS) regulations for the protection of human subjects in research requires that an investigator obtain the legally effective informed consent of the participant or participant's legally authorized representative. However, research participants have commonly been found to lack basic understanding of fundamental aspects of the studies in which they are participating.<sup>2,3</sup> The informed consent process is one of many aspects of research that should be periodically examined in an attempt to restore trust in the research process and also to increase inclusion of minority groups.<sup>4</sup>

The ethical guidelines related to informed consent are based on the

#### The Declaration of Helsinki:

<http://www.wma.net/en/30publications/10policies/b3/17c.pdf>

#### 45 CFR Part 46 - Protection of Human Subjects (The Code of Federal Regulations):

[http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr46\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr46_06.html)

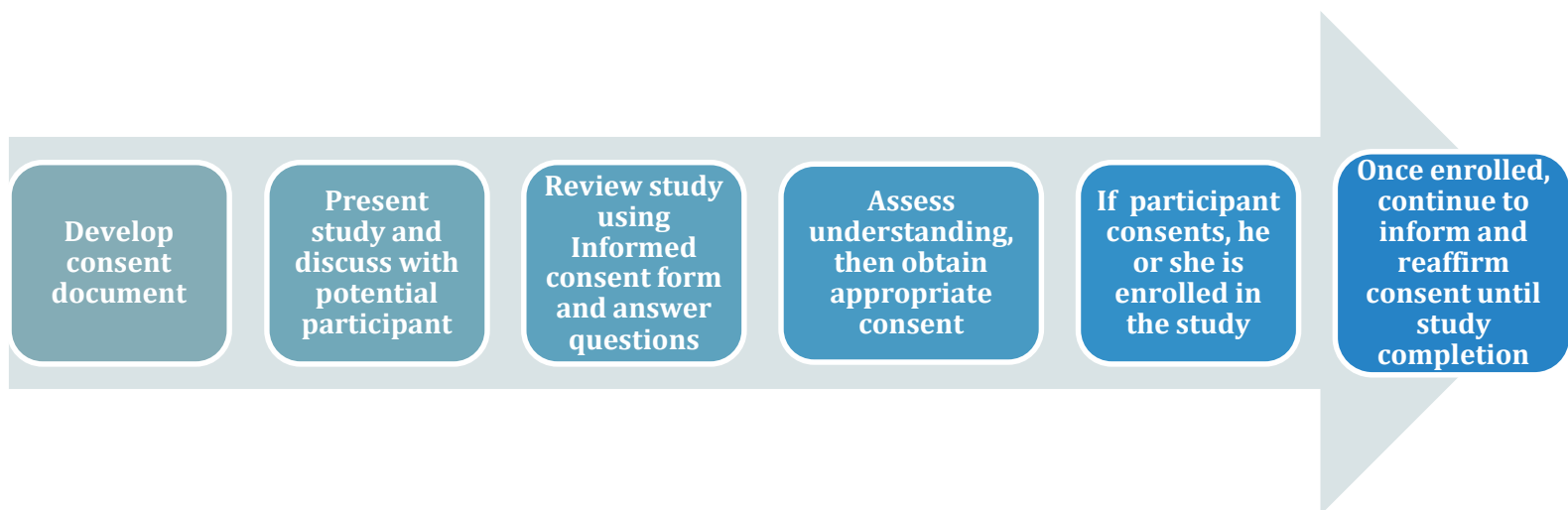
#### The Belmont Report:

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

## MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

There are many steps in the informed consent process<sup>21</sup> (see **figure 1**) and the informed consent document is only one component of the entire consent process. It is a tool for obtaining consent from research participants<sup>5</sup>, which is an absolute requirement for research that poses even a minimal degree of risk.<sup>6</sup>

**FIGURE 1: THE INFORMED CONSENT PROCESS**



Conceptually, the informed consent process includes the following key components<sup>7</sup>:

1. Assessing the decision-making capacity or competence of the potential research participant.
2. Disclosing relevant information about the proposed research.
3. Ensuring that the potential participant understands the details of the study.
4. Ensuring that the potential participant is in the position to make a voluntary choice.
5. Authorizing a decision by the potential participant. If the participant agrees to participate, ensure that he or she signs an informed consent form.

