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FOR LEARNING FOR LISTENING FOR LIFE

Patient-Centered Consent Process

CONTENTS

Patient-Centered Consent Process

REFLECTION CHECKLIST

Share this with your colleagues to see what your research department thinks about these issues.

Question	Very well	OK	Not Very Well	Don't know
1. How well do we use visual, auditory, written, and kinesthetic approaches to facilitate trial discussion?	❒	❒	❒	❒
2. How well do we explain randomization?	❒	❒	❒	❒
3. How well do we assess the patient (stress, emotional, learning) needs for receiving information?	❒	❒	❒	❒
4. How well do we assess comprehension?	❒	❒	❒	❒
5. How well do we solicit questions during the consent process?	❒	❒	❒	❒

If you answered, "OK" or "Not very well" to more than two of these questions, your site may need to implement changes in this area.

Patient-Centered Consent Process

Best Practice Tip Sheet

Action	How to do it
Collect Data to Inspire Action	❒ Implement specific process and outcome measurements for accrual and conduct quarterly analysis to track progress on all trials. ❒ Implement a quarterly/monthly review system to assess accrual progress and develop specific corrective action plans.
Implement SOPs	○ Routine elements of the informed consent process: ○ Assess patients' needs and preferences for information. ○ Evaluate the health literacy needs of the patient and family in the consent process. ○ Compare the standard treatment with what is being studied according to the protocol. ○ Utilize the patient-centered decision support tools/diagrams and question lists [iii]to help the patient consider care options. ○ Assess comprehension. ○ For low literacy and Limited English Proficient populations around the consent process: ○ Ensure procedural alignment with AHRQ Health Literate Organization[iii] principles. ○ Ensure procedural alignment with National Standards on Culturally and Linguistically Appropriate Services[iv] guidelines for interpretation and translation. ○ Use the guidelines for easy-to-read consent documents/use NCI template. ○ Use (or advocate for the use of) the OHRP-approved[v] "short form" with LEP and/or low literacy patients. ○ Use professional interpreters (in person or by phone) as a communication bridge. ○ For decision aid utilization: Regardless of the literacy level, many patients don't even have a sense of the questions to be asked during the consent process.[vi,vii] ○ For translation of documents:

	○ Anticipate which trials might have non-English speaking patients, based on the previous incidence data, and build that into the budget of the study. ○ Find out whether earned honorariums could be voluntarily donated to institutional fund to address translation services not covered by trial sponsors[viii] ○ For use of interpreters
Improve Staff Education	○ Provide adequate and ongoing communication training to staff who obtain informed consent from patients to ensure high-quality, patient-centered communication around the consent process[ix,x,xi]
Improve Internal Systems	○ Provide adequate and ongoing communication training to staff who obtain informed consent from patients to ensure high-quality, patient-centered communication around the consent process[xii,xiii,xiv] ○ Ensure that all staff members use appropriate communication skills during consent[xv,xvi,xvii] ○ Speak slowly and use simple language to explain complex concepts. ○ Use the "teach back" technique—ask the patient to repeat in their own words their understanding of the purpose and procedures and rights outlined in the consent document. ○ Use the "chunks and checks" technique—provide the patient with only two or three concepts a time and check for the understanding of the information through teach back. ○ Ensure all staff members use visual, auditory, written, and kinesthetic approaches to aid in trial discussion (beyond consent form) such as: ○ A simple chart to illustrate the differences of treatment off and on a trial. ○ A generic calendar that shows what will happen during the study with weeks for appointments and tests. ○ A chart about expected side effects from the treatment being studied in a clinical study as compared to those in a standard treatment. ○ A picture (not a schema) about how the groups are assigned in the study.

