Simplifying Informed Consent

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Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services
Learning Objectives

After this presentation, attendees will be able to
• Explain why getting meaningful consent is critical to enrolling research participants
• Describe important components for meaningful consent
  ▪ Explain new requirements in revised Common Rule
• Identify techniques for simplifying and creating a meaningful consent document
Human Research: An Inherent Ethical Tension

Research: a systematic investigation… designed to develop or contribute to generalizable knowledge

- Research promotes the common good
- Research subjects are the means to achieve this goal; their support is vital!
- Research subjects must be treated with respect and appropriately protected from harms
Why is Informed Consent Important for Research?

Purpose is to help people make informed decisions about whether to participate

- Ethical ideals:
  - Individuals decide for themselves according to their own values and opinions (autonomy)
    - Voluntariness
    - Informed Consent
  - Those whose autonomy is compromised should be protected
    - Special attention to undue influence and coercion
    - Additional protections
Informed Consent in the Common Rule

- Must be obtained and documented before beginning any activities done for research purposes (unless waived)
- Informed consent must provide information:
  - **Needed** for an informed decision about participation
  - In language **understandable** to the potential participant
  - Under circumstances that promote voluntariness

§46.116(a)
Informed Consent Empowers Participants & Builds Trust

- Research is teamwork
- Willing participants are key to success
The Important Question

How to make sure prospective participants have a fair chance of getting/understanding the information they need to make a decision about whether to be in a study?
New Informed Consent Requirements in the Revised Common Rule

Focus on the information needs of prospective research participants, including:

• Information that a reasonable person would want to have in order to make an informed decision about participation

• Information presented in sufficient detail and organized and presented in a way that facilitates understanding of why one might or might not want to participate

46.116(a)(4) & §46.116(a)(5)(ii)
If you were asked to participate in a research study, ask yourself: *What information would you need to make an informed decision about participation and how should this information be presented?*
Which Context?

- Context of where researchers are coming from, why they want to do the research, and what they hope to find
- Context under which prospective participants receive and understand the information
The Importance of Context in Health Research

- People are unfamiliar with concepts about research
- Decisions affecting one’s health are personal
- Decisions to participate in health research add further complexity
Context Makes Content Easier to Understand

“Randomization means you will be assigned to a group randomly, like the flip of a coin”

Tell people what randomization means to them!

- You cannot choose the group you are in
- Assignment not based on what is better for you
- You must be okay with being assigned to any of the study groups
- If you have a strong preference for one group, you might not want to participate
Context Instructs on Content and Presentation

Providing a detailed list of isolated facts ≠ Facilitating understanding

<table>
<thead>
<tr>
<th>Neurological</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chronic nerve damage</td>
</tr>
<tr>
<td>• Peripheral nerve damage</td>
</tr>
<tr>
<td>• Psychological intolerance</td>
</tr>
<tr>
<td>(fear of loss of LAP</td>
</tr>
<tr>
<td>monitoring function)</td>
</tr>
<tr>
<td>• Stroke/transient ischemic</td>
</tr>
<tr>
<td>attack</td>
</tr>
<tr>
<td>• Subdural, epidural</td>
</tr>
<tr>
<td>hematoma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiac</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Acute coronary syndrome</td>
</tr>
<tr>
<td>(sudden worsening of chest</td>
</tr>
<tr>
<td>pain, heaviness or</td>
</tr>
<tr>
<td>pressure)</td>
</tr>
<tr>
<td>• Arrhythmias (irregular</td>
</tr>
<tr>
<td>heart rhythm)</td>
</tr>
</tbody>
</table>

- Cardiac tamponade
- Damage to heart valves
- Emergency heart surgery
- Emergency vascular surgery
- Low cardiac output state
- Heart block
- Hypotension
An Example of Providing Context and Grouping Information for Prospective Participants

What could be the side effects from the infusions?

The study drug has been given to a small number of healthy (not sick) people in research studies in the United States to test for safety of the drug. It has also been given to Ebola survivors in West Africa and to people with acute Ebola virus disease in the DRC. Some of these people had side effects.

