

Creating Effective Pediatric Assent Forms: Overcoming Common Obstacles

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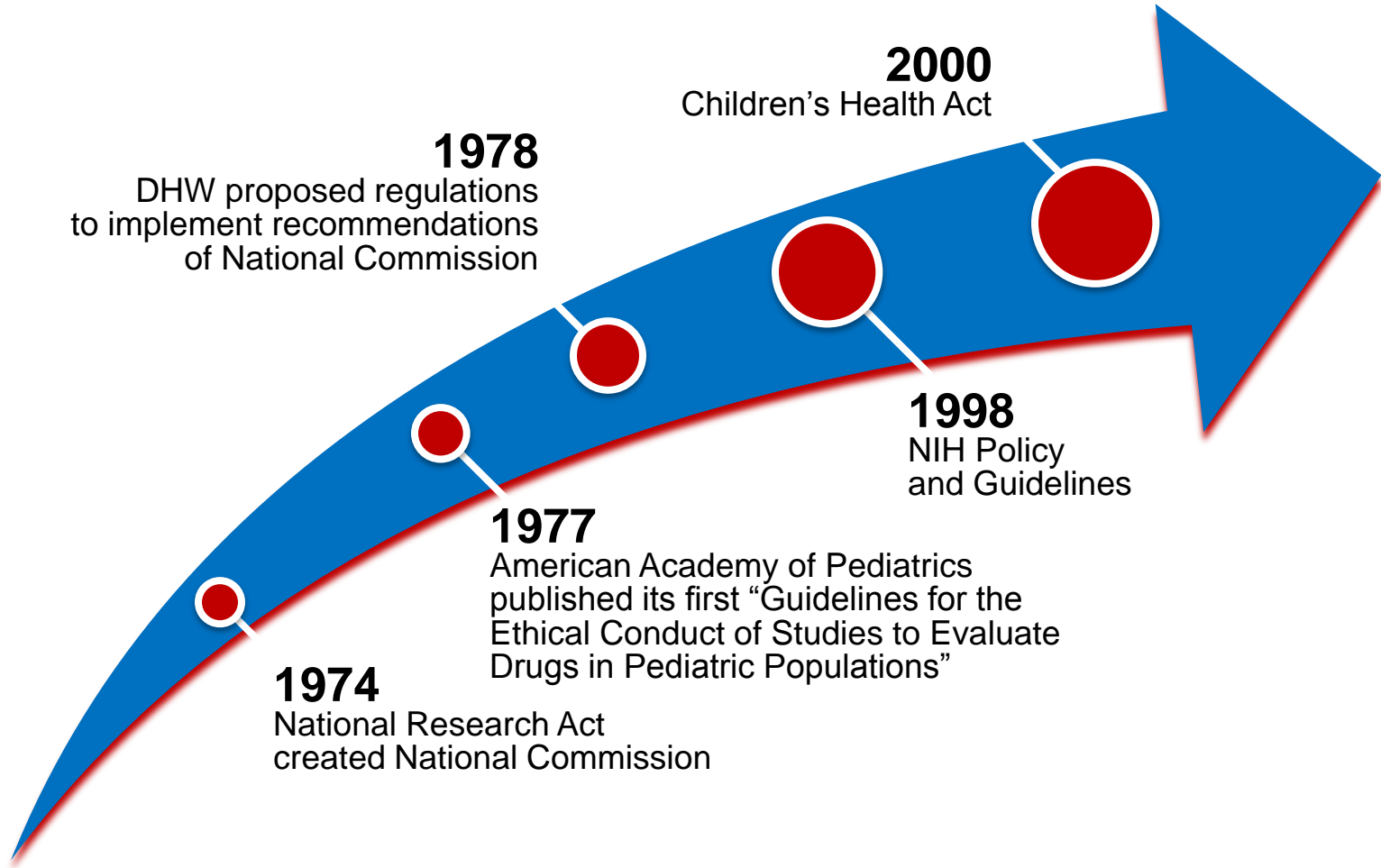
Disclosure

I have no relevant financial relationship in relation to this educational activity

Objectives

- Identify common obstacles to solicitation of effective assent
- Apply basic tools to construct effective and appropriate pediatric assent forms
- Attain methods to solicit meaningful, age-appropriate pediatric assent