	○ Create a shame- free environment *for addressing varied degrees of health literacy* ○ Identify those with low literacy skills. Clues: comments that they left their glasses home today, taking a long time to complete forms, incomplete forms, and inability to described medications they are taking, how they take them and what they are for. ○ Give permission to ask questions by saying something like, "Many people have difficulty reading and understanding the medical information I give them so I want to make sure I give you time to ask questions if there's something you don't understand."
Use "incentives" for staff and physicians	❒ Use internal, visible "scoreboard" or "thermometer" on <u>accrual</u> ○ Send monthly accrual reports to all the members of a research team and all the treating physicians[xviii] ○ Highlight leaders in a monthly newsletter/email[xix] ○ Establish a quarterly competition and award "prizes" to teams with the highest total accrual, and the highest increases from previous quarters[xx] ❒ Implement an incentive system to demonstrate commitment to clinical trials accrual (that meets with IRB approval) ○ Acknowledge high accruing physicians/high accruing teams through an appropriate internal venue ❒ Recognize accomplishments and encourage new actions (by clinical area/individual physician/research team) to accrue a certain number/percentage of patients

Clinical Trials Engagement: Tips for Educating Patients from Diverse Ethnic/Racial Groups

It is important to understand what patients themselves want in order to enhance their trust. For patients from ethnic and racial minority groups in particular, and likely many others, these include the following[xxi]:

- Honest and respectful communication from the research team
- Provision of complete information regarding the risks and benefits of the clinical trial
- Assurance that the participant has the complete knowledge of the clinical trial's procedures and expectations, as well as any additional treatment options outside of the clinical trial
- Provision of sufficient time to consider options after introduction of the consent form until a decision must be made
- Using additional media (e.g., videos and pamphlets) to explain the research
- Provision of time for the participants to confer with friends and family members
- Financial incentives

Working with Patients from Diverse Ethnic/Racial Groups

More than ever, the population of patients within the health care system is racially and ethnically diverse. The same holds true in the clinical trials setting. While it's important to be aware of the potential clinical trial participation concerns and challenges faced by the diverse racial/ethnic groups, it is equally important to recognize that simply being a member of an identified group doesn't make the group homogenous. Person-centered communication is critical to understand and address the specific needs of individual patients.

Patient Decision Aid

Patient Clinical Trials Checklist – Developed by Richard Brown, PhD (Massey Center), this list is intended to serves as a prompt for patients in helping them to consider potential questions to pose to their doctor and research staff at their appointment during a clinical trial participation is discussed

Understanding My Choices

1. What is the usual (standard) treatment for people in my situation?
2. Why are you offering me this particular trial? Does it ask an important question in treatment?
3. Are there choices other than the trial and the standard treatment?
4. What other trials am I eligible for? What makes me eligible or ineligible?

Finding Out More Information about This Trial

1. How can I learn more about the trial? Can I speak to someone who is already participating in this trial?

Understanding The Trial's Purpose and Background

1. What is the purpose of this trial?
2. What is already known about this treatment's success?
3. How does the treatment work?

Understanding the Possible Benefits

1. What benefits could I possibly get if I participate in the trial?
2. How would others benefit if I participate in the trial?
3. Has the benefit of the new treatment already been proven in people like me?
4. (If doctor describes response to treatment) What does response rate mean? How long would a response last?

Understanding the Possible Risks

1. What are the risks of taking the new treatment? Are there any long-term or permanent side effects of the treatment?
   Are there any serious or rare side effects I should know about?

2. Will there be side effects on the trial I won't get on the standard treatment? Are there different side effects depending on which arm I am randomized to receive?
3. Whom can I call if something goes wrong?
4. If I get a side effect or injury because of being in the trial, will I get compensation?

Differences between Participating in a Trial and Having a Standard Treatment

1. If I participate in a clinical trial, will it require me to have extra tests, to attend more clinics and will it cost me extra money? (Extra parking, extra medication?)
2. How often will I need to come in for treatment, and is that different from if I took the standard treatment?
3. Will the treatment be offered by experienced staff? Where will the treatment be given?

