

## How Well Does the Average U.S. Adult Read?

By Norman M. Goldfarb

FDA regulations and ICH guidelines both require that “the information that is given to the subject or the representative [in the informed consent process] shall be in language understandable to the subject or the representative.”<sup>1</sup>

Read literally, these regulations require that informed consent forms be understandable to the least skilled reader in a study’s population. However, the common interpretation of this requirement is that informed consent forms should be written to be understandable by the *average* adult, who reads at the eighth- or ninth-grade level. Leaving aside the fact that most informed consent forms are written at higher reading levels, two questions remain:

- What does it mean for a document to be readable at a certain grade level?
- Where did the eighth- or ninth-grade reading levels come from?

### National Survey of Reading Ability

There is a huge body of literature on literacy – how well people understand what they read – and readability – how easy a document is to read.<sup>2</sup> The most representative results on literacy come from the 1992 National Adult Literacy Study (NALS).<sup>3</sup> NALS tested 13,600 adults age 16-64, including those who spoke English as a second language, on their ability to read every-day and educational documents. It excluded about 5% of the population that reads below the grade 1.5<sup>th</sup> level or could not take the test for physical or mental reasons. Table 1 shows this data correlated with grade levels.<sup>4</sup>

**Table 1. U.S. Adult Literacy in 1992**

Reading Level	Score	Grade Level	% of Adults
None or N/A	000-149	0.0-1.4	5%
Rudimentary	150-199	1.5-3.5	20%
Basic	200-249	3.6-7.6	26%
Intermediate	250-299	7.7-11.9	30%
Adept	300-349	12-15.9	16%
Advanced	350-500	16+	3%

### How Reading Comprehension Tests are Scored

It is easy to argue that informed consent requires 100% comprehension, but the NALS standard for literacy in independent reading is 80% correct answers on a comprehension test. (A lower standard, of 50% correct answers, was used for assisted classroom reading, but is a long way from the informed consent regulatory requirement.)<sup>3</sup> The NALS literacy statistics thus overstate the ability of readers to understand 100% of a document. If a sentence in an informed consent form is not important enough for 100% comprehension, it should probably be removed from the document.

## Educational Attainment

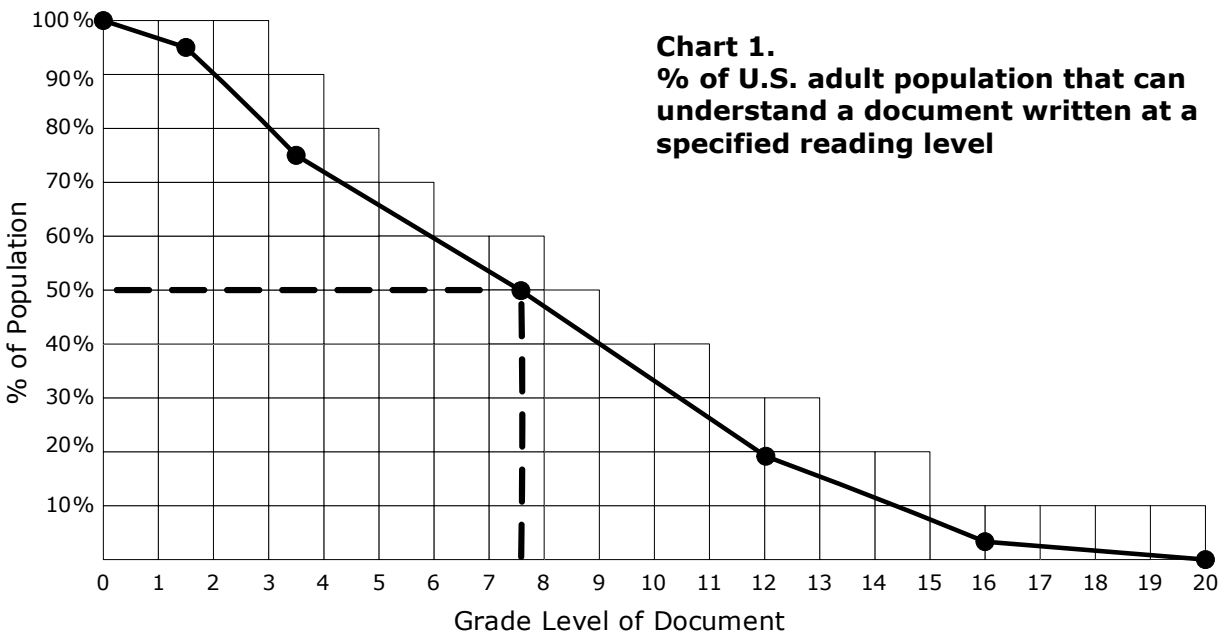
Table 2 compares years of education to reading ability.<sup>5,6</sup> The average high school graduate reads at the 9.4<sup>th</sup>-grade level, 2.6 years below his/her educational attainment. The average four-year college graduate reads at the 13.8<sup>th</sup>-grade level, 2.2 years below his/her educational attainment. The averages mask enormous variability in the reading skills of people with any particular educational attainment; a specific high-school graduate may be functionally illiterate or read better than most college professors.

**Table 2: Educational Attainment vs. Reading Ability**

Educational Attainment	Average NALS Score	Grade Equivalent
Less than 9th grade	177	2.6
Some high school	231	6.1
High school graduate (12 <sup>th</sup> grade)	270	9.4
Some college or associate degree	301	12.1
4-year degree (16 <sup>th</sup> grade)	322	13.8
Advanced degree	336	14.9

## Ability of U.S. Adults to Understand a Document

Chart 1 presents the NALS results in a graphical format that can be used to measure the percentage of the U.S. adult population that can read a document written at a specified grade level:



As can be seen from the above chart, only about 50% of the U.S. adult population can understand a document written at the 7.6<sup>th</sup>-grade level. The 8<sup>th</sup>-9<sup>th</sup> grade standard is thus overoptimistic. Further, NALS literacy statistics overestimate the ability of the average potential research subject to understand informed consent forms and HIPAA authorizations:

- Informed consent forms probably require 100%, not 80%, comprehension.
- Informed consent forms are not your typical every-day documents. They are long and complex, often written by highly-educated lawyers, with numerous unfamiliar medical and research concepts and terminology. How many clinical research personnel understand 100% of their informed consent and HIPAA authorization forms?
- Potential research subjects are not representative of the U.S. population – many have ailments that may be stressful and distracting. They may be taking medications that distort their mental capacity.
- Potential research subjects do not read informed consent forms as an academic exercise – they are literally reading them for their health.
- Potential research subjects often read informed consent forms in uncomfortable and distracting surroundings, with an implied time limit.
- To repeat the obvious, 50% of the adult population reads below average.

Two factors somewhat offset these problems:

- Study personnel are available to explain the forms.
- Minorities, immigrants, the elderly, and the poor are significantly under-represented in many studies.

To the author's knowledge, the literacy of clinical trial subjects in the clinical research context (absent informed consent form issues) has not been studied. However, it is probably safe to say that any informed consent or HIPAA authorization forms written above the 8.0<sup>th</sup>-grade level probably does not comply with regulatory and ethical requirements.

## **Acknowledgements**

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## **References**

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6. 2000 U.S. Census

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