Historical Perspective on Assent

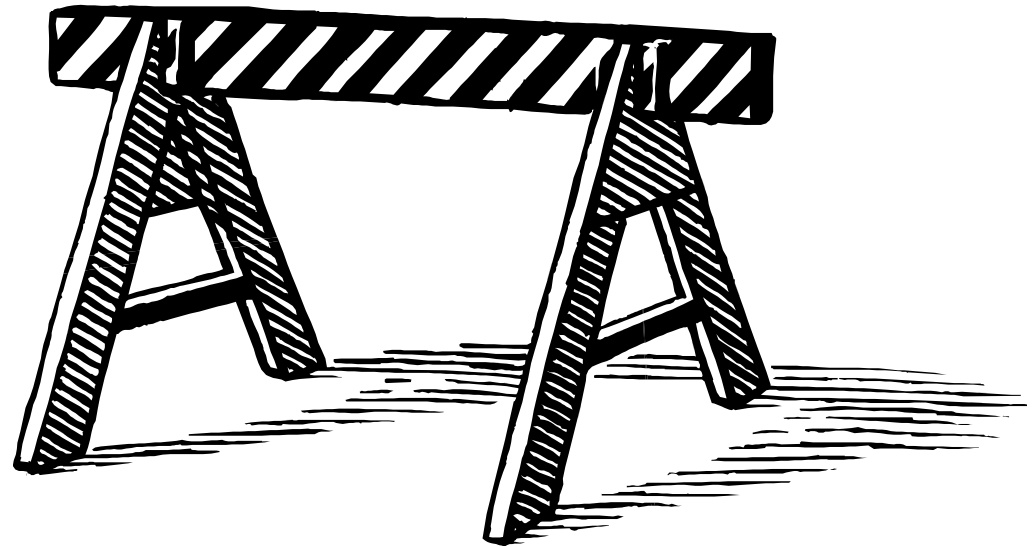


Obstacles to Effective Assent

- 1) Perception of assent as an afterthought
- 2) Inadequate direction from sponsors and/or IRBs
- 3) Failure to address differences in developmental ages and reading grade levels
- 4) Difficulty of creating readable forms that adequately explain elements of assent
- 5) Not planning ahead: logistics of assenting process

Obstacle # 1

Perception of assent as an afterthought



Why is Meaningful Pediatric Assent Important?

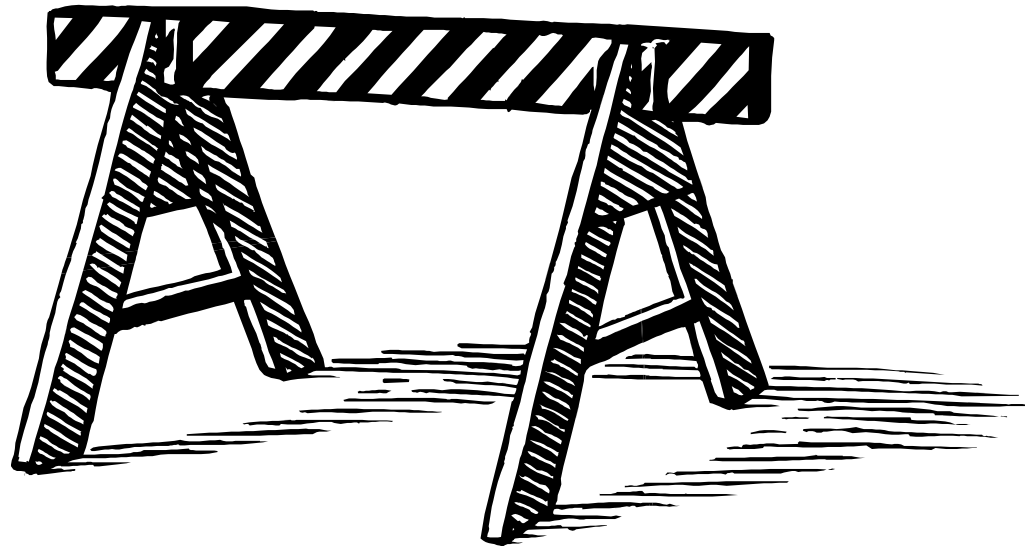
- Encourages shared decision-making, active participation of research subject
- Supports ethical standard of respect for all persons
- Alleviates feelings of powerlessness

Unguru et al, *Pediatrics* 2010

- Studied what children aged 7 to 18 with cancer understood about their research-related treatment and their preferences for inclusion in decision-making
- 100% wanted to be involved in decision-making, but 49% did not have or recall having a role in decision to enroll and 38% did not feel free to dissent to enrollment

Obstacle # 2

Inadequate direction from sponsors
and/or IRBs regarding assent



Such as....