Researchers must ensure that the informed consent form provides details of the study in a culturally appropriate and understandable manner. While the need for consent forms that are informative and comprehensible is readily accepted, insufficient attention is given to making sure that the forms are actually understandable, especially to minority populations.<sup>4,6</sup> In order to strengthen the informed consent process, researchers must consider 1) the cultural and

## MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

contextual issues that influence reactions to informed consent among minority populations, 2) the ability of researchers to successfully address these issues, and 3) potential participant's comprehension of information delivered during the informed consent process.<sup>6,8</sup> The following sections will discuss this further.

### BARRIERS TO EFFECTIVE CONSENTING

There are cultural and contextual factors that may influence informed decision-making among individuals from racial and ethnic groups. These factors include lack of trust due to a history of mistreatment by academic and medical institutions, misinformation about the informed consent process, and the inability to comprehend the informed consent form.<sup>1, 3, 8</sup> Focus group and survey data with African Americans have revealed a sense of distrust arising from a legacy of mistreatment in the health care system and research abuses. African Americans are less likely to trust that research will be fully explained to them and more likely to believe that he or she would be used as a guinea pig without his or her consent. Many individuals from racial and ethnic groups have stated that signing an informed consent form is the equivalent to “signing away your rights” and that the purpose of informed consent is to protect researchers from lawsuits.<sup>4, 8, 17, 23</sup>

### ADDITIONAL BARRIERS TO EFFECTIVE CONSENTING INCLUDE: <sup>10, 11</sup>

- Participant language and cultural issues.
- Poor quality of consent form and related educational materials.
- Participant misunderstanding of information in the informed consent form.
- Researchers' inability to detect patient's lack of comprehension.
- Participant unawareness that they can refuse or delay the decision.
- Lack of time.
- Special patient circumstances and human factors (i.e. cognitive capacity, stress, timing).

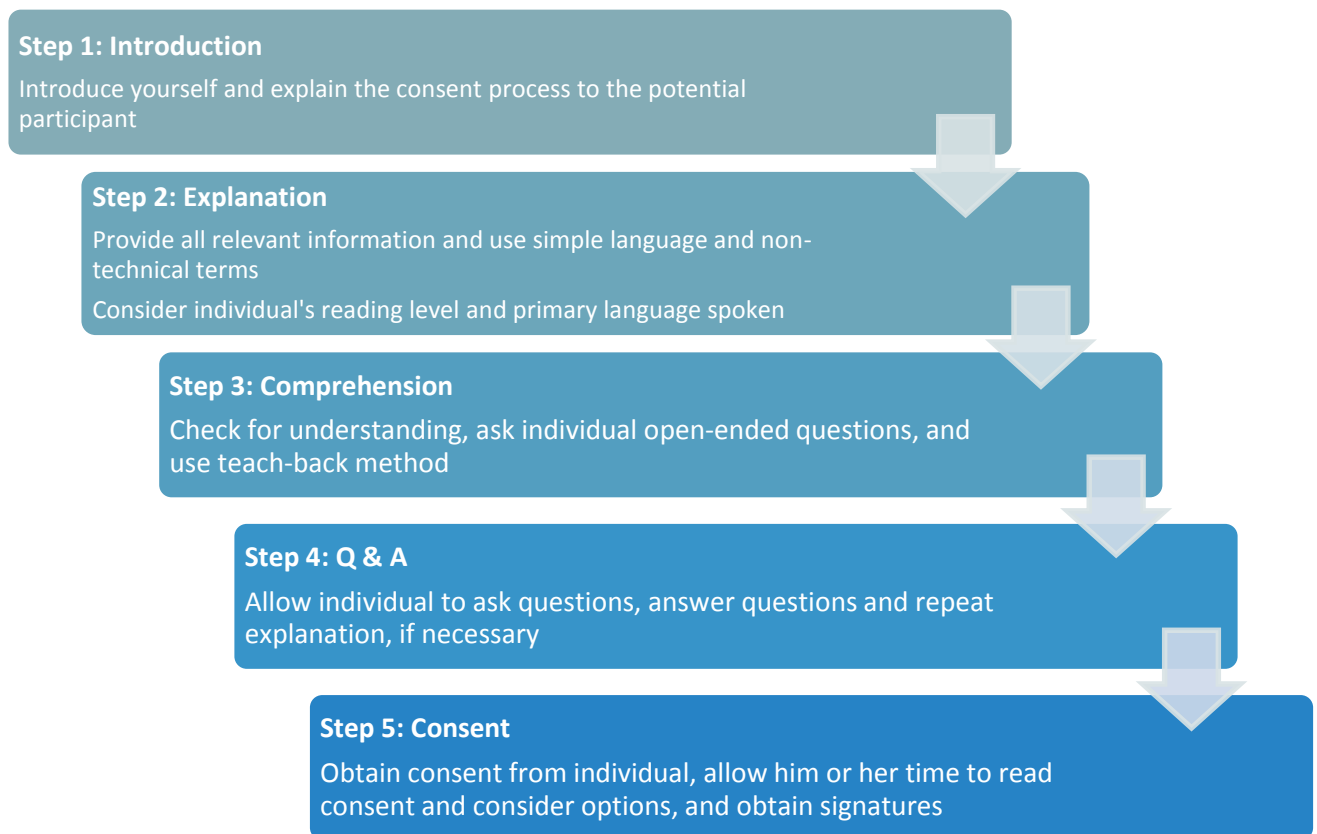
# MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

