Informed Consent Key Information Checklist

Tufts CTSI
Tufts Clinical and Translational Science Institute

For use with RESEARCH informed consent forms.

Purpose: Informed consent forms for research must BEGIN with a concise Key Information section organized and presented in a way that helps potential participants understand why they may or may not want to join a research study. This Checklist is designed to assess the Key Information section of informed consent forms for features that make information easy to read, understand, and use to make an informed consent decision.

How to apply:

- Review Checklist and **Tips for Users** (page 3) for additional guidance on criteria for assessment.
- Read the **Key Information section** of your informed consent form.
- Mark each Checklist criteria as present (Yes=1), not present (No=0), or not sure (Not sure=0).
- Apply **ONLY** to the **Key Information section**, not the full informed consent form.
- Add total criteria present, divide by the number of criteria, and multiply by 100 to calculate the score. The higher the score, the easier the Key Information is to read, understand, and act on.

Readability Criteria		Present or Not Present		
Writing				
1	**Active voice.** Uses active voice (e.g., will use) rather than passive voice (e.g., will be used) more than 90% of the time.	◯ Yes	◯ No	◯ Not sure
2	**Word choice.** Avoids scientific jargon. Uses common, everyday words at least 90% of the time.	◯ Yes	◯ No	◯ Not sure
3	**Defines main topic.** Provides a definition of the main health issue or topic the study is aiming to address.	◯ Yes	◯ No	◯ Not sure
4	**Numbers.** Avoids complex math, including probability of risk statistics and calculations that require numeracy skills.	◯ Yes	◯ No	◯ Not sure
5	**8th grade level.** Reads at an 8.9 grade level or below, calculated using readability statistics in Word.	◯ Yes	◯ No	◯ Not sure
Design				
6	**Headers.** Labels sections or chunks of information with headers that clearly describe sections.	◯ Yes	◯ No	◯ Not sure
7	**Font size.** Avoids fancy font types or styles and font size smaller than 11-12 point.	◯ Yes	◯ No	◯ Not sure
8	**White space.** Uses lists with bullet points or numbers to increase white space on the page.	◯ Yes	◯ No	◯ Not sure
Understandability Criteria		**Present or Not Present**		
9	**Purpose of study.** Includes statement: "*purpose of the study is...*" The purpose is stated, not implied.	◯ Yes	◯ No	◯ Not sure
10	**Main reason to join the study – benefits.** Includes description or list of potential benefits.	◯ Yes	◯ No	◯ Not sure
11	**Main reasons not to join the study – risks.** Includes description or list of potential risks and side effects.	◯ Yes	◯ No	◯ Not sure

12	**Information being collected.** Describes the information being collected from AND about participants.	Yes	No	Not sure
13	**Study procedures.** Describes what participants will need to do AND how much time it will take.	Yes	No	Not sure
14	**Study is research.** Includes statement: "*study is research*" or "*research study*." Makes clear it is not a treatment consent.	Yes	No	Not sure
15	**Participation is voluntary.** States participation is voluntary; participants have a choice to be in the study or not.	Yes	No	Not sure
Actionability Criteria		**Present or Not Present**		
16	**Consent process.** Describes how participants give consent, what they need to do, such as sign, verbal, or other.	Yes	No	Not sure

Total	0
	16
Multiply by 100	
Score	0%

How to calculate score: Add total items present (Yes = 1). Divide by number of items (16 items). Multiply by 100 to get % score. The goal is 16 / 16 x 100 = 100%.

How to interpret the score: A higher score means the key information in your document is easier to read, understand, and act on than a lower score. Revise based on which items on the Checklist are missing to increase the score. The goal is to achieve a score of 100%.

0% - 50% = Poor Requires substantial revision

51% - 75% = Fair Fill remaining gaps

76% - 99% = Good Address missing item(s), as needed

100% = Excellent Includes all Checklist components

Tips for Users

Key Information. The Office for Human Research Protection (OHRP) 2018 Common Rule Part 46.116 states informed consent forms must begin with concise and focused key information organized and presented to help potential participants understand why they may or may not want to participate in research. The Checklist is designed to assess this key information section ONLY.

Readability Criteria

Active Voice. Active voice is easier to read than passive voice, which is indirect and obscures who is doing the action. Use readability statistics to calculate the percentage of passive voice in your writing. If passive voice is used more than 10%, edit your writing until active voice is used more than 90% of the time.

Word Choice. Scientific jargon is language used by scientists that includes words rarely used by people outside of science. To avoid jargon, use a plain language glossary for clinical research to find everyday words and definitions. If more than 10% of your words are jargon, edit until you use common words more than 90% of the time.

Define Main Topic. Use a plain language glossary for health care to find everyday words and definitions to help describe what health topic or issue you are studying using language people who are not familiar with your research can understand.

Numbers. Numeracy is the ability to use numbers to accomplish tasks and can be challenging for people. Avoid asking people to make calculations. Instead, use these tips for simplifying numbers including: 1) use frequency instead of percent, 2) keep denominators consistent, and 3) include visuals to help explain trends and patterns.

8th Grade Level. Reading grade level is calculated using readability formulas. Use Word's readability statistics to check grade level. Aim for 8.9 grade or below by using shorter words and sentences and following plain language principles.

Design. Plain language guidelines include both writing and design principles. Use the following plain language design guidelines to increase the readability of your written documents, including:

- **Headers**. Use bold headers and short paragraphs of text.
- **Font Size**. Use clear font types, size 11-12 point.
- **White Space**. Use bullet points and lists to add white space.

Understandability Criteria

Understandability. Understandability means including the key content that a potential participant needs to make a decision. The Checklist reflects guidance from the 2018 Common Rule and associated content recommendations that key information include: the purpose of the study, potential risks, potential benefits, study procedures, information collected, that the study is voluntary and for research.

Actionability Criteria

Consent Process. Actionability means participants have enough information to make a decision and take action. Consent must clearly explain how consent will be how consent will be obtained (e.g., signature, verbal, computer) and what participants need to do to give consent.

For any questions, please contact info@tuftsctsi.org with subject line: Informed Consent Checklist Inquiry.

This work was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number UM1TR004398. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.