- Not specifying number of forms to be used or not requiring separate assent form at all
- Not providing training for pediatric researchers and staff
- Not giving guidance about the minimum age to give assent

IRB Responsibilities in Pediatric Research

- 1** Review and approve research protocols involving minors
- 2** Ensure adequate provisions are made for soliciting the permission of each child's parents or guardian
- 3** Determine whether children in study are capable of providing assent and if so, confirm that adequate provisions are made for soliciting their assent

Minimum Age of Assent

1979: Belmont Report (report by National Commission)

- Recommended age 7 for age of assent

1977, 1995, 2010: AAP Committee on Bioethics and AAP Committee on Drugs

- Recommends age 7 as minimum age of assent for medical decision-making including research

Real Life Experience: Cohort Group

8 pediatric studies conducted under IND applications at 96 sites between 2004 and 2009

Study	Indication	Clinical Setting	Age Range
1	Bipolar Disorder Type 1	Outpatient	7-17 years
2	Spasticity due to Cerebral Palsy	Outpatient	2-16 years
3	Sedation	Inpatient (Intensive Care Unit)	3 months – 18 years
4	Status Epilepticus	Inpatient (Emergency Room)	3 months – 18 years
5	Status Epilepticus	Inpatient (Emergency Room)	3 months – 18 years
6	Blood Pressure Control	Inpatient (Operating Room)	0-17 years
7	Blood Pressure Control	Inpatient (Intensive Care Unit)	0-17 years
8	Suspected or Complicated Intra-abdominal Infections	Inpatient (Intensive Care Unit)	Neonates (0-91 days)