## INCORPORATING CULTURAL CONSIDERATIONS INTO THE ONE-ON-ONE INTERACTION

### Participant-Researcher Interaction: Starting the Conversation

The interaction between a researcher and potential participant is very critical during the consenting process. **Figure 2** describes the process of reviewing a consent form with a potential participant.

Figure 2: STARTING the Conversation<sup>11</sup>



Often times, the beginning of the informed consent process can become an “opening ritual.”<sup>2, 8</sup> Researchers may only focus on the signing of the informed consent form rather than realizing that this is one of the initial steps in building a relationship with the participant. However, a

## MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

growing body of evidence shows that many participants are misinformed about research and lack clear understanding of information specific to research studies in which they are involved.<sup>8,16</sup> Issues with informed consent in any context, and especially when the potential participant is from a minority group and the researcher is not from that group, is the unequal power relationship and the participant's feeling of obligation to the researcher.<sup>16</sup> Researchers can address these issues by being transparent and authentic in their approach. During the explanation of the informed consent process, researchers should emphasize the mutual gain from participation in the study. Participants from minority groups need assurance that they will have access to the research findings and that the welfare of the community is of mutual interest to all involved in the research study. It is important to maintain honesty and keep communication open when reviewing the informed consent form and discussing the research process. This provides a strong foundation for the development of trust. Researchers should encourage questions and be address all questions as they arise. This confirms the researchers desire to ensure a clear understanding of the information.<sup>3, 8, 10</sup>

### PARTICIPANT COMPREHENSION

Deficiencies in patient understanding include lack of awareness of being a participant in a research study, poor recall of supplied information, inadequate recall of important risks of procedures or treatments, and lack of awareness of the ability to withdraw from a research study at any time.<sup>2,15,17</sup> Obtaining informed consent for participation in research can be particularly challenging because it requires a level of comprehension beyond that required for consent to usual care.<sup>8,10,20</sup> An important ethical consideration for researchers is ensuring that participants understand the details of the study. Studies show that participants frequently have poor recall of the information provided during consent, do not understand key terms such as “randomization” and “placebo”, expect to receive the best available treatment despite having been informed of the randomized trial design, and experience confusion about the dual roles of physician and researcher.<sup>8, 17</sup> Language can also be an issue in securing informed consent. The use of an interpreter may help, but different concepts of illness and issues of translation and cultural bias on the interpreter's part can compromise the extent to which information is understood. In some cultural groups there may be little or no understanding of medicine, and researchers lacking knowledge of traditional belief systems may be wrong to conclude that the individual lacks capacity.<sup>16</sup>

It is recommended that following the discussion with the participant, researchers should document how the patient's comprehension was assessed. To understand a treatment or

## MODULE 3: CULTURAL CONSIDERATIONS IN THE INFORMED CONSENT PROCESS

research protocol, a participant must receive, encode, retain, and process the information. Recall and knowledge alone does not always imply understanding.<sup>17</sup> However, the same techniques that are used to gauge a patient's understanding of standard treatment can be used to assess understanding of a research study. A few suggestions include:

- Monitor the patient's body language and note verbal and nonverbal responses to the conversation. (i.e. is the patient engaged in the conversation? Are they asking good questions that indicate understanding about what is being said?)<sup>13</sup>
- Use the "teach-back method." Ask the participant to summarize the take-home messages. This "teach-back" can be elicited quite easily with a prompt such as: "Please tell me what I have just said to you" or "What will you tell your family members when you go home today?"<sup>13</sup>
- Provide information in addition to the formal consent document. This may include providing informational handouts about the research topic or study. This can enhance the participant's understanding of the study.<sup>8</sup>

### AUTONOMY AND THE ROLE OF THE FAMILY

Many individuals will not make any decisions without first consulting with family members.<sup>8, 16</sup> In India, many people place much trust in their family. The sense of wellbeing depends less on a feeling of personal control. Therefore, the Western idea of respect for the individual may conflict with traditions that define persons by their relations to others. In the researcher-participant relationship elements such as loyalty, integrity, solidarity and compassion may be considered more important than autonomy.<sup>16</sup> In some communities, where the family or community is an integral part of the decision-making process, and risks and benefits of research participation are considered in terms of how the larger group will be affected, investigators should allow enough time for participants to engage in the relevant group decision-making process.<sup>6,8,16</sup> Autonomy varies considerably between cultural groups. In contrast to the emphasis on personal choice that is often seen in the United States and Europe, communal and hierarchical patterns of decision-making may take precedence. Over the past few years, some American Indian tribes have developed their own Institutional Review Boards to obtain some degree of control in the research process and to prevent the perceived misuse and misinterpretation of research data. Many of these IRB's have been instrumental in requiring researchers to give back to the community by providing updates or summary reports and data files. In addition, many tribes require that the tribal council review and approve all research

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projects for their communities. The researcher must present the study design in language understandable to the community or risk having the project disapproved due to a misunderstanding of the purpose and design.<sup>9</sup> In these specific cases, in addition to ensuring proper IRB approval from the medical or academic institution's IRB, researchers would also have to establish relationships with the tribal IRBs.

Involving family members in discussions about research studies could help participants feel less burdened about making this decision on their own. This could also provide an opportunity to address any cultural or religious barriers that may exist. Keep in mind that participants might be influenced by family members' negative and positive attitudes regarding research participation. For example, a Hispanic mother and child in a study must acknowledge traditional family power structures that may exist. A mother may be reluctant to enroll in the study unless her husband approves. Or, if the mother does agree to participate without consulting her husband, he may reverse her decision to re-establish his authority.<sup>23</sup> If family members are involved in the discussions about taking part in research, these attitudes and beliefs will be brought out in the open. Researchers are encouraged to keep communication open and answer all questions asked by the individual and his or her family. The goal is to ensure that all patients, families, and the public receive consistent and accurate information so they, in turn, can make more informed decisions about their care and, ultimately, increase their satisfaction with the research process.<sup>8</sup>

### Here are some helpful tips on including family members<sup>22</sup>:

- ✓ Discuss the role of the patient's family in decision making.
- ✓ Encourage the patient to take the informed consent home and allow the family to review.
- ✓ Engage in a sensitive dialogue with family members to address concerns or misconceptions about what is involved in the research study.

## Developing an Informed Consent Form

### Language, Literacy & Layout

Many participants with the capacity to consent do not clearly understand one or more aspects of informed consent form. Low literacy is likely an important factor. Approximately, half of American adults read at or below an eighth-grade reading level.<sup>12</sup> Numerous studies have shown that the majority of consent documents for medical diagnosis and treatment are written at or above the twelfth-grade reading level.<sup>6, 12</sup> This level is substantially higher than that of the

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majority of the U.S. population, whose average reading abilities are at the eighth-grade level.<sup>6</sup> Commonly, it is recommended that an informed consent form should be written at a sixth to eighth grade reading level, although some research suggests that a lower reading level might be more appropriate.<sup>13, 14, 15</sup> Researchers can use computer programs to quickly assess the reading level of a consent form. Numerous readability formulas such as the SMOG, the fog, the Fry, and the Flesch-Kincaid are available, and the reliability among these formulas is high.<sup>14, 15</sup> Researchers must be aware that solely decreasing the reading level will not ensure that all potential participants clearly understand the study and will give consent.<sup>2</sup> Easy-to-read consent forms might not be sufficient for potential research participants who lack familiarity with providing informed consent or the activities of participating in research.<sup>2</sup> Informed consent documents should be accurate, thorough, and written with the target population in mind.<sup>2,13</sup> The National Cancer Institute developed recommendations for improving the readability of informed consent forms, which are found in **Table 1**.