Understanding how the trial is carried out

1. Is the new treatment available only when I participate in a trial?
2. How long has the trial been going on? How many people will be studied and how many are participating in the trial already? Are there any concerns about the trial or treatment so far?
3. Apart from the hospital staff, will other people have access to my medical records? Who? How will my confidentiality be ensured?
4. If the new treatment is beneficial, how can I get it (if I am not already on it)? How will I be informed of the results of the trial?
5. How will the results of the trial be used?

Understanding Randomization and Blinding

1. Is this trial randomized? What does that mean and why is it important?
2. Will I know the treatment I am getting, or is this trial blinded? What does that mean and why is it important in this trial? Will I ever know what treatment I am getting?

Understanding the Possible Conflicts of Interest

1. Are you in charge of the trial (the principal investigator)? If not, what's your role in the trial?
2. Is there a payment made by the trial sponsor/company to the hospital or to you as my doctor if I go on this trial? Could you tell me how much money is spent and is this usual?

How is the money spent?

Understanding My Right to Join or Not to Join the Trial

1. Will you still treat me if I decide not to participate in the trial?
2. Do I have time to think about whether to participate in the trial (a day or two, or a week)? Will taking time to decide affect how well the treatment works?
3. Can I withdraw from the trial at a later stage? Will I be penalized in any way?
4. If I join the trial will I be losing out on any new treatment opportunities (such as another trial or standard treatment later)?

Alternative Therapies

1. Can I still have alternative therapies if I participate in the trial (e.g. vitamins, herbal remedies, naturopathy, and dietary changes)?

Learning Styles and the Consent Process

How can you accommodate different learning styles in the consent process? [xxii][xxiii]

Learning Style	What do to during the consent process
Visual	Visual material
	Handouts—easy to read
	Variety of technology—computers, overhead, video, TV, Internet
Auditory	Rephrase key points.
	Vary speed, volume, and pitch.
	Write down the key points.
	Positioned to hear the message clearly
	Use multimedia—tapes, music, etc.
Kinesthetic	Frequent breaks to move around
	Learner writes own notes.
	Provide tactile activities/show where patient would go/see
	Product samples

Active Educational Approach:

Explaining Challenging Concepts

This resource provides investigators and research staff with reasonable responses to common questions.

Question 1: What is a clinical trial?

- A clinical trial is a research study that involves people. It helps improve knowledge about ways to prevent, find, or treat diseases or conditions.
- There are many different kinds of research studies—those for people suffering from a condition/disease, as well as the studies for people who want to prevent a condition/disease in the future.

For people currently needing a treatment for a disease or condition	For healthy people or people with a disease or condition in their families
• Treatment • Genetics • Quality-of-Life/Supportive Care	• Prevention • Screening and Early Detection • Diagnostic • Genetics

Question 2: Aren't patients who join research studies just "guinea pigs?

- Everyone who takes part in research studies has rights that are protected under the law. As part of something called informed consent, a person has the right to know everything that is going to happen in a study before the agreement to take part. He/she has the right to leave a study at any time and for any reason.
- If someone is participating in a research study, he/she would always receive appropriate treatment.
- Placebos, “sugar pills,” or fake medicines can be used in certain types of research studies (will be used in this study), but no one is ever given fake medicine instead of appropriate treatment. All participants would learn about this possibility before they decide to join a research study.

Question 3: Why should a person join a research study, if studies only benefit people in the future?

- While the overall purpose of a research study is to answer a research question, people can and do benefit themselves from taking part.
    - **Clinical trials provide high-quality care to patients.** Many experts believe that therapies offered through CCTs should be considered the **preferred treatment choice** for physicians and patients.
    - **Clinical trials give proper** medical attention to patients.
    - **Patients** participating in trials can have access promising new approaches to care that may not be available outside of a trial.
- For any kind of research study, many participants feel good about providing information that can help their community in the future.

Question 4: Is participating in a research study the "last resort" for someone who has xxx?

- No. Taking part in a research study is not limited to people who have no other care options left. In many cases, receiving treatment through a clinical trial or research study can be the first treatment people receive for their condition/disease.
- There are also research studies available for healthy volunteers who look at ways to prevent, detect, or better understand the risk of condition/disease.