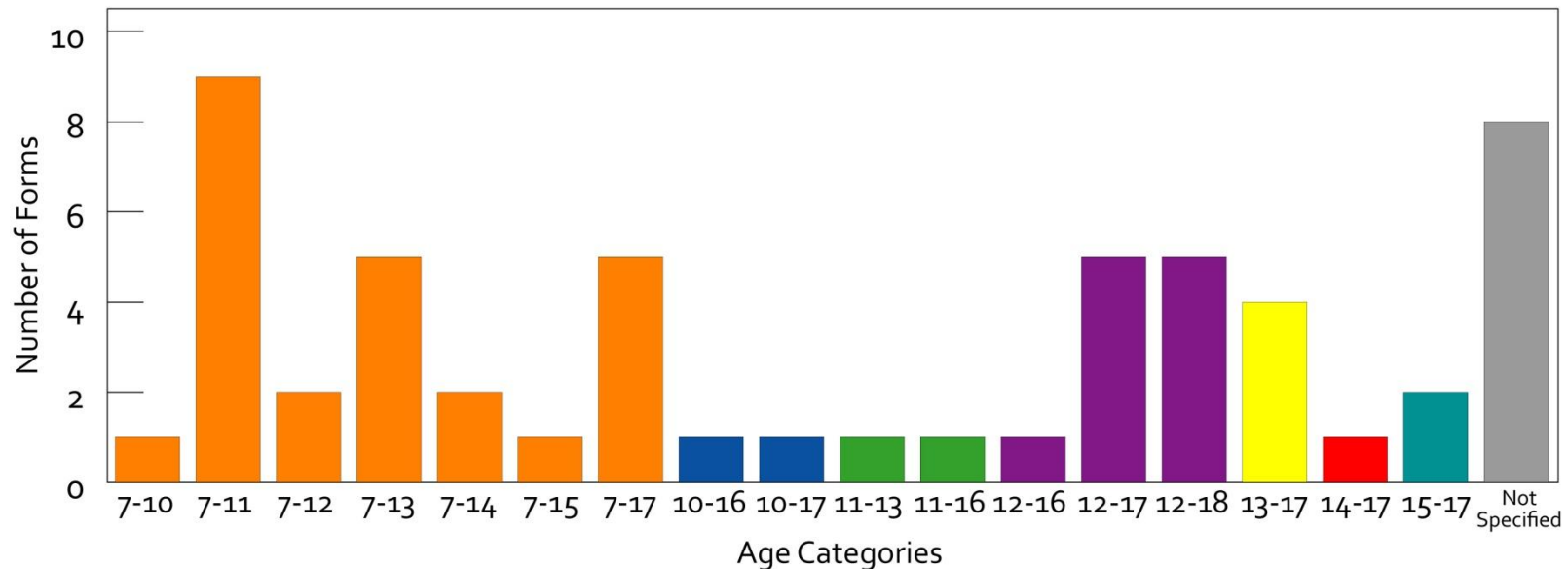
Cohort Group and Assent

- Pediatric assent waived at 37 sites and within two of the 8 studies due to condition under treatment
- Remaining 59 sites solicited pediatric assent as they/their IRB deemed appropriate

Cohort Group and Assent

40 of 59 sites required and approved one or more separate assent forms (total of 55 forms)

Pediatric Assent Forms by Age



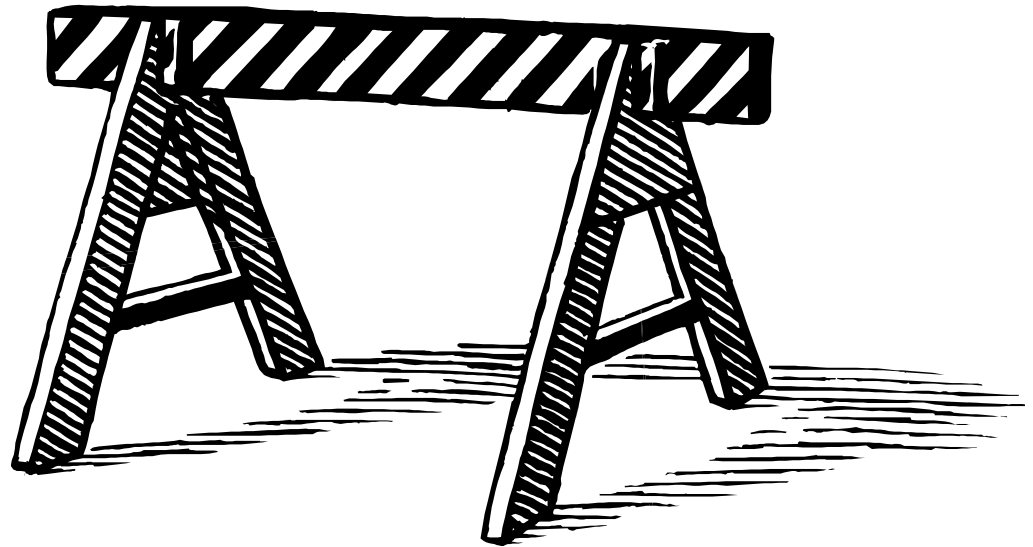
Cohort Group and Assent

**19 of 59 sites had no separate assent form
(child or adolescent signed parental permission)**

- Minimum age to sign ICF not stated at 9 sites
- Other 10 sites listed minimum age to sign ICF anywhere from 7 to 15 years old
- Likelihood of child as young as 7 comprehending parental consent form?

