Plain Language, Teach-back, and Guidance for Re-consent
Session Objectives

The Informed Consent Process

• Describe best practices in obtaining informed consent.
  – Use of plain language
  – Use of the teach-back method

• Review Reconsent best practices
Introduction

Informed Consent ≠ Obtaining Signature on the Consent Form
Informed Consent

- Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation
- Facilitating the potential subject's comprehension of the information
- Providing adequate opportunity for the potential subject to ask questions and to consider whether to participate
- Obtaining the potential subject's voluntary agreement to participate
- Continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

Conversation

(21 CFR 50.20.)
Health Literacy

- Defined as the ability to:
  - Obtain, process and understand basic health information and services
  - Make informed health care decisions (act on information)
  - Access/navigate health care systems

Centers for Disease Control and Prevention, 2021
Poll

True or False?

Healthcare professionals can determine an approximate literacy level of their patients from information on their education and occupation?

FALSE
Health Literacy

1/3 US Adults
Basic or Below

Red Flags for Low Literacy

- Frequently missed appointments
- Incomplete registration forms
- Non-compliance with medication
- Unable to name medications, explain purpose or dosing
- Identifies pills by looking at them, not reading label
- Unable to give coherent, sequential history
- Ask fewer questions
- Lack of follow-through on tests or referrals
Steps for Obtaining Informed Consent

**Introduction**
- Conduct consent process in a private and quiet place
- Be prepared to accommodate participants with disabilities
- Allow adequate time for consent based on study complexity and patient/family needs or medical situation

**Explanation**
- Use simple language and non-technical terms
- Consider potential participant’s reading level and primary language spoken
- Reassure potential participant that participation is not required, and standard of care options should be presented

**Comprehension**
- Ask potential participant, family or support system open-ended questions
- Consider the teach back method
- Consider evaluation tools

**Q&A**
- Answer questions from potential participant family, or support system
- If necessary, repeat explanation when available

**Consent**
- Give potential participant time to read consent and consider options
- Obtain signatures and copy to participant
- Document consent process
- Copy and file
Plain Language

• A way of communicating that everyone in your audience can easily understand
• Relevant to the reader/listener
• Clear and concise
• Easy to follow
• Conversational and direct
• Designed to be inviting and help readers find important information

Plain Language Association International.
http://plainlanguagenetwork.org/index.html
Explanation

• Assess the participant
  – Primary language spoken
  – Reading level – GU IRB 8th grade or lower
• Non-technical terms should be used

Examples

Glomerulonephritis
*inflammation of the tiny filters in your kidneys*

Hyperlipidemia
*a condition in which there are high levels of fat particles (lipids) in the blood.*
Glossaries of lay terms

- http://irb.ufl.edu/irb01/forms/glossary.html
- https://www.magiworld.org/IcfGlossary
- http://kidshealth.org/kid/word/
- https://researchcompliance.stanford.edu/panels/hs/forms/definitions
# Practice: Plain Language

<table>
<thead>
<tr>
<th>Medical/Research Terminology</th>
<th>Plain Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>A treatment given in a study</td>
</tr>
<tr>
<td>Protocol</td>
<td></td>
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<tr>
<td>Withdraw</td>
<td></td>
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<tr>
<td>Enroll</td>
<td></td>
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<tr>
<td>Adverse Event</td>
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<tr>
<td>Efficacy</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td></td>
</tr>
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Comprehension

- Verify and document subject’s understanding of the study and their responsibilities.
What is Teach Back

- Communication strategy that confirms patient understanding in a non-shaming way
- Research based health literacy intervention
- Asking patients to explain, in their own words, what they need to know and/or do
- **Not** a test or a quiz
- Chunk and Check Information
- Person providing the information/education takes responsibility
- In our clinic we will be using the universal approach to health literacy
Teach-Back Method

- Patients explain health information in their own words.

What risks would you be taking if you joined this study?

I understand that I could possibly have some nausea and diarrhea when I start the medication.

The 5Ts for Teach-back

Delivery

Triage: focus on just one topic for teach back.

Tools: use a model, a written tool, a poster, graphics, etc. to help you explain what you want your patient to know.

Take Responsibility: “I want to make sure I did a good job explaining....”

Tell Me: ask the patient to tell you, in their own words, what they will do or what they understand. Be explicit about what you want the patient to say back.

Try Again: if necessary.

Reception
Take Responsibility

• Non-Shaming
• 2 elements
  – Acknowledge the complexity or amount of information
  – Imply that you are the person being tested, not the patient

  – Example: “I just gave you a lot of information and I want to make sure I did a good job explaining this to you”
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Questions and Answers

• Open-ended questions
  – “What questions do you have for me?”
  – “What would you like to hear more about?”
• Repeat Information as necessary
• Provide ample opportunity for Q&A
Methods and Considerations

RECONSENT
Reconsent

• Research subjects be informed of any significant new findings identified during the course of the research which may impact the subject’s willingness to continue participation.