Question 5: I understand that in some research studies, people are placed in different groups. Why can't they choose the group they join?

- Research studies are done to figure out if a new way of preventing, finding, or treating a condition/disease is safe and more effective than what is used today. If it was known ahead of time which treatment worked best, it would not be necessary to do the study.
- By giving people an equal chance to be assigned to any group in a study, we can ensure that people in all the groups are similar and comparable. Each person has a fair and equal chance of receiving the new medicine or approach being studied or receiving commonly accepted care.

If you choose to participate in this trial, you would get (choose one):

- Either the most accepted treatment or a new treatment that doctors hope will be better. We don't know yet **if** it is better than what is now used to treat you, but we do

know the new treatment is safe* and effective for your condition/disease. (RANDOMIZED)
- A treatment is already known to be safe* in humans. What we don't know yet for sure is how effective it is for your condition/disease. (PHASE II)
- A treatment is already known to be safe* and effective in animals with a condition/disease. What we don't know yet is if it's safe or effective for your type of condition/disease. (PHASE I)

Question 6: What kinds of questions should be asked about a research study one is considering?

Some questions that participants may want to ask regarding a study include the following:

- Who is paying for the study to be done?
- Who has reviewed and approved the study?
- What is the research question this study is asking?
- How is my safety in the study taken care of?
- How will the results be shared with me?

Possible Risks and Benefits

- What are the possible risks and benefits of the study? How do those risks compare to the treatment I would get off of a study?
- How would my costs be covered for unforeseen risks, such as the cost of hospitalization?
- How will I be told about new risks identified during the study?

Participation

- How long will I need to be a part of the study? Will there be follow-up visits or calls after the study?

Cost Issues

- Will I have to pay for any medicines, tests, or other charges? If so, what will the approximate charges be?
- What is health insurance likely to cover? Will the money from the study cover costs if I don't have insurance?
- Who can help answer questions from my insurance company or health plan?
- What support is offered to me in a study? For example, will my travel expenses be reimbursed?

Question 7: What happens if someone wants to stop participating in a research study?

- All types of research are voluntary. People always have the right to leave a research study at any time and for any reason.

Question 8: Will I have to pay to be a part of a research study?

- The short answer is—it depends.
- Some studies are free for participants. Costs are paid for by the group doing the study.
- Some studies may have costs for participants, and sometimes, these are paid for by insurance.
- What's important to know is that taking part in health research does not guarantee free medical treatment and care, and there may be limitations on what costs are covered.
- Before deciding to participate in a research study, it is important that people understand what their costs will be.

Question 9: I've read that patients can die if they decide to get treatment within a research study. Why would anyone want to be a part of a study with all those risks?

- Anyone interested in research should understand that research studies have both benefits and risks. Potential benefits include:
    - Participants have access to promising new treatments that are often not available outside of a study.
    - New medicines being studied may be more effective than commonly accepted forms of care.
    - Participants receive regular and careful medical attention from a team of healthcare experts.
- There are also potential risks to participate in a research study. These risks may include:
    - The new approach being studied in the research study may not be better than what is commonly offered treatment for that type of
    - New medicines may have side effects or risks that are unknown or worse than those caused by commonly accepted forms of care.
    - Taking part in a research study may demand more time and attention than would be needed for regular medical care, such as more tests, more office visits, or more medications on a complex schedule.

Question 10: Can a person be put in a research study without his or her knowledge?

- No. The law requires that the people in charge of the study explain all the related information, so that people can make an informed decision about participation. This is called informed consent.
- Informed consent is a process where the research team explains in clear and understandable language what the purpose of the study is, what will happen during the study, and what the study's potential risks and benefits are. Participants also have the right to leave the study at any time.
- The informed consent process usually ends by signing a written document stating that he or she entered the study as per his or her own will, without being pressured, and that he or she has the complete knowledge and understanding of the study risks and possible benefits.

Question 11: Why are there restrictions regarding who can join each study?