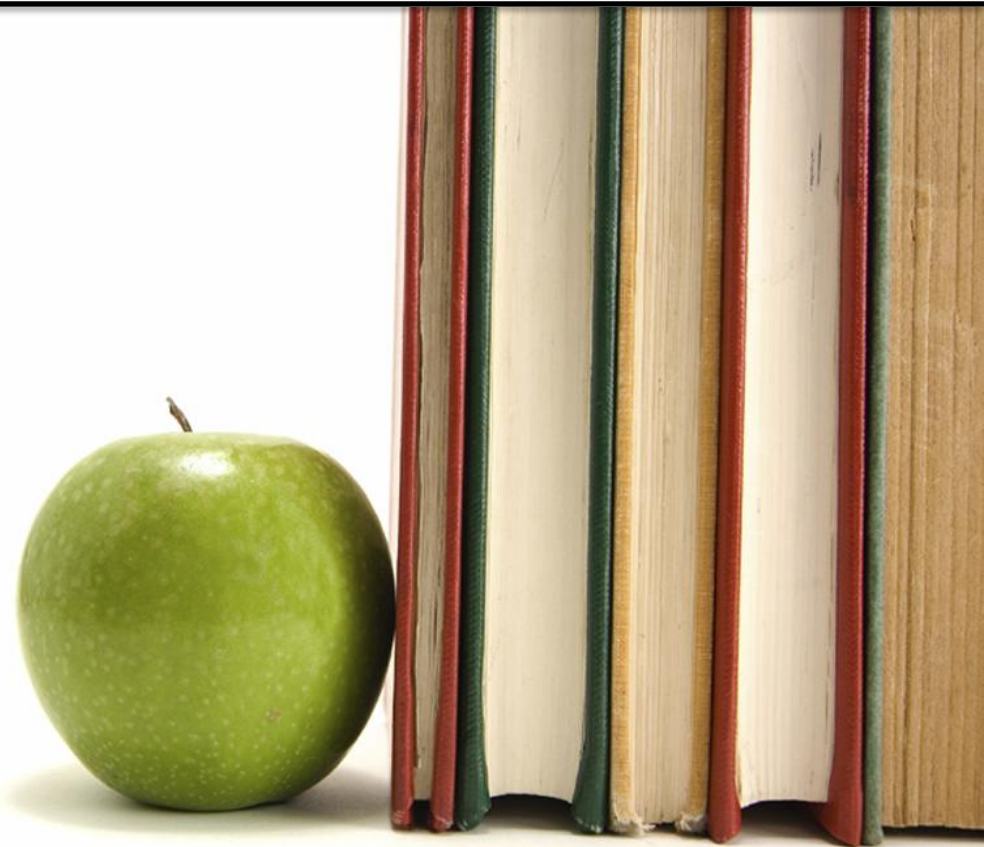
Obstacle # 3

Failure to address differences in developmental ages and reading grade levels



At what grade level does the average adult read and comprehend information?

- a) 12th grade or higher
- b) 10th – 11th grade
- c) 8th – 9th grade**
- d) 6th – 7th grade
- e) 4th – 5th grade



Creating Forms

One size *doesn't* fit all!

- Determine whether your IRB has specified minimum age to give assent
- Consider ages of children involved and how many forms will be needed
- Write and rewrite as needed until each form is written at the reading grade level of the youngest person who will sign but still contains all relevant information

Forms Should be Easy to Comprehend

“The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.” (45 CFR 46.116)

Readability is defined as the quality of written language that makes it easy to read and understand

- Equates to grade reading level
- ***Readability Statistics*** give you information about grade level and ease of reading

Readability Statistics

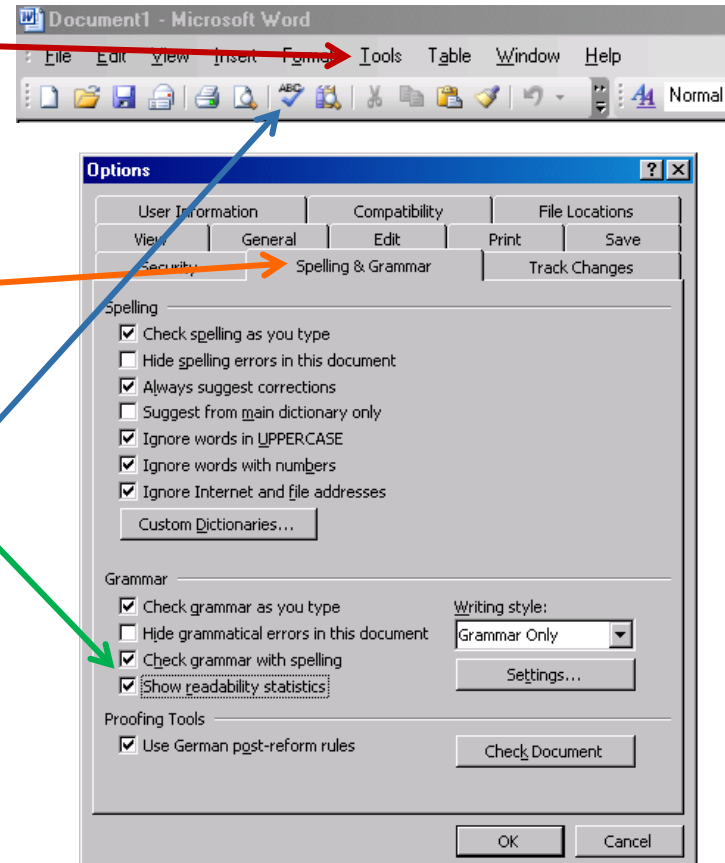
Flesch Reading Ease and Flesch-Kincaid Grade Level