The most common side effects included:

- Abnormal liver function test results
- Abnormal blood clotting test results
- Constipation
- Nausea
- Vomiting
- Decreased appetite
- Headache

Less common side effects (seen in 1 person) included:

- Dizziness
- Itching
- Shaking of the leg and arm
- Indigestion

The abnormal liver function tests lasted longer than a few days but came back to normal levels during the studies. You will receive results from the tests during your participation. If you have any abnormal test results that may require more medical care, we will share these results with you.

None of the side effects in these studies have been serious. Some people may have some side effects after the infusion. Other people may have no side effects. These side effects are temporary and should not last more than a few days.
Present Information in Context that Makes Sense

Consider framing information under headings of questions a prospective participant might ask

Examples:
• What is the problem researchers want to study?
• Why do researchers think that this drug might work?
• What are researchers hoping to find out about this drug?
• Why am I being asked to participate?
• What does it mean for me to participate?
Know Your Audience and What Concerns Them

Examples of things that worry prospective participants:

• If I participate in this study, can I still participate in another study that may offer an intervention that I prefer?
• During my participation, what happens if important information about the study intervention becomes available?
• What happens if my condition gets worse?
Be Specific With Important Information

• Don’t just say “we are trying to find out if drug X is effective”

• Instead, be specific, give details about what you mean, e.g.,
  “We want to find out if drug X might shorten how long you stay in the intensive care unit by a few days”
Potential Participant Perspective

What one patient said about his thoughts when an interventional treatment study was being explained:

“\textit{I didn't pay a lot of attention. I was mostly thinking up questions I would need answered regarding my own care, the treatment plan being proposed, how I might be affected, etc.} After all, informed consent requires I be as informed as possible in order to make the best judgement for myself.”
What Would It Mean to Participate?

• Explain information in a way that would help prospective participants understand the **pros and cons**, the **why and why not**

• Consider this example:

  A randomized trial to study the use of back brace to prevent spinal curving in teenagers
What Would It Mean to Participate?

What to expect if your child is assigned to the group required to wear a back brace?

• If the back brace prevents more curving of the spine, your child could benefit from a slowing the curving process and less chance of needing surgery.

• Your child may find wearing a back brace inconvenient, restrictive, and uncomfortable. The brace could injure the skin and may lead to skin ulcers. Also, your child may feel stressed or embarrassed around others.

• If the back brace does not prevent curving of the spine, then your child could experience these problems without receiving any benefits.
What Would It Mean to Participate?

What to expect if your child is assigned to the observation group (no back brace)?

• Your child will not experience inconveniences, discomfort, skin problems, or stress that may result from wearing a back brace.

• Your child’s spinal condition may or may not progress further before bone growth matures. If the curving continues to progress:
  ▪ You and your child’s doctor may not want to continue participating, and decide to treat your child’s condition outside of the study.
  ▪ If the back brace prevents more curving of the spine, it is possible that your child may miss the window of time to benefit from wearing it to prevent more curving.
What are Some of the Reasons You May or May Not Want Your Child to Participate in this Study?

<table>
<thead>
<tr>
<th>Possible Reasons to Want to Participate</th>
<th>Possible Reasons to Not Want to Participate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• I don’t know what’s best for my child and since doctors don’t know either, participating seems like a reasonable decision.</td>
<td>• My child doesn’t want to wear a brace at all if it can be avoided.</td>
</tr>
<tr>
<td>• My child’s participation could help researchers find better treatment for other children with the condition.</td>
<td>• We want to take action now to prevent any chance of progression. We want a brace and do not want to be randomized.</td>
</tr>
<tr>
<td>• Back braces are expensive. Participation would give my child a chance to get the braces for free.</td>
<td>• We want to make the decision with our own doctor and don’t want to leave the matter to chance.</td>
</tr>
</tbody>
</table>
## Another Example of Why Someone Might or Might Not Want to Participate

### Possible Reasons to Want to Participate

- I don’t know if I want to get the studied drug. I don’t know how to choose. And since doctors don’t know either, I think that participating in the research study is reasonable.
- I want to help advance science. I want to help researchers find out if the studied drug could help treat people with my condition.
- I want to try the studied drug and participating in this research gives me a chance to get it.
- Participating in this research is the only way that I get a chance to try out the study drug.
- Participating in this research seems like a lot of fun. I think the experience will be valuable.