Researchers should be mindful of the terminology used within the consent form. As a researcher, you may have a clear understanding of a medical condition or research terminology that will be used. However, these terms may be foreign to potential participants and will need to be explained clearly and understandably through the form. For example, a potential participant may not know the meaning of “opt-out.”<sup>18</sup> Prior to administering the consent form, consider having a community advisory board or members of the target population review the form to ensure that it is clearly written and understandable. Also, patient advocates can provide invaluable feedback regarding the readability of informed consent documents. If such colleagues are available, it is helpful to include them to assist the research staff in preparing the necessary documents. They can provide expert guidance to address common concerns and ensure that the document provides the right amount of detail desired by the potential participant.<sup>13</sup>

### **ADDITIONAL RESOURCE:**

#### **Plain Language.gov**

Document Checklist for Plain Language

<http://www.plainlanguage.gov/howto/quickreference/checklist.cfm>



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**Table 1: Recommendations for improving the readability of the Informed Consent document<sup>19</sup>**

### **Text includes:**

- Words are familiar to the reader. Any scientific, medical, or legal words are defined clearly.
- Words and terminology are consistent throughout the document.
- Sentences are short, simple, and direct.
- Line length is limited to 30-50 characters and spaces.
- Paragraphs are short. Convey one idea per paragraph.
- Verbs are in active voice (i.e., the participant is the doer of the act).
- Personal pronouns are used to increase personal identification.
- Each idea is clear and logically sequenced (according to audience logic).
- Important points are highlighted.
- Study purpose is presented early in the text.
- Titles, subtitles, and other headers help to clarify organization of text.
- Headers are simple and close to text.
- Underline, bold, or boxes (rather than all caps or italics) give emphasis.
- Layout balances white space with words and graphics.
- Left margins are justified. Right margins are ragged.
- Upper and lower case letters are used.
- Style of print is easy to read.
- Type size is at least 12 point.
- Readability analysis is done to determine reading level (should be eighth grade or lower).

### **Avoid:**

- Abbreviations and acronyms.
- Large blocks of print.
- Words containing more than three syllables (where possible).

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### **Graphics are:**

- Helpful in explaining the text.
- Easy to understand.
- Meaningful to the audience.
- Appropriately located. Text and graphics go together.
- Simple and uncluttered.
- Images reflect cultural context.
- Visuals have captions.
- Each visual is directly related to one message.
- Cues, such as circles or arrows, point out key information.
- Colors, when used, are appealing to the audience.
- Avoid graphics that won't reproduce well.

## MODULE 3: REVIEW

### Awareness



- Be aware of the strengths, challenges and barriers you encounter when writing consent forms or consenting potential participants.
- If you were a potential research participant, what researcher traits and qualities would be important to you? How would you want someone to discuss the informed consent form with you?
- What factors influence your own decision-making processes?

### Knowledge



- Strengthening the informed consent process requires investigators to consider several interrelated factors: the cultural and contextual issues that influence potential participants' reactions to informed consent.
- The role of the family can be an important factor in the decision-making process.
- Informed consent documents should be accurate, thorough, and written with the target population in mind.

### Skill



- Create a community advisory board that includes members of the target population. Have members review the informed consent form to ensure that it is clearly written and understandable.
- Use open ended questions, explain technical terms, and use the “teach back” method.
- Keep communication open and answer all questions asked by the individual and his or her family.

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### Module 3: References

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## FOR ADDITIONAL INFORMATION

### **For Additional Information**

The Case Center for Reducing Health Disparities offers seminars, trainings, and presentations to researchers associated with Case Western Reserve University, including affiliated hospital staff, trainees, and community-based investigators. These trainings review key steps in conducting culturally competent research. This includes assisting researchers in the process of integrating cultural considerations into developing research questions, study design, data collection, analysis, and dissemination of findings. The purpose of these trainings is to increase researcher's knowledge, skill, and confidence in engaging and meeting the needs of culturally and linguistically diverse populations.

For more information about the Reshaping Research guide or our cultural competency trainings, please contact:

Katrice D. Cain, MA  
Program Development Manager  
Case Center for Reducing Health Disparities  
Phone: 216-778-8467  
Email: [kcain@metrohealth.org](mailto:kcain@metrohealth.org)