- Common method to check readability statistics
- Spelling & Grammar function of Microsoft Office Word
- Reading Ease gives index from 0 (hardest) to 100 (easiest)
- Grade Level assesses reading grade level*

*Older versions of Word don't assess levels higher than 12th grade

Using Word 97-2003 for Checking Readability Stats

- 1) Under the **Tools** menu, chose Options which will open a pop-up menu.
- 2) On the **Spelling & Grammar** tab, check the **Show Readability Statistics** box and click OK
- 3) On the Standard toolbar, click on **Spelling & Grammar** icon to run the readability statistics for your form

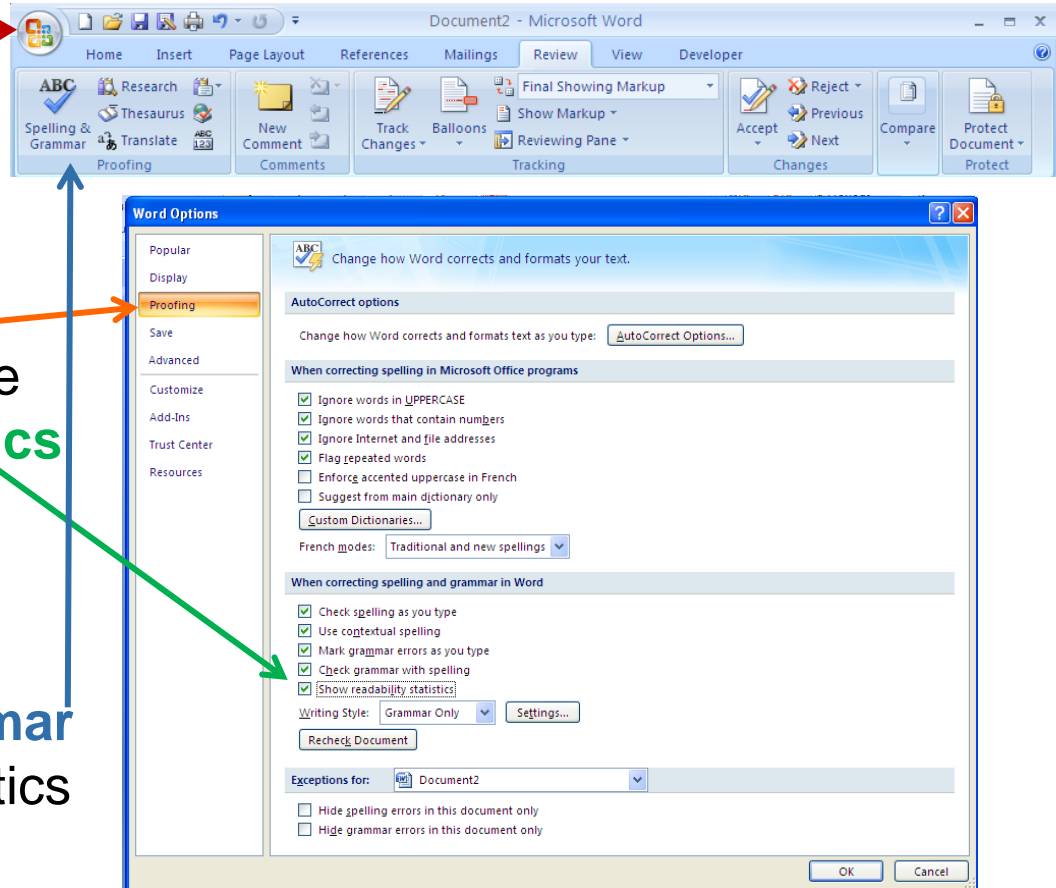


Using Word 2007 for Checking Readability Stats

1) Click on the **Microsoft Button** and then Word Options which will open a pop-up menu.