### Possible Reasons to Not Want to Participate

- I don’t want to participate in research. I don’t want more uncertainties.
- I don’t want any chance of getting an unproven treatment.
- I know that the study drug may not work and may have unwanted side effects, but I really want to try it. I will see if I can get it without participating in the study.
- I won’t be able to support my child through all the study visits and procedures.
- I won’t have time even if I wanted to participate.
Presentation that Facilitates Understanding

How things are presented can help with reception and understanding!

For example,

• Break up dense text with sectioning, pictures and icons
• Compare by putting information side by side
• Include a schematic diagram of the study

Presentation is not just about making something look pretty!
Example of Sectioning Using Colors & Icons

Who is the research study recruiting?
We are recruiting people like you who have been diagnosed with sudden onset inflammation of the pancreas, also called acute pancreatitis, to participate in a research study.

What’s the current treatment for acute pancreatitis?
There is no known treatment to block or reduce inflammation in the pancreas. Current treatment for acute pancreatitis is mainly supportive, to reduce symptoms. This includes providing IV fluids to rest the bowel, controlling pain, and monitoring the disease for the development of complications.

Why are we doing this research study?
We want to find out if a drug called Drug B can reduce the severity of pancreatic inflammation and related medical complications in patients just diagnosed with acute pancreatitis.
**Compare What it Means to be Assigned to One Group Versus Another**

<table>
<thead>
<tr>
<th>If you receive the test drug (active) 50% chance</th>
<th>If you receive the placebo (inactive) 50% chance</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will receive usual care + the test drug.  You will NOT know it is the active test drug.</td>
<td>You will receive usual care + the placebo.  You will NOT know it is the inactive placebo.</td>
</tr>
<tr>
<td>We do not know whether the test drug will help treat your opioid use problem. If it is effective, it may reduce your craving for opioids, lessen your withdrawal symptoms, and help you stay off of opioids.</td>
<td>You will receive no known medical benefit from the placebo.  You will not benefit or be harmed by the test drug because you are not getting it.</td>
</tr>
<tr>
<td>If the test drug is not effective, then you will not get any benefits receiving it. It is possible that the test drug could worsen your opioid use problem.</td>
<td>The placebo you receive will not make your opioid use problem worse.</td>
</tr>
<tr>
<td>Side effects from the test drug may include XXX. You may experience these regardless of whether the test drug is effective.</td>
<td>A placebo does not contain any drug. It does not have any side effects and is not a treatment for opioid use problems.</td>
</tr>
</tbody>
</table>
Provide Information Using a Diagram

Diagrams may help people better picture the design of the study and what it means to choose one option over another.
Write in Plain Language

- Use common everyday words
- Use shorter words with fewer syllables
- Avoid jargon; explain terms
- Use active voice if possible
- Write it in conversational style
- Use short sentences; keep paragraphs short
- Break up complex concepts into sections
Is This Understandable Language?

On what the study drug is:
XXX is a human monoclonal antibody that blocks the interaction between PD-1, PD-L1 and PD-L2. Binding of these ligands to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of the PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. XXX is a human immunoglobulin (IgG4) monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response, resulting in decreased tumor growth.

Can you convey this information more simply?
Is This Understandable Language?

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XXX is a human monoclonal antibody that blocks the interaction between PD-1, PD-L1 and PD-L2. Binding of these ligands to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of the PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. XXX is a human immunoglobulin (IgG4) monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response, resulting in decreased tumor growth.

**What about?**

XXX works on the body’s defense system. It could help our body’s T-cells control and even reduce tumor growth.
Is This Understandable Language?