- Research is done based on strict guidelines to ensure patient's safety, while allowing researchers to answer the question that is being studied.
- For example, some people have other health problems that could be made worse by the treatment offered in a study and, therefore, they would be excluded from taking part.
- What might restrict someone from taking part in a research study may be:
    - The person's age
    - The person's gender
    - The prior treatments the person has had
    - The other medical conditions the person may have

Question 12: I've read about some terrible things that have been done in the name of research, quite recently! How can these kinds of things still be going on?

- Past research abuses have led to strong laws that protect the people who participate in research. However, there are potential abuses in the research system that can violate these laws.
- We must be committed to drawing attention to this problem; doctors who are found guilty of violating human subjects' protection should be appropriately punished.
- We also must ensure that those interested in research are informed of all the risks and benefits of participating, in a manner they understand, so that they can make an informed choice about whether to take part.

Active Educational Approach:

Teach Back to Assess Comprehension[xxiv]

Some examples of language to use:

Example 1

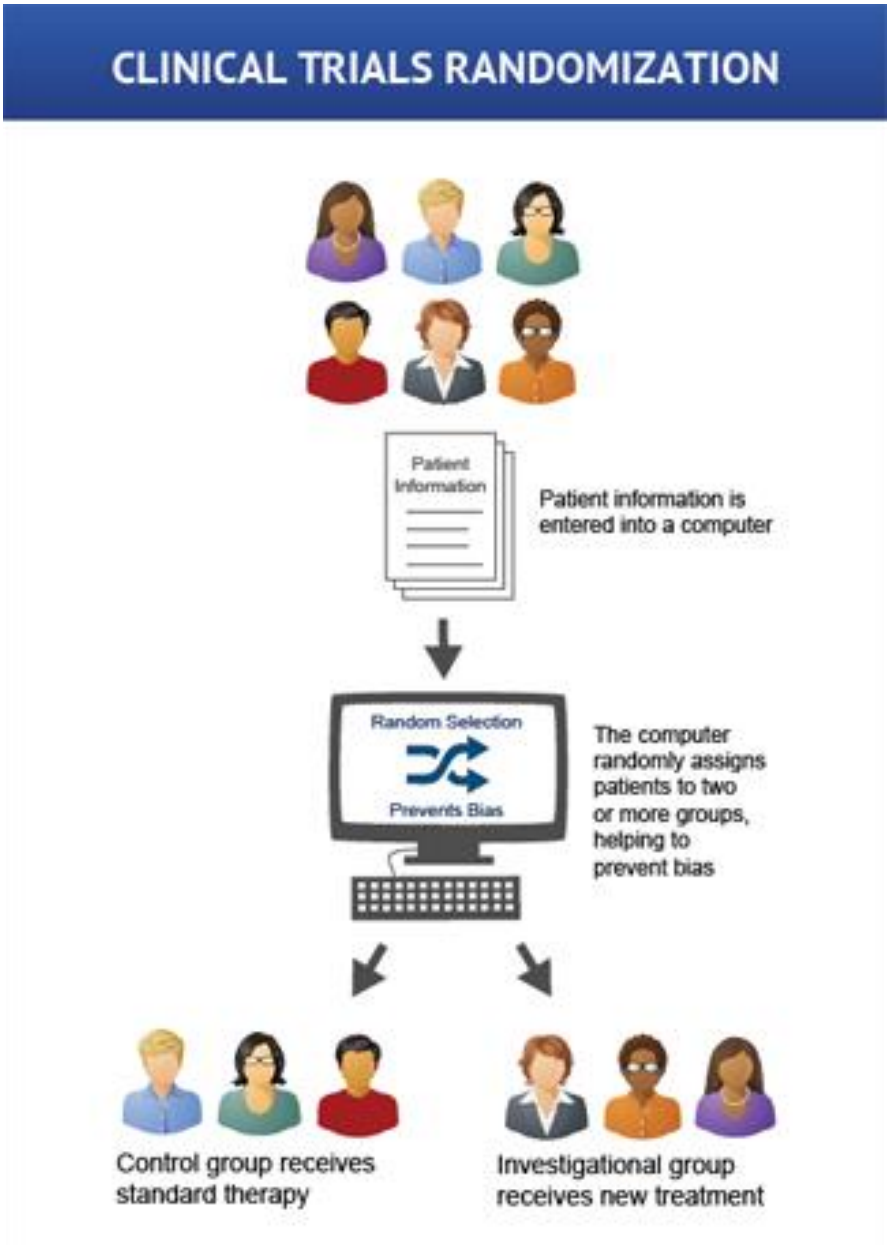
- I want to make sure I explained everything clearly. If you were trying to explain what you're doing in this study to a family member, what would you say?
- Let's review the main side effects. What are the two things I asked you to watch out for?
- What questions do you have?

