



## Invited Commentary | Ethics

# Informed Consent—We Can and Should Do Better

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Informed consent is fundamental to the ethical and legal doctrines respecting research participants' voluntary participation in clinical research, enshrined in such documents as the 1947 Nuremberg Code; reaffirmed in the 1964 Declaration of Helsinki, revised in 1975, and the 1978 Belmont Report; and codified in the United States in the 1981 Common Rule, revised in 2018 and implemented in 2019.<sup>1</sup>

Informed consent generally is understood to represent a process, with the informed consent document having a central role. The characteristics of a well-designed consent form are well known: the document must contain information, some statutorily defined, necessary to allow a participant to make an informed decision; be written at a reading level appropriate for its audience; and be of a length that enables complete and thorough reading. Yet, the content and structure of this document has been the subject of discussion for at least 3 decades, with a consistent consensus throughout this time that these documents are too difficult to read, too complex, and too long and, as a result, frequently fail to facilitate truly informed consent by study participants. While much of the blame for the failure to provide sufficiently detailed, readable, and brief consent forms has been laid at the feet of sponsors and investigators, the reality is that, while it is possible to incorporate 2 of these 3 elements into a consent form, it is all but impossible to incorporate all 3, ie, concise, sufficiently detailed yet easily readable, for anything but the simplest of clinical trials.

The study by Emmanuel and Boyle<sup>2</sup> reviews the consent forms for the COVID-19 vaccine phase III randomized clinical trials conducted by 4 major pharmaceutical companies that resulted in US regulatory approvals for 3 of the 4 vaccines, in the context of these issues. The study by Emmanuel and Boyle<sup>2</sup> highlights the deficiencies of the COVID-19 vaccine trial consent forms in these areas, proposes revised consent form language to improve readability, understanding, and length, and underscores how the medical community has not responded adequately to the decades-long valid criticisms concerning informed consent forms. The revisions proposed by Emmanuel and Boyle<sup>2</sup> to the relatively straightforward COVID-19 vaccine trials' consent forms yielded a document that was substantially longer than ideal, with an overall higher-grade reading level than optimal, underscoring the fundamental inability to successfully incorporate all 3 of the desirable qualities for a consent form into a single document.

Consent forms should be written at a level understandable to the average prospective participant. Many authorities, including the National Cancer Institute,<sup>3</sup> relying on the 2015 Institute of Medicine report "Informed Consent and Health Literacy," recommend an eighth-grade reading level or lower for informed consent forms, but this may be too generous a standard. The average American reads at the seventh to eighth grade level, with half of US adults unable to read a book written at the eighth grade level. The most recent study of literacy among US adults, the Survey of Adult Skills conducted through the Program for the International Assessment of Adult Competencies (PIAAC), supports this, indicating that more than half of US adults would struggle to fully comprehend current consent forms, and among self-declared individuals in fair or poor health—those most likely to participate in clinical trials with greater than minimal risk—31% have PIAAC Level 1 (ie, basic sight vocabulary and can read short texts on familiar topics to locate a single piece of information) or lower literacy skills.<sup>4</sup> Therefore, it is reasonable to conclude, as Emmanuel and Boyle<sup>2</sup> and many others have, that a sixth grade reading level is more appropriate, noting that even this level would not address the substantial proportion of the population with literacy levels below this.<sup>5</sup>

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Consent forms also should be of a length that can be easily read by the average study participant. Evidence exists that the longer a document is, the less likely people are to read it fully. In the educational context, people are unlikely to read an entire document containing more than 1000 words (ie, approximately 4 pages), and it has been proposed that consent forms should be limited to no more than 1250 words.<sup>6</sup> Yet consent form lengths have increased steadily over the past 4 decades, with few consent forms fewer than 10 pages in length, and most substantially longer. The COVID-19 consent forms reviewed by Emmanuel and Boyle<sup>2</sup> were a mean of more than 8000 words (range, 7821 to 9340 words), and despite their best efforts, Emmanuel and Boyle<sup>2</sup> were only able to reduce the length to just under 3000 words.

Finally, there is the issue of the actual content of the consent form. The list of mandatory items alone runs to more than 270 words in the Revised Common Rule, highlighting the challenge of writing a consent form that is complete and understandable in fewer than 1000 or even 1250 words. Compounding this is the perception that many sponsors and institutions appear to want to use consent forms primarily as legal instruments to protect against civil litigation, undermining both the primary function of the document, as well as its accessibility, to study participants.

The study by Emmanuel and Boyle<sup>2</sup> should be recognized as a wake-up call to sponsors, investigators, institutional review boards, and regulators to reevaluate how consent forms are drafted, reviewed, and used, along with a reappraisal of the entire consenting process. After decades of largely fruitless effort, an acknowledgment of the seemingly insurmountable challenge of drafting sufficiently detailed but easily readable and not overly lengthy documents would allow the reimagining of the entire consenting process. Considerations could include placing even greater emphasis on the discussion component of the consent process while deemphasizing the role of the consent form, a greater use of multimedia and other technology, more formal scripting of consenting discussions, mandatory documentation of confirmation of adequate comprehension by study participants, and even regulatory reform, among other improvements. Such an appraisal and revision to the process would be neither simple nor without cost, but if history is any guide, failure to act is likely to lead to having the exact same conversation a decade from now.

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## ARTICLE INFORMATION

**Published:** April 28, 2021. doi:10.1001/jamanetworkopen.2021.10848

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**Conflict of Interest Disclosures:** Dr Grant reported having equity in and serving as General Counsel of TheraBionic.

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