On why the research is being done:

The comprehensive treatment of cognitive impairment and other medical conditions may best be treated by lifestyle modifications (e.g., cognitive and exercise training)… Studies that implement both targeted neurocognitive and exercise training interventions (rather than each alone) are showing greater promise on improving cognitive function in older adults. Combining these two intervention modalities simultaneously may be more effective than either intervention alone…..

Can you convey this information more simply?
Is This Understandable Language?

On why the research is being done:
The comprehensive treatment of cognitive impairment and other medical conditions may best be treated by lifestyle modifications (e.g., cognitive and exercise training)....Studies that implement both targeted neurocognitive and exercise training interventions (rather than each alone) are showing greater promise on improving cognitive function in older adults. Combining these two intervention modalities simultaneously may be more effective than either intervention alone.....

What about?
We want to know if doing brain training together with physical exercise can help older adults improve brain function more than doing just one alone.
Injection drug use is the leading risk for HIV infection. In addition, hepatitis C virus (HCV) infection among injection drug users (IDU) ranges from 30% to 90%. These infections are an enormous public health challenge because they involve a chronic carrier state, resulting in ongoing transmission and costly medical consequences for those infected. To date there are no vaccines to prevent these infections, so a critical type of prevention involves reducing the risk of exposure. Reducing risks such as syringe and drug paraphernalia sharing and sexual behaviors among IDU can reduce rates of infection. We know that some interventions to change behaviors have worked in IDU but there have been no thorough studies in younger people who have begun to engage in risky behaviors to determine whether specific education programs can reduce rates of HIV and HCV infections among IDU by changing risky behaviors. Specifically, this study will test whether a program focused on peers teaching peers about high-risk behaviors is effective in encouraging the “teachers” to also change their high-risk behaviors.

HIV and Hepatitis C are infections that commonly affect IV drug users because of their habits of sharing contaminated needles. These infections cause serious long-term health problems requiring long and expensive treatments that are not always effective.

The best option for IV drug users is to avoid getting infected in the first place by learning what they need to do to reduce the risks of infection.

We are doing this study to find out if teaching IV drug users how to teach others like themselves to avoid the risks of infection, could also help the teachers reduce their own risks.
Requirement for Key Information Section

Provide **concise & focused** presentation about **why one might or might not want to participate**

(§46.116(a)(5)(i))

“...the key information summary as an opportunity to **orient, guide, and assist** potential subjects in the decision making process”

SACHRP Recommendation on Key Information (Oct. 17, 2018)
What One Patient Advisory Panel* Said

The first page of a consent document is critical “real estate” for communicating valuable information.

It would be opportunity lost if they are filled with information that patients generally could not care less about, such as:

- Headers with technical titles and information about funding agencies and investigators
- Generic introductions and descriptions about research participation

INFORMED CONSENT FORM

TITLE:
Efficacy of Novel Agents for Treatment of SARS-CoV-2 Infection Among High-Risk Outpatient Adults: An Adaptive Randomized Platform Trial

PROTOCOL NO.:

SPONSOR:
University of [redacted]

INVESTIGATOR:
Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S):
Phone Number
Phone Number (24 hours)
[24 hour number is required]

We are asking you to be in a research study. This study is being conducted by [Site Name] and the University of [redacted]. This form describes the study procedures and gives you information to decide whether you wish to be in the study. Being in the study is entirely your choice (voluntary).

What should I do?
1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. Take time to consider this, and talk about it with your family and friends.

The first part of this consent form gives you a summary of this study.

The second part of this consent form gives you more details about the study procedures and any risks to you.

PURPOSE OF THE STUDY

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus that causes coronavirus disease (COVID-19). The purpose of this study is to understand if taking hydroxychloroquine (HCQ) or HCQ plus azithromycin may be used to help treat people infected with early SARS-CoV-2 infection. Currently, there are no FDA-approved treatment drugs for SARS-CoV-2 infection or COVID-19.