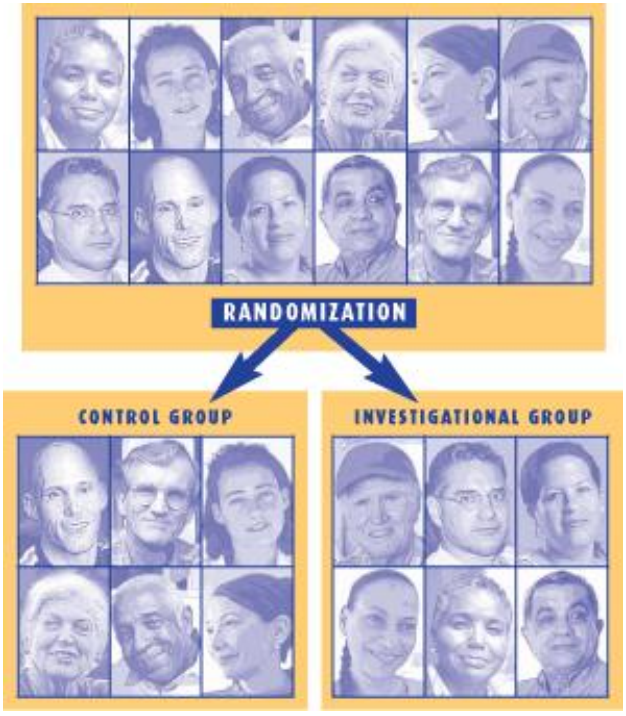
Example 2

- Tell me in your own words what this study is all about.
- Tell me what you think will happen to you in this study.
- What do you expect to gain by taking part in this research?
- What risks might you experience by participating in the research?
- What are your alternatives (other choices or options for participating in this research)?

Active Educational Approach:

Use of Illustrations to Explain Concepts





A computer assigns patients into different groups. No one can choose the group they are in

One group gets the standard treatment

One group gets the treatment being studied

Adapted from National Cancer Institute

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Sample Calendar – ***This calendar provides an example of a simple visual aid that can be shared with the patients to explain what the patient can expect regarding a treatment in a clinical trial compared to a standard treatment received.***

Comparison Calendar of Standard of Care vs. Trial Requirements										
Study Requirements		Cycle Number	1	2	3	4	5	6	7	8
		Week Number	Start	3	6	9	12	15	18	21
		Date	Jul-4	Jul-11	Jul-18	Jul-25	Aug-1	Aug-8	Aug-15	Aug-22
Drug Treatment 	**Standard of Care:**	xxxxx	✓	✓	✓	✓	✓	✓	✓	✓
	Clinical Trial:	xxx +/- YYY (see note below)	✓	✓	✓	✓	✓	✓	✓	✓
Procedures 	**Standard of Care:**	Exam + x-ray + urine test	✓							✓
	Clinical Trial:	All of the above + EKG + MUGA	✓		✓		✓		✓	✓
Imaging 	**Standard of Care:**	MRI or CT Scan	✓							✓
	Clinical Trial:	All of the above + mammogram + ultrasound	✓				✓			✓
Blood Draws 	**Standard of Care:**	CBC, Chemistry	✓				✓			✓
	Clinical Trial:	All of the above + Pharmacokinetics	✓	✓	✓	✓	✓	✓	✓	✓
NOTES: Sue will call to schedule all imaging										
Note: You have an <u>equal chance</u> of being assigned to two different groups. One group gets standard treatment. The other group gets the new treatment being studied.										