[45 CFR 46.116(b)(5); 21 CFR 50.25(b)(5); ICH E6 4.8.2]
Reconsenting

- Notify the IRB of minor or significant changes
- What process will be used to inform subjects of change
- IRB will review proposal and approve or require modification
- Attach all materials needed for re-consent
Reconsent Process

• Whether the new information is related to risks to or safety of the subjects;
• Whether the new information is a significant change from what was previously disclosed or explained to subjects;
• Whether the new information may impact a subject’s willingness to continue with study participation; and
• Whether the subjects are still active in the study or have completed their participation.
Examples of Changes

• Significant
  – Additional risks or safety information were identified
  – Extend duration of study participation
  – Additional study visits or activities
  – Additional samples collection etc;
  – Drug dosing or schedule has significantly
  – PI change

• Minor
  – Study previously required 5cc of blood but now requires 10cc of blood
  – Changes to surveys unless new questions pose new risks
## Considerations for reconsenting

<table>
<thead>
<tr>
<th>Who?</th>
<th>What?</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects actively undergoing research intervention</td>
<td>Additional risks or change in risk severity or frequency</td>
<td>Does the change affect subjects differently?</td>
</tr>
<tr>
<td>All subjects</td>
<td>Change in level of discomfort or other inconvenience</td>
<td>If yes, clearly define each subset affected differently by the change (i.e. males, females, specific age groups, subjects in active treatment, specific study arm, subjects off study, etc.)</td>
</tr>
<tr>
<td>Subset of subjects</td>
<td>Procedural changes including remuneration or reimbursement</td>
<td>Could the change affect a subjects decision to remain in the study?</td>
</tr>
<tr>
<td></td>
<td>New alternative options available</td>
<td>Regulatory, ethical or policy requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New research findings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Will the change involve a different level of commitment from the subject?</td>
</tr>
</tbody>
</table>
# Considerations for reconsenting

<table>
<thead>
<tr>
<th>When?</th>
<th>Where and how?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Immediate</td>
<td>• Complexity and need for interactive explanation and discussion</td>
</tr>
<tr>
<td>• Before next study visit</td>
<td>• Need for physical demonstration or other presentation of information</td>
</tr>
<tr>
<td>• Before specific study procedures</td>
<td>• Timeline for next subject visit</td>
</tr>
<tr>
<td>• Within specified time period</td>
<td>• Verification of subject identity if not consented in person</td>
</tr>
<tr>
<td>• Varies with affected participant subset</td>
<td>• Any subject limitations such as age, disabilities, language, vulnerable population</td>
</tr>
<tr>
<td>• Alternate plan if revised consent version not yet available when needed for subject</td>
<td></td>
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</table>

- Are subjects coming in for visits or are study procedures done at home?
- Are subjects impacted now or in the future?
- Are subjects who have completed study procedures/visits impacted?
- Logistics (including any travel, expense or inconvenience to subjects)
Methods for Reconsenting

• Consent Form Addendum
• Consent with a Revised Full Document
• Letter
• Telephone call
## Considerations for Determining Methods of Notification

<table>
<thead>
<tr>
<th>Participant Affected by Changes</th>
<th>Participant Not Affected by Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Participant Still Active in Study</td>
<td></td>
</tr>
<tr>
<td><strong>Examples:</strong></td>
<td><strong>Examples:</strong></td>
</tr>
<tr>
<td>• New risk or increase risk of drug</td>
<td>• New procedure that the subject will not undergo (such as at baseline)</td>
</tr>
<tr>
<td>• New risk or increased risk of procedure subject will undergo</td>
<td>• Arm/treatment not affected by change or risk (on a different treatment)</td>
</tr>
<tr>
<td>• Changes to remuneration / reimbursement</td>
<td>• Subgroup not affected (women only- pregnancy testing)</td>
</tr>
<tr>
<td><strong>Method of Notification:</strong></td>
<td><strong>Method of Notification:</strong></td>
</tr>
<tr>
<td>• Re-consent</td>
<td>• Typically, no notification needed</td>
</tr>
<tr>
<td>• If next study visit is greater than 30 days, notify via phone or letter, reconsent at next in-person visit</td>
<td></td>
</tr>
</tbody>
</table>
Considerations for Determining Methods of Notification

<table>
<thead>
<tr>
<th>Study Participant has Completed Procedures and All Study Visits</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participant Affected by Changes</strong></td>
<td><strong>Participant Not Affected by Changes</strong></td>
</tr>
</tbody>
</table>
| **Examples:**  
  • Newly identified long-term or late-occurring risk | **Examples:**  
  • Changes to procedure or protocol  
  • Newly identified immediate, short-lasting risk |
| **Method of Notification:**  
  • Letter to notify of potential long-term or late-occurring risk  
  • Phone | **Method of Notification:**  
  • Typically, no notification needed |

Adapted from the Mayo Clinic
CHECK POINT

TRUE  or FALSE
All changes to the study procedures or risks require a modification to the full informed consent and re-consenting participants face to face.
Questions?