HCQ is currently approved to treat malaria and autoimmune diseases. The FDA first approved HCQ in 1955. Overall, it is safe and well tolerated. We don’t know if HCQ is an effective treatment for COVID-19.

Azithromycin is an antibiotic used to treat pneumonia and sinus infections. We don’t know if azithromycin in combination with HCQ is an effective treatment for COVID-19.

Key Information for Hydroxychloroquine Prophylaxis for healthcare workers at high risk for SARS-CoV-2 infection

You are being invited to take part in a research study about using hydroxychloroquine prophylaxis for healthcare workers at high risk for SARS-CoV-2 infection (also called COVID-19).

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if this drug can help prevent respiratory infections caused by SARS-CoV-2. Your participation in this research will last about 90 days.

The purpose of this research is to evaluate the efficacy of hydroxychloroquine (HCQ) to prevent severe acute respiratory syndrome due to SARS-CoV-2 infection among health care workers at high risk of occupational exposure to SARS-CoV-2.

This drug is approved by the FDA for other conditions, but not for respiratory infections caused by SARS-CoV-2. There are currently no drugs approved by the FDA for this condition and the FDA has issued an “emergency use authorization” for HCQ, use https://www.fda.gov/medical136537/download.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to participate in this study because you work in a high risk unit with potential exposure to SARS-CoV-2 and this drug may help prevent severe acute respiratory infections. You may also want to participate in order to help find a treatment for this condition. For a complete description of benefits, refer to the Detailed Consent section.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study because this drug may not help prevent a respiratory infection due to SARS-CoV-2, or because you might lose privacy and/or confidentiality. For a complete description of the risks, refer to the Detailed Consent and to the Appendix.

Alternate treatments or procedures would include having access to the study medications without taking part in this study. There is currently no standard of care treatment for treating the SARS-CoV-2 viral infection.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is [redacted].
Example of Description of Study Procedures in a Key Information Section of an Actual Study

Questions:
Do participants need all this detail to make a decision about participation or not?

STUDY PROCEDURES
We are testing HCQ and HCQ+azithromycin in adults who have had a laboratory confirmed SARS-CoV-2 infection within the past 72 hours. We are inviting you to participate because you have been referred by your healthcare provider or have been self-referred. Here is what the study involves:

• You will be contacted by our research team and asked to join this study. You will be in this study for approximately 28 days and no in-person visits are necessary - every interaction will occur via telephone, telehealth, internet, or mail. If you are selected for a substudy you will complete extra sample collections throughout the study and 28 days after your first visit.
• We will ask you to complete a brief enrollment survey about medical history, current & past symptoms, date of COVID-19 diagnosis, current use of medicines, and demographics. These questions will be asked either by telephone or answering questions in an online survey.
• We will ask you to sign Health Insurance Portability and Accountability Act (HIPAA) forms so we may access your COVID-19 related medical records.
• You will complete a short survey about your current health for 14 days. We will ask you to meet with study staff via telehealth roughly every 3-4 days during the study. You will have the option to request to meet with study staff via telehealth more frequently. We will ask you to check your temperature, oxygen saturation, pulse, and respiratory rate twice a day. We will also ask you to check your heart rhythm using a device. We will provide all supplies to you to do these assessments. The procedures will take about 30 minutes each day.
• You will be asked to self-test for your current COVID-19 status by swabbing the inside of your nose with a special swab called a nasal swab. We will ask you to repeat this procedure with a new swab daily while in the study. Once you have swabbed the inside of your nose, you will put your swab in a special tube for storage.
• You may also be asked to prick your finger to collect drops of blood called dried blood spots on a special card. We may ask you to collect these blood spots at enrollment, partway through the study, and at the end of the study.
• We will provide you with all of the supplies you need to collect your samples. The supplies will arrive in a couriered package, and we will give you envelopes and postage to either mail them back or a courier will come collect them.
• To test for novel coronavirus, the swabs will be sent to the XXX University. Your results may not be available for weeks after the study is completed. When your results are available, we will provide them to you. These swabs are not part of routine clinical care.

