

Checklist for Easy-to-Read Informed Consent Text

(Adapted from National Cancer Institute, Bethesda, MD)

- Words are familiar to the reader or are clearly defined and are used consistently throughout
- Define abbreviations or acronyms at first use
- Words are of 2 syllables or fewer
- Sentences are short, simple and direct
- Line length is limited to 30-50 characters and spaces
- Paragraphs are short; each paragraph conveys one idea
- Verbs are in active voice (i.e., the subject is the doer of the action)
- Personal pronouns are used to increase personal identification
- Each idea is clear and logically sequenced (according to audience logic)
- Statement that the study involves research to ___ and the purpose for including the participant in the research is presented in the first paragraph
- Layout balances white space with words and graphics
- Titles, subtitles and other heads help to clarify organization of text
- 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
- Avoid:
 - Large blocks of print
 - Words containing more than 3 syllables (where possible)

Graphics

- Helpful in explaining 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
- Graphics must reproduce well

Readability

- Evaluate readability level with readily available indices such as Flesch Reading Ease, Flesch-Kincaid Grade Level, and Passive Sentences

Readable Alternative Words/Phrases for Informed Consent Text

Additional information about	Other facts about/more facts about
A substantial portion	Many
Adverse	Bad
Approximately	About
Arise	Happen
Assess	Measure
Benefit	Help
By agreeing	If you agree
By telephone	By phone
Commonly	Most often
Compensation	Payment
Completed	Finished
Concerning	About
Confidential/Sensitive	Private
Convenient	Handy
Continue	Keep on going
Decision	Choice
Designed	Planned
Determine if you	Find out if you
Determine the effect of	Find out what happens
Determine whether	Learn if
Discontinue	Stop, drop
Discover	Find
Discuss	Talk about
Educational background	Level of schooling
Enrolling	Joining/being in
Entitled to otherwise	Have a right to receive apart from this
Exhibit	Show
Experience	Feel, notice
Five occasions	5 times
Frequently encounter	Commonly, usually
Further	More
However	But
Implemented	Put in place
In addition	Also
Including	Along with
In the event that	If
Indicated	Shown
Informed	Told
Initially	First
Inquiries	Questions
Instructed	Told
Interested in...	Would like to know about...
Interviewed	Talked to
Involves	Uses
Involved in	Part of
Likelihood	Chance of
Make it possible to	Allow us to

Monetary	Money
Monitor	Check on, measure
Opportunity	Chance
Participants will	You will
Participate	Be, take part
Perceive	Think, feel
Permitted	Allowed
Preliminary	First
Previous studies	Studies done before
Prior to	Before
Produced by	From
Protected	Kept private
Provide explanations for	Explain why
Provided/providing	Given/giving
Questionnaire	Survey form
Ramifications	Problems/results/outcomes
Receive	Get
Regulations	Rules
Required	Needed
Researchers/scientists/investigators	People doing the study
Schedule an appointment	Set a time
Seeking	Trying, looking
Several	Some/few/a number of
Significant	Important
Strategies	Ways
Substantial	Large/big
Terminate	Stop
The information we collect	What you tell us
To the extent legally permissible	To the extent allowed bylaw
Understand	Learn/see
Voluntary	Up to you
Waive rights	Give up rights
With regard to	About
Withdraw	Quit
Your understanding of	What you know about...

Source: Harold C. McGraw, Office of Educational Research, Baltimore County Schools, Towson, MD, and C. William Erwin and Cynthia McCaskill of Duke University.

Further adapted by Eastern Band of Cherokee Indians Medical Institutional Review Board, July 2018