Working with Potential Participants Who Do Not Speak English: HHS Guidance[xxv]

OBTAINING AND DOCUMENTING INFORMED CONSENT OF SUBJECTS WHO DO NOT SPEAK ENGLISH

Department of Health and Human Services regulations for the protection of human subjects requires that informed consent information be presented in a language understandable to the subject and, in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117).

Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, in a language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. OPRR strongly encourages the use of this procedure whenever possible. Alternatively, §46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document (see sample attached) should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

It is the responsibility of the IRB to determine which of the procedures at §46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

Working with Potential Participants Who Do Not Speak English: Working with Interpreters

Interpretation is the process of understanding and analyzing a spoken or signed message and re-expressing that message faithfully, accurately, and objectively in another language, taking the cultural and social context into account. Interpretation is not the same as translation. Translation involves written words, whereas interpretation involves spoken words.

Remember, the appropriate translation of written materials and the use of interpreter services are together the key to effective communication.

The most effective way to conduct an interpreted interaction is through the triadic interview process, which consists of the following components:

- A pre-interview session
- The triadic interview process, as shown in the image below
- A post-interview debriefing (when necessary)

The positioning of the participants during an interpreted encounter is important for effective communication. The interpreter should be considered a member of the health care team, but remain as unobtrusive as possible

Interpreters should use first-person speech, as if the interpreter were speaking in the patient's or the doctor's voice, as opposed to third-person speech, as if the interpreter were speaking about the patient or doctor.

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Communication Training Materials for Research Staff

HRSA Effective Communication Tools for Healthcare Professionals

This comprehensive course is designed to improve patient-provider communication skills—quite relent in the research stetting—by enhancing your awareness and knowledge of the three main factors contributing to unified health communication:

- Health literacy
- Cultural competency
- English language proficiency

The intent of developing better patient-provider communication is to make possible better health outcomes.

Upon completion of this course, health care providers and staff will be able to implement patient-centered communication practices that appropriately address patients with limited health literacy, to demonstrate cultural competency, and to address the needs of patients with limited English proficiency (LEP).
To view the course, click http://pilot.train.hrsa.gov/uhc/mainmenu.htm

AMA Foundation Health Literacy Kit/ Video

Included as part of its Health Literacy Kits, the AMA Foundation has created informational and instructional videos with case studies. The 2007 video, "Health literacy and patient safety: Help patients understand," gives more detailed techniques and specific steps for physicians and their staff on helping patients with limited health literacy.
To view the video see "Health literacy and patient safety: Help patients understand" (YouTube)

Culturally and Linguistically Appropriate Service (CLAS) Standards - Training for medical staff

The enhanced CLAS standards, resources and trainings can be accessed online here:
https://www.thinkculturalhealth.hhs.gov/

Program for Readability in Science & Medicine (PRISM) – The PRISM Readability Toolkit

This toolkit is a guide for researchers on the use of plain language in consent forms and study materials. A toolkit and online training are available online.

The Toolkit Includes:

- Plain language principles and strategies
- Quick reference guide and editing checklist
- Plain language alternatives to complex terms
- Easy-to-read template language for consent forms and HIPAA authorizations
- Links to helpful readability resources

Ten Attributes of Health Literate Health Care Organizations

This report produced by the Institute of Medicine in 2012 describes 10 key characteristics that health organizations should have, promoting and supporting the ability of patients to read and understand health information.
A PDF of this report can be accessed here: http://iom.edu/~/media/Files/Perspectives-Files/2012/Discussion-Papers/BPH_Ten_HLit_Attributes.pdf
The free toolkit and online training can be accessed here:
http://www.grouphealthresearch.org/capabilities/readability/readability_home.html#online-training-ftn

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