This study does not replace or affect any care you might receive from your doctor.
Example of Key Information on a Cancer Study

• Why are we doing this study?
  ▪ The new idea is …
  ▪ Why might it help?
  ▪ The purpose of this study is to … No one knows the answer – that’s why the trial is being done.

• What are the tradeoffs for you? A discussion of pros and cons integrating the most common and the most serious side effects, with the potential benefits the investigators are hoping to find
  ▪ Why would you not want to be in this study?
  ▪ Why would you want to be in this study?

• How will the research be done? Include a discussion on randomization

(Extracted from presentation by S. Woloshin, Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School, see Session Summaries at www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2018-workshop/index.html)
An example for conveying key information

Research to Study a Type of Walking Training to Help Adults Over 65 Maintain Balance

Why are we doing this research study?
For people over 65, falls are common and can result in serious injuries. We know from past studies that seniors rely mostly on visual cues to control balance while walking. We think that we can use responses to visual cues as a training tool to improve their walking balance. This is the first study to test this idea.

What do study volunteers have to do?
Seniors who volunteer for the study will come into the study center two times. Each visit will last about 3 hours. During each visit, volunteers will walk normally on a treadmill for about 20 minutes while looking at an image on the wall. On one of the visits, the image on the wall will be still. On the other visit the image on the wall will move slightly from side to side while the volunteer walks. Researchers will record the volunteer’s posture and stability using a 3D camera and sensors from the treadmill. (Read detailed descriptions of the study procedures on P. X of this form.)

Volunteers will wear a safety harness when they walk on the treadmill to protect them from falling. We will also monitor them for safety. There are minimal risks of harm to volunteers participating in this study. Volunteers can stop walking or participating at any time.

What does participation in the study mean to you?
If you choose to participate, you could help us learn more about how to help seniors improve their walking balance. There is a small chance that your walking balance may improve for a short time after a treadmill training. There is no cost to participate. We will pay you $20 after each study visit to help cover the costs of transportation.

Participation in this research is voluntary. You do not have to participate. There may be other types of walking balance training for seniors your health care providers can recommend.
An example for conveying key information

Research to Study the Biological Effects of Aspirin on Smokers

We do not expect participants in this study would receive any meaningful health benefits. By participating in this study, you will help us learn more about whether aspirin could be used to prevent lung cancer.

Why are we doing this research study?
Smokers have a higher risk of getting lung cancer. Some scientists suggest that aspirin might be able to help, but we need evidence to support this. In this study, we want to study how different doses of aspirin might affect certain cells and cell mechanisms that might indicate protections against cancerous changes for chronic smokers. This research would help us better understand if aspirin could be used to prevent smokers from developing lung cancer.

What do study participants have to do?
This study asks healthy smokers to take a pill once a day for 12 weeks. The study will assign participants randomly, like the flip of a coin, to one of two groups. One group of participants will get
Simplifying Consent Documents

• Simplify complex information:
  ▪ Consider the context people seek and understand information
  ▪ Organize content to respond to their need and use of the information

• Use plain language

• Use visual aids to facilitate understanding

• Review it and run it by patient research advocates

• Make use of the new key information section to orient and guide people in decision-making
OHRP PUBLIC OUTREACH RESOURCES

www.hhs.gov/About-Research-Participation

Educate prospective participants!
Resources also in Spanish!
Contacts and Resources

• Contact us or submit your questions to OHRP@hhs.gov
• Visit OHRP website at www.hhs.gov/ohrp
• Bookmark this page for quick reference to OHRP resources on the revised Common Rule: www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html
• Check out OHRP 2018 Exploratory Workshop Meeting new Challenges in Informed Consent in Clinical Research [September 7, 2018]
• Check out OHRP Luminaries Lecture Series Use of eConsent in Human Subjects Research [February 4, 2020]
Remember!

Please refer to the text of the revised Common Rule available on OHRP’s website for a complete and accurate description of the regulatory requirements.