2) On **Proofing** tab, check the **Show Readability Statistics** box and click OK

3) On the Review ribbon, click on **Spelling & Grammar** to run the readability statistics for your form



Sample Passage Comparison: Assent Form for Ages 7–11

Sample 1

To take blood samples, we will have to insert a needle into your veins. We will try not to hurt you and will try to put in a plastic tube that stays in your vein so we don't have to stick you with a needle again. We will also try to give you a medicine that will numb the pain. Even though we will try not to hurt you, there may be some pain with the blood samples. Remember that you can say no at any time and we will not try to stick you more than three times for any sample or to place the catheter.

Sample 2

To test your blood, we will give you a needle stick in your arm. We will try not to hurt you. We will try to put a soft plastic tube in your vein so we don't have to give you another needle stick for other blood tests. First we will put a special numbing cream on your arm so the needle stick does not hurt so much. Even though we will try not to hurt you, it might hurt when we do the blood tests. You can say no at any time. We will not try to stick you more than three times for any test or to put in the tube.

Readability Results

Sample 1

Readability Statistics	
Counts	
Words	107
Characters	396
Paragraphs	1
Sentences	5
Averages	
Sentences per Paragraph	5.0
Words per Sentence	21.4
Characters per Word	3.6
Readability	
Passive Sentences	0%
Flesch Reading Ease	85.4
Flesch-Kincaid Grade Level	6.6

Sample 2

Readability Statistics	
Counts	
Words	112
Characters	402
Paragraphs	1
Sentences	7
Averages	
Sentences per Paragraph	7.0
Words per Sentence	16.0
Characters per Word	3.5
Readability	
Passive Sentences	0%
Flesch Reading Ease	96.9
Flesch-Kincaid Grade Level	3.7

Hints to Increase Reading Ease

- Use smaller words with fewer syllables
- Use at least 12 point font
- Use shorter sentences
- Decrease number of passive sentences

Hints to Increase Reading Ease

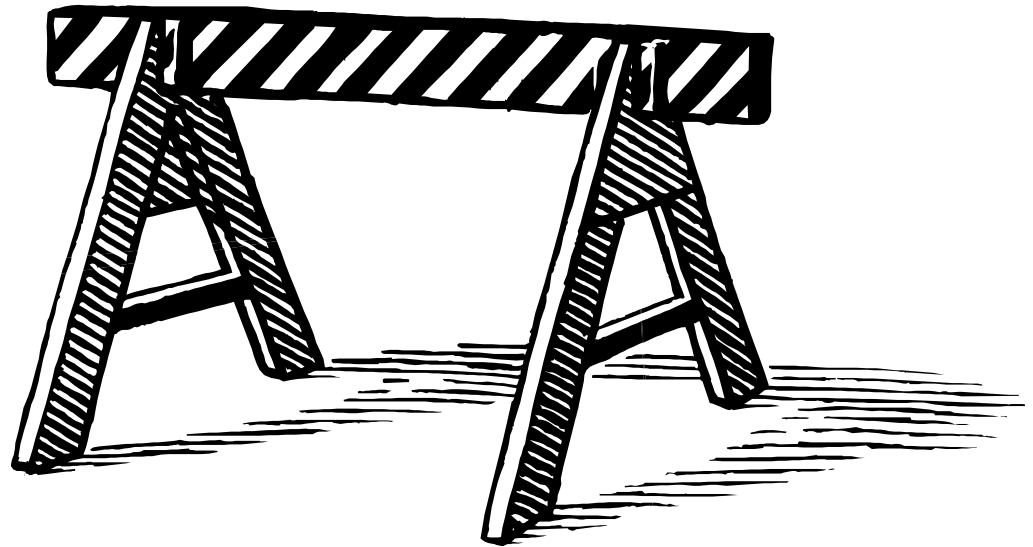
Use simple terms rather than medical terms:

- Medication or medicine → Drug or study drug
- Investigator or physician → Study Doctor
- Participate → Take part
- Bacteria → Germ
- Catheter → Tube
- Intravenous → In your vein

Assent Form Readability Exercise

Obstacle # 4

Difficulty of creating readable forms that adequately explain elements of assent



Elements of Assent in Research

AAP: Goal is to help child achieve developmentally appropriate awareness including:

- Overview of basic study procedures
- Disclosure that participation is voluntary
- Explanation that what child is being asked to agree to is research (not medical care)

Researcher Responsibilities in Assent

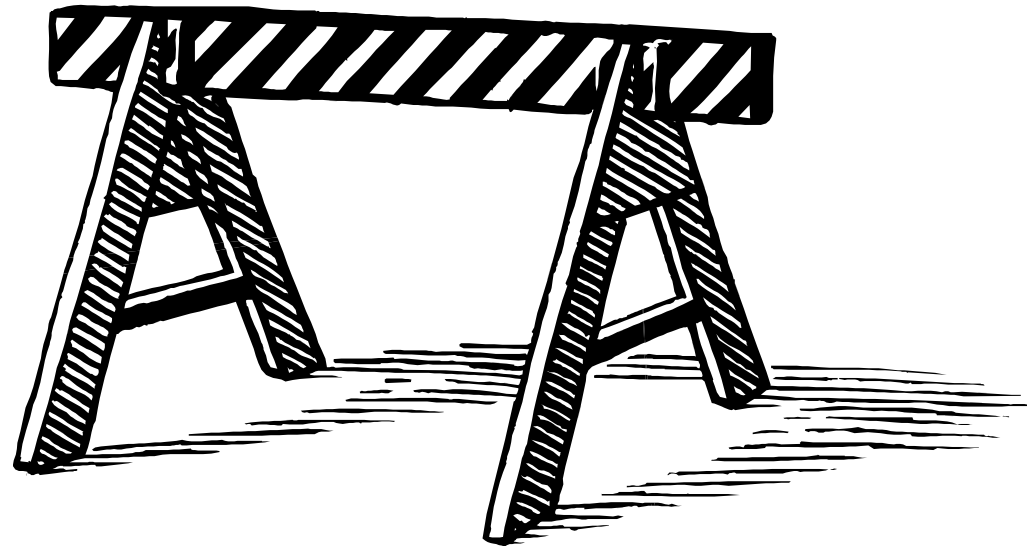
- Be aware of approving IRB's SOPs regarding assent and be prepared to follow them
- Ensure that child/adolescent has clear understanding of what it means to be in the study
 - Create forms that address all elements
 - Use of comprehension checklist can help evaluate level of understanding

Financial Disclosure

AAP recommends not disclosing any financial information to child until study participation ends to avoid possible coercion

Obstacle # 5

Neglecting to address logistics of assenting process



Practical Issues

- Who will conduct discussion?
- Will parent(s) be present?
- Where will discussion take place?
- Will information be written or read to child?
- How will process be documented?
- What happens if child/adolescent refuses?

Confirm Adequate Provisions for Soliciting Assent

- Know whether approving IRB has any specific requirements or guidelines regarding assenting procedure
- If not, develop your own process in advance (who, where, when and how) and follow it
- Consistency is key
- Practice, practice, practice!

Documentation

“When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.” (45 CFR 46.408)

How often is a separate note about the assenting process written?

Recommendations on Documentation

Note should contain:

- Date and time of discussion
- Names/roles of those present including who actually conducted the assenting discussion
- Information about whether form was read to child/adolescent or they read it themselves
- Notation that any question(s) subject had were addressed
- Comment that assent was obtained prior to any study-related procedure being performed

Summary: Questions to Consider

- How many different forms will be needed and for which age groups?
- At what minimum age does the approving IRB specify that assent be solicited?
- What is the readability level of each form? Does the readability level match the minimum age specified on the form?
- Does each form contain the required elements?

Summary: Questions to Consider

- If the study involves compensation, does this information appear in the assent form? If not, when is the child told about the compensation and is this consistent with guidelines of the approving IRB?
- Where will assenting process take place?
- Who will obtain assent?
- Will parent(s) be present?
- How will the assenting process be documented?

Acknowledgement

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